Development, licensing and option agreement for XOMA 052 for multiple indications

Xoma
Les Laboratoires Servier

Jan 04 2011
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Companies: Xoma
Les Laboratoires Servier
Announcement date: Jan 04 2011
Deal value, US$m: 555.0 : sum of upfront, milestone and funding payments

Details
Announcement date: Jan 04 2011
Start date: Dec 30 2010
Expiry date: Dec 30 2010
Industry sectors: Bigpharma
Pharmaceutical
Cardiovascular
Immunology » Inflammation
Therapy areas: Metabolic » Diabetes
Oncology
Ophthalmics
Technology types: Antibodies » Monoclonal antibodies
Small molecules
Deal components: Licensing
Option
Stages of development: Phase III
Worldwide
Excluded geography: Asia » Japan
North America » United States

Financials
Deal value, US$m: 555.0 : sum of upfront, milestone and funding payments
Upfront, US$m: 35.0 : upfront payment
Milestones, US$m: 470 : milestone payments
Royalty rates, %: n/d : upto mid teens tiered royalty payments
Funding, US$m: 50.0 : R&D funding
n/d : 50% additional expenses for Behcet's uveitis indication

Termsheet
4 January 2011

XOMA and Servier to jointly develop and commercialize XOMA 052 in multiple indications.

XOMA will receive approximately $35 million upfront, up to approximately $470 million in milestone payments and tiered royalties up to a mid-teens percentage rate.

XOMA retains development and commercialization rights for Behcet's uveitis and other inflammatory and oncology indications in U.S. and Japan.
XOMA will receive approximately $35 million upfront, up to approximately $470 million in milestone payments and tiered royalties up to a mid-teens percentage rate.

XOMA retains development and commercialization rights for Behcet's uveitis and other inflammatory and oncology indications in U.S. and Japan. Servier receives similar rights in the rest of the world. * Servier will fund the first $50 million of XOMA 052 development expenses and 50% of further expenses for the Behcet's uveitis indication. XOMA 052 is expected to advance into Phase 3 development in Behcet's uveitis in 2011. * Servier will fund development for diabetes and cardiovascular disease indications in exchange for worldwide rights.

Servier will fund development for diabetes and cardiovascular disease indications in exchange for worldwide rights.

XOMA retains an option to reacquire the development and commercialization rights to the diabetes and cardiovascular indications in the U.S. and Japan by paying an option fee and partial reimbursement of incurred development expenses. If XOMA reacquires these rights, it has the ability to license them to one or more third parties.

"This is an important collaboration for XOMA as we gain a seasoned partner in Servier and it allows us to accelerate XOMA 052 into Phase 3 development this year in Behcet's uveitis, an orphan indication for which we have reported positive proof-of-concept results. The agreement advances our strategy of focusing on opportunities in the U.S. where we can directly participate in the development and commercialization of our novel products," said Steven B. Engle, Chairman and Chief Executive Officer, XOMA. "This agreement substantially increases our cash resources while reducing future cash requirements, provides a pathway to commercialization of XOMA 052 in the near term, and supports development in diabetes and cardiovascular disease while maintaining our ability to participate in these programs. As a result, we can accelerate development of a new approach that targets the inflammatory cause of multiple diseases and has the potential to dramatically improve the lives of patients."

"Servier is a world-class pharmaceutical company with 2010 revenues of 3.7 billion euros and a long history of successful innovation and collaborations, global franchises in diabetes and cardiovascular disease and established operations in the geographical regions where Behcet's disease is most prevalent," Mr. Engle continued. "They are an ideal partner to maximize the clinical and commercial potential of XOMA 052."

"XOMA 052 gives us a later-stage asset to develop for diabetes and cardiovascular diseases, which are both areas of strength for us, as well as for rare diseases," said Emmanuel Canet, M.D., Ph.D., Servier's President, Research and Development. "With this therapeutic antibody designed to inhibit interleukin-1 beta we are reinforcing our strategy in the field of biologics and developing novel approaches aimed at treating severe diseases. We are especially eager to shepherd the development of XOMA 052 for the treatment of patients with Behcet's uveitis, a population that has very few options and may face eventual blindness."

In 2011, XOMA and Servier expect to hold discussions with multiple regulatory agencies to initiate Phase 3 studies of XOMA 052 in Behcet's uveitis, a debilitating ophthalmic inflammatory condition that often leads to vision-threatening complications including blindness. XOMA 052 has already received orphan drug designations for Behcet's disease from regulators in the U.S. and European Union, which support an expedited path to commercialization. XOMA expects to release results from two ongoing Phase 2 studies in patients with Type 2 diabetes in the first quarter of 2011.

XOMA will receive approximately $35 million in an upfront payment consisting of $15 million and a 15 million euro loan, which does not have to be repaid until 2016. Regarding milestone payments, if XOMA reacquires diabetes and cardiovascular rights in the U.S. and Japan, then the milestone payments could be up to $470 million as mentioned above. If XOMA does not reacquire these rights, then the milestone payments could be up to $800 million. XOMA will be responsible for XOMA 052 manufacturing throughout clinical development and launch and anticipates being a long-term manufacturer. This adds to the company's potential profit participation during the life of the commercial product.
XOMA will host a conference call and webcast to discuss its agreement with Servier today, January 4, 2011, at 8:30 am ET. The webcast can be accessed via the Investors section of XOMA's website at http://investors.xoma.com/events.cfm and will be available for replay until close of business on March 31, 2011.

Behcet's Disease

Behcet's (pronounced beh-CHETS) disease causes chronic inflammation of the blood vessels, or vasculitis, among other complications. Uveitis is a vasculitis of the blood vessels in the eye which can be vision-threatening. Behcet's uveitis is one of the most severe forms of uveitis which can lead to blindness and affects approximately 50% of Behcet's disease patients.

XOMA estimates that there are 250,000 patients diagnosed with Behcet's disease worldwide including 20,000 in the U.S. Onset of the disease occurs most commonly in adults in their twenties, thirties and forties, and is typically more severe in men.

Without immediate treatment, major exacerbations of Behcet's uveitis may lead to retinal detachment, macular edema, vitreous hemorrhage, glaucoma and eventual blindness. The effects of these exacerbations on vision are cumulative. Patients often experience multiple exacerbations per year, requiring treatment to control the frequency and severity of attacks of this chronic disease. No therapies are approved in the U.S. to treat Behcet's disease. It is treated with corticosteroids and immunosuppressive drugs, which can have significant side effects, including diabetes and hypertension, and can contribute to other eye diseases like glaucoma and the formation of cataracts. These drugs also can adversely affect the neurological, pulmonary, gastrointestinal, hematological and cardiovascular systems.

XOMA has completed a successful proof-of-concept Phase 2 trial of XOMA 052 in patients with Behcet's uveitis. As previously reported, all seven patients displayed rapid reduction of intraocular inflammation and improvement in visual acuity or other ophthalmic measures after a single treatment with XOMA 052 and following discontinuation of immunosuppressive drugs such as cyclosporine and/or azathioprine. Follow-up results demonstrated that each of the five patients re-treated with XOMA 052 due to a recurring uveitis exacerbation responded again to XOMA 052 treatment and maintained their response for several months. The drug was well-tolerated, and no drug-related adverse events were reported.

XOMA 052 and Interleukin-1 Inhibition

XOMA 052 is a potent monoclonal antibody with the potential to improve the treatment of patients with a wide variety of inflammatory diseases and other diseases including cancer. XOMA 052 binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine involved in Behcet's uveitis, diabetes, cardiovascular disease, rheumatoid arthritis, gout, and other auto-inflammatory diseases. IL-1 is a well-validated therapeutic target, with three marketed IL-1 inhibitors that have been used by more than 200,000 patients overall. By binding to IL-1 beta, XOMA 052 inhibits the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation.

To date, nearly 600 patients have been enrolled in XOMA 052 clinical trials. XOMA has completed enrollment in two Phase 2 clinical trials in patients with Type 2 diabetes and expects three month interim results from the Phase 2a trial in the first half of January 2011 and six month results from the Phase 2b trial in this quarter. The Phase 2 trials follow a successful 98 patient Phase 1 program in Type 2 diabetes in which XOMA 052 was shown to be well-tolerated, demonstrated evidence of biological activity in diabetes measures and cardiovascular biomarkers, and had a half-life that may provide convenient dosing of once per month or less frequently. The company has also demonstrated the potential for XOMA 052 in in vivo models of cardiovascular disease and in an in vitro model using human myeloma, or plasma cell cancer, cells.

Servier

Servier is the leading independent French pharmaceutical company, established in 1954 by its founder, Dr. Jacques Servier. The group is established in 140 countries and 86% of Servier products are prescribed outside of France. Sales turnover in 2010 reached about 3.7 billion euros. More than 25% of Servier's turnover is invested in Research and Development. Servier R&D counts 19 International Centers of Therapeutic Research, and its principal therapeutic research orientations are cardiovascular diseases, diabetes, neuropsychiatric disorders, cancer and osteoarticular diseases. Servier has an extensive history of more than 150 successful partnerships for product discovery, development, regulatory approval and availability for patients. More information is available at: www.servier.com.

About XOMA

XOMA discovers, develops and manufactures novel antibody therapeutics for its own proprietary pipeline as well as through license and collaborative agreements with pharmaceutical and biotechnology companies, and under its contracts with the U.S. government. The company's proprietary product pipeline includes:

- XOMA 052, a potent anti-IL-1 beta antibody entering Phase 3 clinical development in Behcet's uveitis, for which it has been designated an orphan drug, and in Phase 2 clinical development for Type 2 diabetes with cardiovascular biomarkers, Type 1 diabetes, and with potential for the treatment of a wide range of inflammatory conditions. * XOMA 3AB, an antibody candidate in pre-IND studies to neutralize the botulinum toxin, among the most deadly potential bioterror threats, under development through funding provided by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (Contract # HHSN26620060008C). * A preclinical pipeline with candidates in
development for autoimmune, cardio-metabolic, inflammatory, ophthalmic and oncologic diseases.

The company has a premier antibody discovery and development platform that incorporates an unmatched collection of antibody phage display libraries and proprietary Human Engineering(TM), affinity maturation, Bacterial Cell Expression (BCE) and manufacturing technologies. BCE is a key breakthrough biotechnology for the discovery and manufacturing of antibodies and other proteins. As a result, 60 pharmaceutical and biotechnology companies have signed BCE licenses, and several licensed product candidates are in clinical development.

XOMA has a fully integrated product development infrastructure, extending from pre-clinical science to approval at its Berkeley, California location. For more information, please visit www.xoma.com.

The XOMA Ltd. logo is available at www.globenewswire.com/newsroom/prs/?pkgid=5960

Filing Data

Not available.

Contract

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the “Agreement”) is made and entered into as of December 30, 2010 (the “Effective Date”) by and between XOMA Ireland Limited, a company with limited liability organized under the laws of the Republic of Ireland, having a place of business at 26 Upper Pembroke Street, Dublin 2, Ireland (“XOMA”) on the first part, and Les Laboratoires Servier, a corporation organized and existing under the laws of France, having offices at 22 rue Garnier, 92200 Neuilly-sur-Seine, France and Institut de Recherches Servier, a corporation organized and existing under the laws of France, having offices at 3 rue de la République, 92150 Suresnes, France (these two entities jointly referred to as “Servier”) on the second part. XOMA and Servier are sometimes referred to herein individually as a “Party” and collectively as the “Parties”.

Recitals

A. Servier is a pharmaceutical company committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human medicine.

B. XOMA owns and controls certain intellectual property related to and has conducted clinical trials with respect to its proprietary IL-1β antibody designated as XOMA 052.

C. Servier and XOMA desire to establish a collaboration for the continued development, regulatory approval and commercialization of products containing XOMA 052, with XOMA retaining certain exclusive development and commercialization rights in the U.S. and in Japan and Servier having exclusive development and commercialization rights in the rest of the world, in accordance with the terms and conditions set forth herein.

Now, Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

1. Definitions

Capitalized terms used in this Agreement (other than the headings of the Sections or Articles) have the following meanings set forth in this Article 1, or, if not listed in this Article 1, the meanings as designated in the text of this Agreement.

1.1 “Acquiror” has the meaning set forth in Section 15.5.

1.2 “Affiliate” means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this Section 1.2, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of such entity by the ownership of at least fifty percent (50%) of the voting stock of such entity.

1.3 “Alliance Manager” has the meaning set forth in Section 2.7.

1.4 “Behçet’s Disease” means a rare inflammatory disorder, also referred to as Behçet’s Syndrome, involving the small blood vessels.

1.5 “Behçet’s Pivotal Trial” means an adequate and well-controlled study (as defined in 21 CFR § 314.126) or foreign equivalent thereof to be conducted with the Product for use in the treatment of Behçet’s Uveitis, as further detailed in the Behçet’s Uveitis Development Plan.
1.6 "Behçet’s Uveitis" means inflammation of the uvea, resulting from Behçet’s Disease.

1.7 “Behçet’s Uveitis Development Plan” has the meaning set forth in Section 3.3(a).

1.8 “Biosimilar Product” means, with respect to the Product in a given country of the Licensed Territory or Retained Territory, any pharmaceutical biologic product that (a) is similar to the Product; (b) has the same route of administration as the Product; (c) obtained regulatory approval under a biosimilar application submitted in accordance with the then-current rules and regulations in such country that referred to or relied on data submitted by Servier, or one of its Affiliates or sublicensees, in an application for Regulatory Approval for the Product in such country; and (d) is sold in the same country as the Product by a Third Party that is not a sublicensee of Servier or its Affiliates and did not purchase such product in a chain of distribution that included any of Servier or its Affiliates or sublicensees.

1.9 “BLA” means a Biologic License Application, as defined in the United States Public Health Service Act, as amended, and applicable regulations promulgated thereunder by the FDA, or any equivalent application that replaces such application in the U.S.

1.10 “Bulk Drug Substance” means Licensed Antibody in bulk form.

1.11 “Cardiometabolic Field” means the prevention or treatment of Cardiometabolic Indications.

1.12 “Cardiometabolic Indications” means: (i) [*]; (ii) Type 2 diabetes (diabetes mellitus type 2); and (iii) [*].

1.13 “Cardiometabolic Indications Option” has the meaning set forth in Section 3.5.

1.14 “Claims” has the meaning set forth in Section 13.1.

1.15 “CMC Activities” means the Manufacturing and other activities necessary or useful for generating the CMC Information required for Regulatory Approval of the Licensed Product, including Manufacture of validation and/or clinical trial materials, that are necessary or useful to obtain or maintain Regulatory Approval of a Product.

1.16 “CMC Costs” means all costs incurred by or on behalf of either Party that are [*]. CMC Costs shall include [*]. For clarity, [*].

1.17 “CMC Information” means Information related to the chemistry, manufacturing and controls of the Bulk Drug Substance or Licensed Product, as specified by FDA or other applicable Regulatory Authority.

1.18 “Commercialization Plan” has the meaning set forth in Section 5.4.

1.19 “Commercialize” means to promote, market, distribute, sell (and offer for sale or contract to sell) or provide product support for a Product. For clarity, “Commercializing” and “Commercialization” have a correlative meaning.

1.20 “Committee” means the JEC, JSC, JDC and/or JMC, or any other committee established by the Parties pursuant to Section 2.1, as the case may be.

1.21 “Competing Product” means any pharmaceutical product other than the Product, which binds to, and inhibits or modulates, IL-1 as its primary mode of action.

1.22 “Confidential Information” of a Party means any and all Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. All Information disclosed by either Party or its Affiliates pursuant to the Mutual Confidentiality Agreement between Servier and [*] dated 01/11/2010 (the “Confidentiality Agreement”) shall be deemed to be such Party’s Confidential Information disclosed hereunder.

1.23 “Controlled” means, with respect to any compound, material, Information or intellectual property right, that the applicable Party owns or has a license to such compound, material, Information or intellectual property right and has the ability to grant to the other Party access, a license or a sublicense (as applicable) to such compound, material, Information or intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such access, license or sublicense.

1.24 “Current Good Manufacturing Practice” or “cGMP” means the then-current standards for the manufacture of pharmaceutical products, pursuant to (a) the FD&C Act (21 U.S.C. 321 et seq.); (b) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211); (c) EC Directive 2003/94 EC of October 8, 2003; (d) the EC Guide to Good Manufacturing Practice for Medicinal Intermediate Products; (e) the International Conference on Harmonization (ICH) ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; (f) any Japanese laws, rules, guidelines, or regulations corresponding to the subject matter of the foregoing; and (g) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant or complement any of the foregoing.
1.25 “CV Indication” means the first cardiovascular indication to be determined by the JSC and approved by the JEC.

1.26 “CV Indication Development Plan” has the meaning set forth in Section 3.4(a).

1.27 “Develop” or “Development” means, with respect to a Product, all activities relating to preparing and conducting non-clinical studies and other analyses, clinical studies, and regulatory activities (e.g., preparation of regulatory applications).

1.28 “Development Budget” has the meaning set forth in Section 3.2(a).

1.29 “Development Costs” means all costs incurred by or on behalf of either Party [•]. Development Costs shall specifically exclude any costs [•]. Development Costs shall include [•].

1.30 “Diligent Efforts” means, with respect to a Party’s obligations under this Agreement, the carrying out of such obligations or tasks with a level of efforts and resources consistent with the level of efforts and resources each Party usually dedicates to, and consistent with the commercially reasonable practices of a similarly situated company in the pharmaceutical industry (in the case of Servier) or biotechnology industry (in the case of XOMA) for, the research, development or commercialization of a similarly situated pharmaceutical product as the Product and at a similar stage of development or commercialization, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions, the profitability of the Product in light of pricing and reimbursement issues, and all other relevant factors. Diligent Efforts shall be determined on a market-by-market or country by country basis, and indication-by-indication basis, and it is anticipated that the level of efforts required shall be different for different markets and indications and shall change over time, reflecting changes in the status of the Product and markets involved. It is also anticipated that the application of Diligent Efforts may result, in the case of Servier, in its determination not to seek Regulatory Approval for and/or Commercialize the Product in one or more countries of the Licensed Territory that are other than the Significant Markets.

1.31 “Dollars” or “$” means the legal tender of the United States of America.

1.32 “Early Option Exercise” has the meaning set forth in Section 3.5(a).

1.33 “Early Option Exercise Date” has the meaning set forth in Section 3.5(a).

1.34 “Effective Date” has the meaning set forth in the first paragraph of this Agreement.

1.35 “EMA” means the European Medicines Agency or any successor entity.

1.36 “EU” means the European Union, as its membership may be altered from time to time, and any successor thereto. The member countries of the European Union as of the Effective Date are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom as well as Norway and Iceland.

1.37 “Executive Officers” means the Chief Executive Officer of XOMA and the Chief Executive Officer of Servier (or their respective designees).

1.38 “FDA” means the United States Food and Drug Administration, and any successor thereto.

1.39 “First Commercial Sale” means, with respect to a Product in a particular country, the first commercial sale of such Product in such country after all needed Regulatory Approvals have been obtained in such country. Sale of a Product by Servier to an Affiliate or a sublicensee shall not constitute a First Commercial Sale; in addition, in no event shall any sales for pre-marketing, testing, or sampling be deemed a First Commercial Sale.

1.40 “Flash 2b Report” means the flash report of the results of the Phase 2b Study containing information with respect to whether the primary and secondary endpoints were met, expected to be produced within seven (7) days of the database lock for such study.

1.41 “Full Data Set” means the full data set from the Phase 2b Study, including safety information (but which is not the final report of such study), expected to be produced within [*] days of the database lock for such study.

1.42 “Global Research and Development Plan” has the meaning set forth in Section 3.2(a).

1.43 “Governmental Authority” means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other
1.44 “IFRS” means International Financial Reporting Standards, as they exist from time to time, consistently applied.

1.45 “IL-1β” means a cytokine protein with a human proprotein form represented by the sequence of amino acids 1-269 of GenBank Accession Number NP_000567.1 and a human mature protein form represented by the sequence of amino acids 117-269 of GenBank Accession Number NP_000567.1.

1.46 “IND” means an Investigational New Drug Application submitted to the FDA for approval to commence human clinical trials, or the foreign equivalent of such application in a country other than the U.S.

1.47 “Indemnified Party” has the meaning set forth in Section 13.3.

1.48 “Indemnifying Party” has the meaning set forth in Section 13.3.

1.49 “Information” means all information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, data, results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms.

1.50 “Initial Behçet’s Development Plan” has the meaning set forth in Section 3.3(a).

1.51 “Initial T2D Development Plan” has the meaning set forth in Section 3.4(a).

1.52 “Initiation” of a clinical trial means the first dosing of the first subject in such clinical trial.

1.53 “Joint Executive Committee” or “JEC” has the meaning set forth in Section 2.2(a).

1.54 “Joint Inventions” has the meaning set forth in Section 9.1.

1.55 “Joint Invention Patents” has the meaning set forth in Section 9.1.

1.56 “Joint Manufacturing Committee” or “JMC” has the meaning set forth in Section 2.5(a).

1.57 “Joint Research and Development Committee” or “JDC” has the meaning set forth in Section 2.4(a).

1.58 “Joint Steering Committee” or “JSC” has the meaning set forth in Section 2.3(a).

1.59 “Late Option Exercise” has the meaning set forth in Section 3.5(b).

1.60 “Late Option Exercise Date” has the meaning set forth in Section 3.5(b).

1.61 “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.62 “Lead Cardiometabolic Indications” means Type 2 diabetes and [*].

1.63 “Licensed Antibody” means: XOMA 052 (gevokizumab), an IgG2 humanized monoclonal antibody that binds to IL-1β, as well as any fragment, derivative, modification or subunit of such antibody.

1.64 “Licensed Product” means any therapeutic or prophylactic product that comprises or incorporates the Licensed Antibody as an active pharmaceutical ingredient alone or in combination with one or more other active agents.

1.65 “Licensed Territory” means all countries in the world other than the Retained Territory.

1.66 “Major Cardiometabolic Indications” means any of the following: (a) Type 2 diabetes (diabetes mellitus type 2); or (b) any of the following indications that Servier determines, in good faith and in consultation with XOMA, have projected annual peak sales in the Licensed Territory of the applicable Product of at least [*].

1.67 “Major European Countries” means France, Germany, Italy, Spain and the United Kingdom.
1.68 "Major Markets" means the U.S., each of the Major European Countries, and Japan.

1.69 “Manufacturing” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, inspection, receiving, holding and shipping of Bulk Drug Substance, Licensed Antibody, Products, or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process development, qualification and validation, equipment and facility qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. For clarity, “Manufacture” and “Manufactured” have correlative meanings.

1.70 “Manufacturing Plan” has the meaning set forth in Section 6.2.

1.71 “Marketing Authorization Application” or “MAA” means: (a) in the United States, a BLA, and (b) in any other country or regulatory jurisdiction, an equivalent application for regulatory approval required before commercial sale or use of a Product (or with respect to a subsequent indication) in such country or regulatory jurisdiction.

1.72 “Material Impact” means, with respect to a Party, a material adverse impact on the regulatory status or the commercial sales of the Product in such Party’s applicable territory.

1.73 “Materials” means all compositions of matter, cells, cell lines, assays, samples, animal models and physical, biological or chemical material, but excluding Bulk Drug Substance or Product transferred in accordance with Article 6.

1.74 “MHLW” means the Japanese Ministry of Health, Labour and Welfare or any successor entity.

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1.75 “Net Sales” Except as provided below with respect to clinical trial samples, in the case of sales by or for the benefit of Servier, its Affiliates, and its sublicensees (the “Seller”) to independent, unrelated persons (“Buyers”) in bona fide arm’s length transactions, “Net Sales” means the gross amount billed or invoiced by Seller with respect to the Product, less the following deductions, in each case to the extent actually allowed and taken by such Buyers and not otherwise recovered by or reimbursed to Seller in connection with such Product (“Permitted Deductions”): [x].

Net Sales shall not include any consideration received with respect to a sale, use or other disposition of any Product in a country as part of a clinical trial necessary to obtain Regulatory Approval in such country. All of the foregoing elements of Net Sales calculations shall be determined in accordance with IFRS or successor standards and guidelines thereto. In the case of transfers of Product between any of Servier, its sublicensees, and affiliates of any of the foregoing, for subsequent sale, rental, lease or other transfer of such Products to third parties, Net Sales shall be the gross invoice or contract price charged to the third party customer for that Product, less the deductions set forth in clauses (i) through (viii) above.

In the event that a Product consists of a combination of the Licensed Antibody with one or more other active agents, Net Sales, for the purpose of determining royalty payments, shall be discussed and agreed to by the Parties taking into account the relative value of the Licensed Antibody and of the other active agents.

1.76 “New Servier Patents” means any Patent Controlled by Servier or its Affiliates at any time during the Term that (a) is useful for the Development, Manufacture or Commercialization of the Licensed Antibody or Product in the Territory, (b) is not a Servier Collaboration Patent, and (c) provided that, to the extent Servier has paid or is required to pay any royalties or other amounts to any Third Party for use or assignment to it of any such Patent, XOMA has agreed prior to its acceptance of a license to such Patent to pay its portion of such fees or royalties. For clarity, the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate of Servier.

1.77 “Patent” means all: (a) unexpired letters patent (including inventor’s certificates) which have not been held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken or has been taken within the required time period (and which have not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or been abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written agreement), including any substitution, extension, registration, confirmation, reissue, re-examination, supplementary protection certificates, confirmation patents, patent of additions, renewal or any like filing thereof; (b) pending applications for letters patent which have not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority or court for whatever reason (and from which no appeal is or can be taken), and/or abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written consent, including any continuation, division or continuation-in-part thereof and any provisional applications; and (c) any international counterparts to (a) and (b) above.

1.78 “Permitted Deductions” has the meaning set forth in Section 1.73.

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1.79 “Phase 2 Clinical Trial” means a study of the Product in human patients to determine initial efficacy, pharmacological effect, or dose range and/or regimen finding before embarking on any Phase 3 Clinical Trial, as further defined in 21 C.F.R. 312.21(b), as amended from time to time.
or the corresponding foreign regulations.

1.80 “Phase 2a Study” means that certain Phase 2a clinical trial being conducted by XOMA or its Affiliates as of the Effective Date and referred to as X052118, with respect to the Product in Type 2 diabetes.

1.81 “Phase 2 Results Package” means all of the following: (a) the interim top line data summary from the Phase 2a Study, (b) the Flash 2b Report, and (c) all then-existing safety data related to the Product.

1.82 “Phase 2b Study” means that certain Phase 2b clinical trial being conducted by XOMA or its Affiliates as of the Effective Date and referred to as X052078, with respect to the Product in Type 2 diabetes.

1.83 “Phase 3 Clinical Trial” means a pivotal study (whether or not denominated a “Phase 3” clinical study under applicable regulations) in human patients with a defined dose or a set of defined doses of a Product designed to ascertain efficacy and safety of such Product for the purpose of enabling the preparation and submission of Marketing Authorization Applications to the competent Regulatory Authorities in a country of the Licensed Territory or Retained Territory, as further defined in 21 C.F.R. 312.21(c), as amended from time to time, or the corresponding foreign regulations.

1.84 “Pre-Exercise Period” means the period running from the Effective Date until the later of (i) Early Option Exercise, (ii) Late Option Exercise or (iii) expiration of the Cardiometabolic Indications Option unexercised.

1.85 “Product” means any Licensed Product in final form.

1.86 “Product Infringement” has the meaning set forth in Section 9.4(a).

1.87 “Product Marks” has the meaning set forth in Section 5.5.

1.88 “Product Specifications” means the specifications for Bulk Drug Substance, attached hereto as Exhibit 1.88, which shall be updated (a) as required in connection with obtaining Regulatory Approval or continuing compliance with regulatory requirements and (b) as agreed upon in writing from time to time by Servier and XOMA.

1.89 “Quality Agreement” has the meaning set forth in Section 6.10.

1.90 “Regulatory Approval” means any and all approvals (including supplements, amendments, pre- and post-approvals, but excluding pricing and reimbursement approvals), licenses, registrations or authorizations of any national, supra-national (e.g., the European Commission or the Council of the EU), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a Product in a regulatory jurisdiction.

1.91 “Regulatory Authority” means the applicable national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity that, in each case, governs the Regulatory Approval of a Product in such applicable regulatory jurisdiction.

1.92 “Regulatory Materials” means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other filings made to or with, or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Develop, Manufacture, market, sell or otherwise Commercialize a Product in a particular country or regulatory jurisdiction.

1.93 “Remaining Field” means the prevention or treatment of all human diseases or conditions (including uveitis and Behçet’s Uveitis), other than those human diseases and conditions comprising the Cardiometabolic Field.

1.94 “Retained Territory” means (a) the U.S. and (b) Japan, including its territories and possessions.

1.95 “Retained Territory License Agreement” has the meaning set forth in Section 3.1(b).

1.96 “Servier Collaboration Patent(s)” means any Sole Invention Patent(s) owned by Servier or its Affiliates pursuant to Section 9.1.

1.97 “Servier Indemnitees” has the meaning set forth in Section 13.2.

1.98 “Servier Know-How” means all Information and Materials that are Controlled by Servier or its Affiliates as of the Effective Date or during the Term and are necessary or useful for the Development, Manufacture or Commercialization of the Bulk Drug Substance or Product and provided that, to the extent Servier has paid or is required to pay any royalties or other amounts to any Third Party for use or assignment to it of any such Information and/or Materials, XOMA has agreed prior to its acceptance of a license to such Information and/or Materials, to pay its portion of such fees or royalties. For clarity, the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate of Servier.
1.99 "Servier Patents" means any (a) New Servier Patents and (b) Servier Collaboration Patents.

1.100 "Servier Technology" means the Servier Patents and Servier Know-How and Servier’s interest in the Joint Invention Patents.

1.101 "Servier Withholding Tax Action" has the meaning set forth in Section 8.14(c).

1.102 "Significant Markets" means [*].

1.103 "Sole Inventions" has the meaning set forth in Section 9.1.

1.104 "Sole Invention Patents" has the meaning set forth in Section 9.1.

1.105 "Specific Diligent Efforts" means, [*].

1.106 "Successful EOP2 Meeting" means an FDA End of Phase 2 meeting at which, [*].

1.107 "Supply Agreement" has the meaning set forth in Section 6.5(b).

1.108 "T2D Development Plan" has the meaning set forth in Section 3.4(a).

1.109 "T2D Phase 2 Studies" means collectively the Phase 2a Study and the Phase 2b Study.

1.110 "Term" has the meaning set forth in Section 11.1.

1.112 "Third Party" means any person or entity other than: (a) XOMA; (b) Servier; or (c) an Affiliate of either Party.

1.113 "Third Party Partner" has the definition set forth in Section 3.1(b).

1.114 "Unsponsored Work" has the meaning set forth in Section 3.8(b).

1.115 "U.S." means the United States of America, including all possessions and territories thereof.

1.116 "XOMA Background Patents" means those Patents listed on Exhibit 1.116 as of the Effective Date.

1.117 "XOMA Collaboration Patent(s)" means any Sole Invention Patent(s) owned by XOMA or its Affiliates pursuant to Section 9.1.

1.118 "XOMA Indemnitees" has the meaning set forth in Section 13.1.

1.119 "XOMA Know-How" means all Information and Materials that are Controlled by XOMA or its Affiliates as of the Effective Date or during the Term and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product or Manufacture of Bulk Drug Substance, including the Know-How listed on Exhibit 1.119 attached hereto. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate of XOMA.

1.120 "XOMA Manufacturing Costs" means [*]. XOMA Manufacturing Costs shall not include [*]. For purposes of this definition, [*].

1.121 "XOMA Patents" means the XOMA Background Patents and the XOMA Collaboration Patents.

1.122 "XOMA Technology" means the XOMA Patents and XOMA Know-How and XOMA’s interest in the Joint Invention Patents.

2. Collaboration; Committees

2.1 Collaboration Overview. The Parties desire and intend to collaborate with respect to the Development, Manufacture and Commercialization of Products as and to the extent set forth in this Agreement, focusing initially on the Development of the Product for Behçet’s Uveitis and the Lead Cardiometabolic Indications, with XOMA retaining rights to the Product with respect to the Remaining Field in the Retained Territory, Servier being granted exclusive rights to the Product with respect to all indications (i.e., the Remaining Field and the Cardiometabolic Field) in
the Licensed Territory and the Cardiometabolic Indications in the Retained Territory, and XOMA having an option to re-acquire such rights in the Retained Territory as set forth in this Agreement (the “Collaboration”). The Parties intend that their respective organizations will work together to facilitate the success, effectiveness and quality of the Collaboration to maximize the commercial opportunity for the Product to the benefit of both Parties, all in accordance with the terms and conditions of this Agreement. The Parties shall establish the committees as described in this Article 2 and may from time-to-time establish other committees or sub-committees to report to the Joint Steering Committee in order to effectively implement the Collaboration as jointly agreed by the Parties.

2.2 Joint Executive Committee.

(a) Establishment. Within thirty (30) days after the Effective Date, the Parties shall establish a joint executive committee (the “Joint Executive Committee” or “JEC”), all in accordance with this Section 2.2. Each Party shall initially appoint at least three (3) representatives to the JEC. The JEC membership and procedures are further described in Section 2.8.

(b) Specific Responsibilities of the JEC. The JEC shall in particular, in accordance with the decision-making principles set forth in Section 2.9, manage the overall Collaboration (including but not limited to the intellectual property strategy, resources allocation and major changes to the Collaboration requiring amendments to the Agreement) and resolve any disputed matter of the JSC.

2.3 Joint Steering Committee.

(a) Establishment. Within thirty (30) days after the Effective Date, the Parties shall establish a joint steering committee (the “Joint Steering Committee” or “JSC”) to monitor and oversee their activities under this Agreement, all in accordance with this Section 2.3. Each Party shall initially appoint at least three (3) representatives to the JSC. The JSC membership and procedures are further described in Section 2.8.

(b) Specific Responsibilities of the JSC. The JSC shall in particular, in accordance with the decision-making principles set forth in Section 2.9:

(i) coordinate the activities of the Parties under this Agreement, including facilitating communications between the Parties with respect to the Development, Manufacture and Commercialization of Licensed Antibody, Bulk Drug Substance, and Product;

(ii) provide a forum for discussion of the Development, Manufacture, and Commercialization of Licensed Antibody, Bulk Drug Substance, and Product;

(iii) review and approve the T2D Development Plan and the Behçet’s Uveitis Development Plan and any other Global Research and Development Plans and associated Development Budgets and any annual or interim updates and proposed amendments thereto;

(iv) review and approve the Manufacturing Plan and associated budget and any annual or interim updates and proposed amendments thereto;

(v) review and discuss Servier’s Commercialization Plan and related activities with respect to the Product throughout the Licensed Territory and (if applicable) the Retained Territory, including pre-launch and go-to-market strategies;

(vi) direct and oversee the JDC, JMC and any other operating committee established by the JSC, on all significant issues that fall within the purview of such committees;

(vii) attempt to resolve issues presented to it by, and disputes within, the other Committees, including the JDC and JMC, in accordance with Section 2.9; and

(viii) perform such other duties as are expressly assigned to the JSC in this Agreement, and perform such other functions as appropriate to further the purposes of this Agreement as may be allocated to it by written agreement of the Parties.

2.4 Joint Research and Development Committee.

(a) Establishment. Within thirty (30) days after the Effective Date, the Parties shall establish a joint research and development committee (the “Joint Research and Development Committee” or “JDC”) to monitor and coordinate the Development of Products under this Agreement. Each Party shall initially appoint at least three (3) representatives to the JDC. The JDC membership and procedures are further described in Section 2.8.

(b) Specific Responsibilities of the JDC. The JDC shall in particular, in accordance with the decision-making principles set forth in Section 2.9:

(i) coordinate the activities of the Parties under and oversee the implementation of the T2D Development Plan, the Behçet’s Development Plan, [""], and any other Global Research and Development Plans agreed to by the Parties;
(ii) prepare annual and interim updates to the Global Research and Development Plans;

(iii) provide a forum for and facilitate communications between the Parties with respect to the Development of the Product, including any additional indications proposed by either Party to be jointly pursued;

(iv) monitor and coordinate all regulatory actions, communications and submissions for Products under each Global Research and Development Plan;

(v) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Development of Products, as directed by the JSC or the JEC; and

(vi) review proposed Unsponsored Work and Territory-Specific Work.

2.5 Joint Manufacturing Committee.

(a) Establishment. Within thirty (30) days after the Effective Date, the Parties shall establish a joint manufacturing committee (the “Joint Manufacturing Committee” or “JMC”) to monitor and oversee the CMC Activities and other activities related to the Manufacture of Bulk Drug Substance and the Product, for Development and Commercial use under this Agreement. Each Party shall initially appoint at least three (3) representatives to the JMC. The JMC membership and procedures are further described in Section 2.8.

(b) Specific Responsibilities of the JMC. The JMC shall in particular, in accordance with the decision-making principles set forth in Section 2.9:

(i) discuss, approve and oversee implementation of and progress against the Global Research and Development Plans as they relate to CMC Activities;

(ii) review the Manufacturing Plan and associated budget and propose updates and amendments thereto to the JSC, for approval;

(iii) coordinate and facilitate cooperation and flow of Information between the Parties with respect to the Manufacture and supply of Bulk Drug Substance and the Product for clinical and commercial use in accordance with Article 6;

(iv) coordinate and facilitate the transfer from XOMA to Servier of the XOMA Know-How as and to the extent provided in Article 6; and

(v) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Manufacture of Bulk Drug Substance or the Product, as directed by the JSC or the JEC.

2.6 Program Director. Within thirty (30) days after the Effective Date, each Party shall appoint and notify the other Party of the identity of a representative having the appropriate qualifications, including a general understanding of pharmaceutical development, to act as its program director under this Agreement (the “Program Director”). The Program Directors shall serve as the primary contact points between the Parties for the purpose of providing each Party with information on the progress of each Party’s development activities under this Agreement on a day to day basis. The Program Directors shall also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. The Program Directors shall attend all JSC and JDC meetings, and shall have the right to attend all other Committee meetings except the JEC meetings, and shall support the co-chairpersons of each Committee in the discharge of their responsibilities. A Program Director may also bring any matter in relation to the Development to the attention of any Committee if such Program Director reasonably believes that such matter warrants such attention. Each Party may replace its Program Director at any time upon written notice to the other Party.

2.7 Alliance Manager. Within thirty (30) days after the Effective Date, each Party shall appoint and notify the other Party of the identity of a representative having the appropriate qualifications, including a general understanding of pharmaceutical development and commercialization issues, to act as its alliance manager under this Agreement (the “Alliance Manager”). The Alliance Managers shall serve as the primary business contact points between the Parties for the purpose of providing each Party with information on the progress of each Party’s business related activities under this Agreement and for any activities not falling within the scope of responsibility of the Program Director. The Alliance Managers shall also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. The Alliance Managers shall attend all JSC and JDC meetings, and shall have the right to attend all other Committee meetings other than JEC meetings. An Alliance Manager may also bring any matter to the attention of any Committee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

2.8 General Committee Membership and Procedures.

(a) Membership. Each of Servier and XOMA shall designate representatives with appropriate expertise to serve as members of each Committee, and each representative may serve on more than one Committee as appropriate in view of the individual’s expertise. Each Party may replace its Committee representatives at any time upon written notice to the other Party. Each Committee shall have co-chairpersons. Servier and XOMA
shall each select from their representatives a co-chairperson for each of the Committees, and each Party may change its designated co-chairpersons from time to time upon written notice to the other Party. The co-chairpersons of each Committee shall be responsible for calling meetings and preparing and circulating meeting agendas and minutes, but the co-chairpersons shall have no additional powers or rights beyond those held by other Committee members.

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(b) Meetings. Each Committee shall hold meetings at such times as it elects to do so, provided that unless the Parties otherwise agree in writing to a different frequency for such meetings, each Committee shall meet at least twice each calendar year, and provided further that the Parties shall, to the extent practicable, schedule meetings of different Committees on the same day and in the same location. Either Party may also call a special meeting of a Committee (by videoconference or teleconference) by at least ten (10) business days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the applicable Committee no later than ten (10) business days prior to the special meeting with materials reasonably adequate to enable an informed decision. No later than ten (10) business days prior to any Committee meeting, the co-chairpersons of such Committee shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Each Committee may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in its meetings, provided that such non-member participants shall have no voting authority at such meetings. Each Committee may meet in person, by videoconference or by teleconference, provided however, at least one (1) meeting of each Committee per calendar year shall be in person unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. In-person Committee meetings shall be held alternately in Berkeley, California, U.S. and Paris, France. Each Party shall bear the expense of its respective Committee members’ participation in Committee meetings. Committee meetings shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The co-chairpersons of a Committee shall be responsible for preparing reasonably detailed written minutes of all meetings of such Committee that reflect, without limitation, all material decisions made at such meetings. The co-chairpersons shall send draft meeting minutes to each member of such Committee for review and approval promptly after each Committee meeting. Such minutes shall be deemed approved unless one or more members of such Committee objects to the accuracy of such minutes within thirty (30) days of receipt.

2.9 Decision Making.

(a) Within JSC and Operating Committees. All decisions within the JSC, JDC, JMC or any other operating Committee other than the JEC shall be made by consensus, with the co-chairperson from each Party having each one (1) vote. If a dispute arises which cannot be resolved within any Committee other than the JSC and the JEC, the representatives of either Party may cause such dispute to be referred to the JSC for resolution. If after reasonable discussion and good faith consideration of the other Party’s views on a particular matter before the JSC, including any disputes referred to the JSC by another Committee, the JSC is still unable to reach a unanimous decision on such matter for a period of [*] days, then either Party may cause such dispute to be referred to the JEC for resolution as provided in Section 2.9(b) below.

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(b) Within the JEC. Upon being referred a disputed matter from the JSC under Section 2.9(a), or arising within the JSC, the JEC shall consider such matter and discuss it in good faith, and shall strive to seek consensus in its actions and decision making process. If after reasonable discussion and good faith consideration of the other Party’s views on a particular matter before the JEC, including any disputes referred to the JEC by another Committee, the JEC is still unable after a period of [*] days to reach a unanimous decision on such matter, then either Party may upon notice to the other Party, refer such matter to the Executive Officers of the Parties for attempted resolution by good faith negotiations within [*] days after such notice is received, including at least one (1) in person meeting of the Executive Officers within [*] days after such notice is received. If the Executive Officers are not able to resolve such disputed matter within [*] days and either Party wishes to pursue the matter, then:

(i) [*]; and

(ii) [*].

(c) Exceptions. Notwithstanding the preceding Sections 2.9(b)(i) and (ii):

(i) Neither Party shall have the unilateral right to decide any dispute with respect to the Development of the Product, whether pursuant to a Global Research and Development Plan, or any Unsponsored Work, where the other Party believes in good faith that such a decision would have a substantial likelihood of having a Material Impact; provided, however, that where such a decision involves the safety of the Product in the deciding Party’s territory (including, by way of example, the content of the safety section of the Product label, whether a recall should be conducted in such deciding Party’s territory, or whether a particular clinical study should be terminated in its territory for safety reasons), the deciding Party shall nonetheless have the final say with respect to such safety matter, notwithstanding that the other Party has asserted that the effect thereof has a substantial likelihood of having a Material Impact.
indications and Behçet's uveitis, the parties may agree to pursue such indications singly or jointly, as provided in section 3.8.

Retained territory license agreement (redacted with respect to those portions of such agreement that are not relevant to the deliberation and such territory and set forth in a global research and development plan. With respect to indications other than the lead cardiometabolic and that, subject to servier's consent not to be unreasonably withheld, but which will be considered only after having received a copy of the products in the retained territory that xoma at such time enjoys (as and to the extent limited by such retained territory license agreement), for all development activities (as and to the extent not prohibited under and subject to section 2.9) conducted in its own territory (i.e., the territory license agreement with a third party partner, then such third party partner shall have all rights to participate in the development of otherwise specified in a global research and development plan, each party shall be responsible and have the final decision-making authority.)

servier agrees that, if xoma enters into such a retained territory license agreement with a third party partner, then such third party partner shall have all rights to participate in the development of otherwise specified in a global research and development plan, and potentially other indications, as and to the extent provided in this agreement, and pursuant to a separate global research and development plan for each indication, it being understood that each party may act either itself or through one or more licensees, sublicensees or subcontractors in its respective territory as permitted under this agreement. the parties intend to coordinate and harmonize their collaborative development activities where practical, including nonclinical and clinical studies, and manufacturing scale-up, to minimize development costs and maximize development efficiencies in both the licensed territory and the retained territory. unless otherwise specified in a global research and development plan, each party shall be responsible and have the final decision-making authority for all development activities (as and to the extent not prohibited under and subject to section 2.9) conducted in its own territory (i.e., the licensed territory for servier and the retained territory for xoma), including those portions of global or u.s. or eu clinical trials conducted in such territory and set forth in a global research and development plan. with respect to indications other than the lead cardiometabolic indications and behçet's uveitis, the parties may agree to pursue such indications singly or jointly, as provided in section 3.8.

2.10 discontinuation of participation on a committee.

(a) each committee, including the jsc and the jec, shall continue to exist until the first to occur of (i) the parties mutually agreeing to disband the committee, or (ii) either party providing to the other written notice of its intention to disband and no longer participate in such committee.

(b) once the jsc and the jec are disbanded in accordance with section 2.10(a), such committee shall have no further obligations under this agreement and, thereafter, the program directors will be the contact persons for the exchange of information under this agreement, and decisions of such committee shall be decisions as between the parties, subject to the final decision making authority under section 2.9 and the other terms of this agreement.

3. development of products

3.1 general.

(a) overview. the parties desire and intend to collaborate in planning and conducting development of the product for each of behçet's uveitis and the lead cardiometabolic indications, and potentially other indications, as and to the extent provided in this agreement, and pursuant to a separate global research and development plan for each indication, it being understood that each party may act either itself or through one or more licensees, sublicensees or subcontractors in its respective territory as permitted under this agreement. the parties intend to coordinate and harmonize their collaborative development activities where practical, including nonclinical and clinical studies, and manufacturing scale-up, to minimize development costs and maximize development efficiencies in both the licensed territory and the retained territory. unless otherwise specified in a global research and development plan, each year included in such plan, or (b) change the trial design of any global clinical trial included in any global research and development plan (including endpoints, sample size, inclusion and exclusion criteria).

(d) limitations of committee authority. each committee shall have solely the powers expressly assigned to it in this article 2 and elsewhere in this agreement or as otherwise agreed to by the parties in writing. a committee shall not have any power to amend, modify, or waive compliance with the terms of this agreement. it is expressly understood and agreed that the control of decision-making authority by xoma or servier, as applicable, pursuant to this section 2.9, so as to resolve a disagreement or deadlock on a committee or between the executive officers for any matter will not authorize either party to unilaterally modify or amend, or waive its own compliance with, the terms of this agreement.

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good faith. in exercising their rights under this section 2.9, all representatives of both parties shall consider, reasonably and in good faith, all input received from the other party, and shall use reasonable efforts to reach consensus on all matters before them. each party's committee members shall perform its responsibilities and exercise any decision making authority based on the principles of commercially reasonable development of products, consistent with good pharmaceutical practices and commercially reasonable consideration of the optimal balance of maximizing long-term profits derived from the sale of products in the context of the estimated costs for development of such products and other relevant considerations. notwithstanding anything to the contrary in this agreement, neither party nor any of its affiliates shall be required to take, or shall be penalized for not taking, any action that is not in compliance with such party's ethical business practices and policies or that such party reasonably believes is not in compliance with applicable laws.

2.10 discontinuation of participation on a committee.

(a) each committee, including the jsc and the jec, shall continue to exist until the first to occur of (i) the parties mutually agreeing to disband the committee, or (ii) either party providing to the other written notice of its intention to disband and no longer participate in such committee.

(b) once the jsc and the jec are disbanded in accordance with section 2.10(a), such committee shall have no further obligations under this agreement and, thereafter, the program directors will be the contact persons for the exchange of information under this agreement, and decisions of such committee shall be decisions as between the parties, subject to the final decision making authority under section 2.9 and the other terms of this agreement.

3. development of products

3.1 general.

(a) overview. the parties desire and intend to collaborate in planning and conducting development of the product for each of behçet's uveitis and the lead cardiometabolic indications, and potentially other indications, as and to the extent provided in this agreement, and pursuant to a separate global research and development plan for each indication, it being understood that each party may act either itself or through one or more licensees, sublicensees or subcontractors in its respective territory as permitted under this agreement. the parties intend to coordinate and harmonize their collaborative development activities where practical, including nonclinical and clinical studies, and manufacturing scale-up, to minimize development costs and maximize development efficiencies in both the licensed territory and the retained territory. unless otherwise specified in a global research and development plan, each year included in such plan, or (b) change the trial design of any global clinical trial included in any global research and development plan (including endpoints, sample size, inclusion and exclusion criteria).

(d) limitations of committee authority. each committee shall have solely the powers expressly assigned to it in this article 2 and elsewhere in this agreement or as otherwise agreed to by the parties in writing. a committee shall not have any power to amend, modify, or waive compliance with the terms of this agreement. it is expressly understood and agreed that the control of decision-making authority by xoma or servier, as applicable, pursuant to this section 2.9, so as to resolve a disagreement or deadlock on a committee or between the executive officers for any matter will not authorize either party to unilaterally modify or amend, or waive its own compliance with, the terms of this agreement.

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solely responsible for Development activities and for obtaining Regulatory Approval for the Product in the Retained Territory. Servier thus agrees that, on written notice by XOMA to Servier after XOMA’s entry into a Retained Territory License Agreement with a Third Party Partner, subject to the terms of any such Retained Territory License Agreement:

(i) Subject to the aforementioned Servier consent, such Third Party Partner shall have the right to have a reasonable number of its representatives attend and participate at all Committee meetings, and the vote of any such representatives shall be included within the vote of XOMA;

(ii) Subject to the aforementioned Servier consent, XOMA shall have the right to designate one or more representatives of such Third Party Partner to act as XOMA’s representatives (in replacement thereof) on any particular Committee (including the JSC but not the JEC);

(iii) Subject to the aforementioned Servier consent, Servier shall have the right to cooperate fully with such Third Party Partner with respect to the Development of Products, to the extent that Servier has the obligation under this Agreement to cooperate with XOMA as to such activities;

(iv) To the extent XOMA and/or such Third Party Partner(s) desire to conduct additional human clinical studies with respect to the Product for use in seeking Regulatory Approval for, or Commercializing the Product in the Retained Territory, any such studies or trials would be subject to Section 3.8, and, to the extent Servier on the one hand, and XOMA and its Third Party Partner, on the other hand, do not agree to pursue jointly any such study as provided in Section 3.8, such study shall be “Unsponsored Work” as provided thereunder and any data with respect to the Product generated thereunder (the “Third Party Data”), shall be available for use by Servier in the Licensed Territory to the extent provided in Section 3.8; and

(v) XOMA shall have the right to disclose to such Third Party Partner all Information regarding Products and all Regulatory Materials disclosed by Servier to XOMA under this Agreement, for use by the Third Party Partner in its Development and Commercialization of Products in the Retained Territory, consistent with Section 4.4(a) and Article 10.

3.2 Global Research and Development Plans.

(a) The Development of the Product under this Agreement for each of the Lead Cardiometabolic Indications and Behçet’s Uveitis, and any other indication the Parties agree to pursue jointly, shall be conducted pursuant to a reasonably comprehensive written research and development plan (each, a “Global Research and Development Plan”), which shall include a detailed budget for all Development activities set forth in such plan (each, a “Development Budget”), and which shall include the resource allocations for the Parties based upon the general principle that the allocation shall endeavor to take advantage of the respective resources, capabilities and expertise of XOMA and Servier, respectively. The Global Research and Development Plan also shall set forth the specific activities to be conducted by each Party and the estimated timeline for Development of the Product in order to obtain the data that the Parties intend will be useful, by both Parties, to obtain Regulatory Approvals of the Product in the U.S. and the EU. The Global Research and Development Plan shall also specify the plans and estimated timeline for preparing the necessary Regulatory Materials for obtaining Regulatory Approval in such countries. Servier shall be the sponsor of all clinical studies conducted in the Licensed Territory and shall be solely responsible for Development activities and for obtaining Regulatory Approval for the Product in the Licensed Territory, and XOMA shall be the sponsor of all clinical studies conducted in the Retained Territory and shall be solely responsible for Development activities and for obtaining Regulatory Approval for the Product in the Retained Territory.

(b) Amendments. Beginning with the first full calendar year following the Effective Date, on an annual basis (no later than [*]), or more often as the JDC deems appropriate, the JDC shall review, consult with the JMC as appropriate, and, as required, prepare an update and amendment to each then-current Global Research and Development Plan, for approval by the JSC. Each such updated and amended Global Research and Development Plan shall reflect any changes, additions, re-prioritization of studies and/or indications within, and/or reallocation of resources with respect to, the Development of the Product for the Lead Cardiometabolic Indications and Behçet’s Uveitis, and any additional indications agreed to pursuant to Section 3.8(a), as applicable. Once approved by the JSC, an amended Global Research and Development Plan shall become effective and supersede the previous Global Research and Development Plan as of the date of such approval.

3.3 Development of Product for Behçet’s Uveitis.

(a) Initial Plan for Behçet’s Uveitis. An initial Global Research and Development Plan for Behçet’s Uveitis, which contains the initial design of Behçet’s Pivotal Trial(s) and the preliminary Development Budget for continued Development of the Product for Behçet’s Uveitis [*], is attached to this Agreement as Exhibit 3.3(a) (the “Initial Behçet’s Development Plan”). The Parties shall update such plan as needed in accordance with Section 3.2(b) (such updated plan, the “Behçet’s Uveitis Development Plan”).

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(b) Responsibilities. Following the Effective Date, the Parties shall commence and conduct the Behçet’s Pivotal Trial(s) and other required studies in accordance with the timeframes and allocation of responsibilities set forth in the Behçet’s Uveitis Development Plan. [*] XOMA shall be responsible for conducting CMC Activities and providing certain clinical trial materials as set forth in Sections 6.4 and 6.5 with respect to the Behçet’s Pivotal Trial(s) and any other related trial.

(c) Development Costs and CMC Costs. Servier shall be responsible for (i) all Development Costs under the Development Budget for the Behçet’s Uveitis Development Plan, up to [*] Dollars ($[*])], and (ii) all CMC Costs for all CMC Activities associated with studies contemplated under such plan, up to [*] Dollars ($[*]). Any amounts incurred in accordance with the Development Budget and Behçet’s Uveitis Development Plan in excess of the above maximum shall be shared equally by the Parties; provided such amounts are not less than [*]% of the budgeted amounts set forth in the Development Budget for such plan, unless the Parties agree in writing to share amounts in excess of [*]% of the budgeted amounts, which agreement shall not be unreasonably withheld. XOMA shall be reimbursed amounts expended under this Section 3.3(c) and the Parties shall reconcile their expenses incurred under this Section 3.3(c), all as provided in Section 3.6.

(d) For clarity, XOMA’s exercise or failure to exercise the Cardiometabolic Indications Option shall have no effect on this Section 3.3 and the Parties’ obligations and responsibilities hereunder with respect to Development of the Product for Behçet’s Uveitis.

3.4 Development of Product for Lead Cardiometabolic Indications.

(a) Initial Plan for Lead Cardiometabolic Indications. An initial Global Research and Development Plan for Type 2 diabetes, which contains the initial plan, including study outlines and estimated timelines, and the preliminary Development Budget for the Development of the Product for Type 2 diabetes [*], will be established by the Parties within [*] days following the Effective Date and will be attached to this Agreement by reference as Exhibit 3.4(a) (the “Initial T2D Development Plan”). The Parties shall update such plan as needed in accordance with Section 3.2(b) (such updated plan, the “T2D Development Plan”). The initial Global Research and Development Plan for the Development of the Product for [*] will be prepared within [*] days of the determination by the JSC/JEC of [*].

(b) Review of Phase 2 Results in Type 2 Diabetes.

(i) XOMA will discuss with Servier the data analysis plan prior to database lock for the Phase 2b Study. Promptly after, but no later than [*] days from XOMA’s receipt of the Flash 2b Report from the Phase 2b Study, XOMA shall supply the Phase 2 Results Package to Servier. XOMA shall thereafter provide the Full Data Set to Servier, for its review, as soon thereafter as it becomes available, but in no event later than [*] days from such data becoming available. After receipt by Servier of the Phase 2 Results Package and the Full Data Set from XOMA, the Parties shall evaluate such results, [*].

(ii) If Servier does not desire to pursue Development, or does not agree on the path for such Development [*], and XOMA does or has a different plan for pursuing such Development or Regulatory Approval in the Retained Territory, XOMA shall, notwithstanding its not having exercised the Cardiometabolic Indications Option at such time, have all rights [*], and, subject to prior approval by Servier (such approval not to be unreasonably withheld), [*]. However, in such case, XOMA would not have the right [*] unless and until it exercised the Cardiometabolic Indications Option pursuant to Section 3.5, and would do so at its or its Third Party Partner’s cost and expense, as Un-sponsored Work, in accordance with Section 3.8(b), unless the Parties otherwise agree. If instead Servier does desire to pursue Development, or a different path for such Development, and XOMA does not, Servier shall nonetheless have all rights to proceed with such continued Development, and XOMA’s rights under the Cardiometabolic Indications Option shall remain in place as such Development progresses.

(c) Responsibilities and Costs During Pre-Exercise Period. XOMA shall be responsible for completing the conduct of the T2D Phase 2 Studies in accordance with the T2D Development Plan, and Servier shall be responsible for conducting or requesting that XOMA conduct, and for all Development Costs associated with, all other Development activities for the Products, including as required additional Phase 2 Clinical Trials, during the Pre-Exercise Period, subject to repayment of a portion of such costs under Section 8.5 following XOMA’s exercise of the Cardiometabolic Indications Option. Following [*], should the data warrant, [*]. XOMA would be responsible for conducting CMC Activities and providing certain clinical trial materials as set forth in Sections 6.4 and 6.5 with respect to the Lead Cardiometabolic Indications, and Servier shall be responsible for all CMC Costs associated therewith, subject to repayment of a portion of such costs under Section 8.5 following XOMA’s exercise of the Cardiometabolic Indications Option. Reimbursement of XOMA’s Development Costs and CMC Costs under this Section 3.4(c) shall be in accordance with Section 3.6.

(d) Responsibilities and Costs Post Early Option Exercise. If XOMA exercises the Early Option Exercise, and except in the case where XOMA pursued Development of the Product in Type 2 diabetes independently as provided in Section 3.4(b)(ii), then either:

(i) If the Early Option Exercise is triggered by [*] Servier has determined to move into Phase 3 Clinical Trials in the Licensed Territory, XOMA (or its licensee) shall be responsible for conducting in the Retained Territory Phase 3 Clinical Trials of the Product in Type 2 diabetes that are designed to meet the requirements of both the FDA and EMA for Regulatory Approval in the U.S. and EU, respectively, and Servier shall be responsible for conducting in the Licensed Territory such Phase 3 Clinical Trials of the Product, all in accordance with the then-current T2D Development Plan; or
Exercise of the Cardiometabolic Indications Option.

Costs as are set forth in Section 8.5. Servier responsible for [*] percent ([*]%) of such costs.

T2D and [*] Development Plans, subject to repayment of a portion of such costs under Section 8.4 in the event XOMA exercises its Late Option Indications in the Retained Territory, and (iii) an obligation to reimburse Servier the relevant percentages of its Development Costs and CMC the Lead Cardiometabolic Indications, in accordance with the Manufacturing Plan, with XOMA responsible for [*] percent ([*]%) of such costs and Servier responsible for [*] percent ([*]%) of such costs.

Servier shall be solely responsible for all Development Costs, in the first instance, incurred after the date of Early Option Exercise to conduct any Joint Phase 3 Program, as set forth in the Development Budget for the T2D or [*] Development Plan, as the case may be, provided that Servier shall have the right to [*]. Notwithstanding the foregoing, following Early Option Exercise of the Cardiometabolic Indications Option, if XOMA enters into a Retained Territory License Agreement for one or more Cardiometabolic Indications, [*], and XOMA thereafter shall be responsible for its [*] percent ([*]%) share on an ongoing basis, and shall [*] commencing with the effective date of the Retained Territory License Agreement.

In addition, following such exercise, the Parties will share the CMC Costs incurred following the date of such exercise, for such Development in the Lead Cardiometabolic Indications, in accordance with the Manufacturing Plan, with XOMA responsible for [*] percent ([*]%) of such costs and Servier responsible for [*] percent ([*]%) of such costs.

(e) Responsibilities if No Early Option Exercise. If XOMA does not effect an Early Option Exercise, until any Late Option Exercise, Servier shall be responsible itself for conducting all Phase 3 Clinical Trials of the Product in the Lead Cardiometabolic Indications and shall not be required to include in such trials any patients residing in the Retained Territory, but shall nonetheless ensure that the study design, endpoints and protocols for such Phase 3 Clinical Trials meet EMA and FDA (except for any studies or requirements that are required only by FDA and not also by EMA) requirements for Regulatory Approval of the Product in the Lead Cardiometabolic Indications. Servier shall be solely responsible for all Development Costs incurred to conduct all such Phase 3 Clinical Trials of the Product in the Lead Cardiometabolic Indications as set forth in the T2D and [*] Development Plans, subject to repayment of a portion of such costs under Section 8.4 in the event XOMA exercises its Late Option Exercise of the Cardiometabolic Indications Option.

(f) Responsibilities If No Option Exercise. Where XOMA does not exercise even its Late Option Exercise, Servier (or its sublicensees) shall remain solely responsible for all Development Costs and CMC Costs incurred in connection with the further Development of the Product in the Lead Cardiometabolic Indications and any other Cardiometabolic Indications, and shall continue to provide for review and approval by the JSC of updated T2D and [*] Development Plans to so reflect such Development, for both the Licensed Territory and the Retained Territory.

3.5 Cardiometabolic Indications Option. Subject to the terms and conditions of this Agreement, Servier hereby grants to XOMA an option to re-acquire all rights (including the right to Develop and Commercialize) to the Product for use in the Cardiometabolic Field, in the Retained Territory (the “Cardiometabolic Indications Option”) as set forth in this Section 3.5. XOMA may exercise such option by written notice to Servier and payment of the Option Exercise Fee set forth in Section 8.4, within the applicable time periods set forth below:

(a) Early Option Exercise. XOMA shall have the right to first exercise the Cardiometabolic Indications Option (the “Early Option Exercise”) at any time following the Effective Date until the date which is no later than [*] days following the earlier of (i) the first [*] or (ii) the first [*] (“Early Option Exercise Date”); or

(b) Late Option Exercise. To the extent XOMA does not effect an Early Option Exercise, it shall nonetheless have the right to exercise the Cardiometabolic Indications Option (the “Late Option Exercise”) after the Early Option Exercise Date, but no later than [*] days after the earlier of (i) [*] required for the submission of the MAA for Type 2 diabetes or (ii) [*] required for the submission of the MAA for [*], but in any event prior to submission of any MAA for the Product for Type 2 diabetes or for [*] (“Late Option Exercise Date”).

(c) Effect of Exercise. Any exercise by XOMA of the Cardiometabolic Indications Option would result in (i) termination of the license granted to Servier under Section 7.1(a)(ii)(B) effective as of such time as the payment of the Option Exercise Fee is received, (ii) reversion to XOMA of the right to use the XOMA Technology to Develop and Commercialize the Product, and Manufacture Product for use in the the Cardiometabolic Indications in the Retained Territory, and (iii) an obligation to reimburse Servier the relevant percentages of its Development Costs and CMC Costs as are set forth in Section 8.5.

3.6 Reconciliation and Reimbursement.

(a) With respect to Development Costs or CMC Costs incurred by XOMA during the prior calendar quarter and which are to be reimbursed as provided under Section 3.3(c) or 3.4(c), (d) or (e), such reimbursement shall be done on the basis of documented employee hours worked,
resolved within the applicable [*] day period, then either Party may submit the matter for non-binding mediation under Section 14.2.

In the event that the matter for resolution in accordance with Sections 2.9(b) or 2.9(c) is not resolved, provided that if, pursuant to 2.9(b), the Executive Officers are not able to resolve the matter within [*] days after the end of each calendar [*], each Party shall provide the other Party with a detailed, activity-based statement of such Development Costs or CMC Costs (the “Cost Report”) (or in each case an estimate of any portions thereof where actuals are not known as of such time) as well as details of any adjustments to be made to the amounts submitted in the previous calendar quarter, in a format to be agreed-upon by the Parties; provided that neither Party’s Development Costs or CMC Costs incurred in connection with the Development of the Product or CMC Activities undertaken in connection therewith which are greater than [*]% of the amount budgeted therefor shall be subject to cost sharing as provided herein unless the other Party has agreed to such overage, such agreement not to be unreasonably withheld. Within [*] days after the end of the calendar quarter, Servier shall provide XOMA with a written report (the “Reconciliation Report”) setting forth in a format to be agreed-upon by the Parties, the calculations of each Party’s share of such Development Costs or CMC Costs. Such Reconciliation Report shall include for such calendar quarter the (i) total Development Costs and total CMC Costs incurred by each Party, and each Party’s respective share thereof, and (ii) the net payment due from one Party to the other Party in accordance with this Section 3.6(b).

Any net payment owed from one Party to the other Party shall be paid within [*] days following such reconciliation (i.e. within [*] days after the end of the calendar quarter) provided that if a Party disputes an amount provided in such Reconciliation Report then such disputed amount shall be reviewed by the JDC (with respect to Joint Development Cost), or JMC (with respect to a CMC Cost), as applicable, and any net payment owed with respect to the undisputed amounts shall be paid within a [*] day period. If requested by a Party, any invoices or other supporting documentation for any payments to a Third Party shall be promptly provided.

3.7 Unsponsored Work and Territory-Specific Work. The costs for all Unsponsored Work (defined below), Territory-Specific Work, shall be borne solely by the Party undertaking such activities.

3.8 Additional Studies or Indications.

(a) Either Party shall have the right, through the JDC, to propose that one or more additional human clinical studies (beyond what is then included in the applicable Global Research and Development Plan) be conducted for a Lead Cardiometabolic Indication or that one or more additional indications in the Cardiometabolic Field (other than a Lead Cardiometabolic Indication) or the Remaining Field (other than Behçet’s Uveitis) be pursued for Development of the Product, and shall provide the JDC with any supporting data or publications supporting such proposal. In such event, the JDC shall consider such proposal and evaluate the supporting data and Information in good faith. If both Parties’ JDC representatives agree to conduct such proposed Development, the JDC shall prepare an amendment to the applicable Global Research and Development Plan to include the proposed studies, for approval by the JSC, and the Parties shall have the diligence obligations with respect to such additional studies or indications as provided in Sections 3.9 and 5.6. The Parties share all costs and expenses incurred to conduct such activities in accordance with the applicable budget and in the proportions set forth in Sections 3.3(c), 3.4(d), and Section 8.5, as the case may be.

(b) If the non-proposing Party (i) does not believe that such additional human clinical studies are necessary for Regulatory Approval of the Product in the applicable Lead Cardiometabolic Indication, or is not interested in pursuing a proposed new indication, (ii) does not wish to fund such proposed studies, and (iii) does not reasonably believe that such proposed activities are substantially likely to create a Material Impact, then the proposing Party shall have the right to perform the proposed activities (the “Unsponsored Work”) at its own expense. The proposing Party shall deliver to the JDC all proposed plans for such Unsponsored Work in advance of commencing such activities and deliver an update on such Unsponsored Work at each meeting of the JDC. Promptly following completion of the Unsponsored Work, the proposing Party shall deliver to the JDC the top-line data summary and shall disclose all other Information resulting from such Unsponsored Work to the other Party pursuant to Section 4.4. Notwithstanding anything to the contrary in this Agreement, the non-proposing Party shall have access to and the right to use all Information resulting from the Unsponsored Work solely as necessary to comply with the regulatory requirements in its territory in particular with respect to safety reporting and a Party’s license rights to such Information shall be limited solely to such purpose. If, following completion of any Unsponsored Work, the non-proposing Party wishes to have the right to use the resulting Information (beyond the rights pursuant to the immediately preceding sentence of this Section 3.7(b)), it may do so upon reimbursing the proposing Party for [*] percent ([*]%) of its reasonable documented costs and expenses of the Unsponsored Work. Once the non-proposing Party has reimbursed such amounts, the Information from such Unsponsored Work shall be included in the proposing Party’s licensed know-how, the activities shall no longer be considered Unsponsored Work, and the applicable indication shall be subject to milestone payments as and to the extent specified under Article 8. If however, the non-proposing Party does in good faith believe the proposed activities are substantially likely to create a Material Impact, the Parties shall submit the matter for resolution in accordance with Sections 2.9(b) or 2.9(c); provided that if, pursuant to 2.9(b), the Executive Officers are not able to resolve the matter within the applicable [*] day period, then either Party may submit the matter for non-binding mediation under Section 14.2.
3.9 Development Diligence; Standards of Conduct. Each Party shall use Diligent Efforts to carry out the activities assigned to it under the Global Research and Development Plans. Each Party shall conduct its activities under the Global Research and Development Plans in a good scientific manner and in compliance with all applicable Laws. Servier will use Diligent Efforts to Develop and obtain Regulatory Approval for the Product in the Lead Cardiometabolic Indications, Behçet’s Uveitis and any additional indications agreed pursuant to Section 3.8(a) in the Licensed Territory and, following the Pre-Exercise Period, if XOMA has not exercised the Cardiometabolic Indications Option, for the Lead Cardiometabolic Indications and any additional Cardiometabolic Indications agreed pursuant to Section 3.8(a) in the Retained Territory, itself or through one or more sublicensees. The Parties agree that as and to the extent Development of the Product is terminated for any indication, they will discuss in good faith another indication to pursue, either jointly or independently as Unsponsored Work.

3.10 Opt-Out Rights of Either Party in Cardiometabolic Field. If XOMA exercises the Cardiometabolic Indications Option under Section 3.5, and thereafter the Parties are conducting a Joint Phase 3 Program or otherwise jointly conducting and funding one or more studies with respect to the Product in a given Cardiometabolic Indication, then on an indication-by-indication basis, upon [*] days written notice, either Party shall have the right to “opt-out” of its obligations to jointly conduct such program for such indication; provided, however, that regardless of such election to so opt-out, the opting-out Party would nonetheless be responsible for its allocated percentage of all Development Costs and CMC Costs allocable to any then-ongoing studies or trials with respect to such Indication, and would have all rights under Section 4.4 to reference and use the data and other results of any such trials or studies, it being understood that any studies or trials initiated and conducted thereafter by the non-opting-out Party would be Unsponsored Work as to which the opting-out Party has only those rights as specified in Section 3.8(b).

3.11 Development Records and Reports. Each Party shall maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf under the Global Research and Development Plans and all Information resulting from such work. Such records, including any electronic files where such Information may also be contained, shall fully and properly reflect all work done and results achieved in the performance of the Global Research and Development Plans in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each Party shall have the right to review and copy such records maintained by the other Party at reasonable times, but no less than [*] in any one calendar year, and to obtain access to originals (including the databases) to the extent needed for patent or regulatory purposes or for other legal proceedings. Each Party shall provide the other party and the JDC with regular reports detailing its Development activities under the Development Plan and the results of such activities at each regularly scheduled JDC meeting, at a level of detail reasonably sufficient to enable the other Party to determine the reporting Party’s compliance with its Diligent Efforts obligations under Section 3.9. The Parties may agree to set up an electronic data room in order to manage the exchange of information in a secure manner.

3.12 Subcontracts. Each Party may perform any of its Development obligations under this Agreement through one or more subcontractors and consultants upon written notice to the JDC, provided that (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractors and consultants undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 10 hereof; and (c) the subcontractors and consultants agree in writing to assign all intellectual property developed in the course of performing any such work under the Global Research and Development Plans to the Party retaining such subcontractors or consultants.

3.13 Personnel. All employees, agents and subcontractors of each Party and its Affiliates conducting activities under this Agreement shall, prior to commencing any such activities, be under written obligation to assign any inventions and related intellectual property rights to the Party by whom they are employed or for whom they are providing services (or its designated Affiliate). The Parties acknowledge and agree that this Agreement shall be deemed to be a joint research agreement under 35 U.S.C. §103(c).

4. Regulatory Matters

4.1 Lead Regulatory Party. In general, XOMA shall be the lead Party for, and have the final say with respect to, subject to Section 2.9, regulatory activities regarding the Product in the Retained Territory for the Remaining Field and, if XOMA exercises the Cardiometabolic Indications Option, for the Cardiometabolic Indications. Servier (or its designee for the Retained Territory) shall be the lead Party for, and have the final say with respect to, subject to Section 2.9, all regulatory activities regarding the Product in the Licensed Territory for all indications and in the Retained Territory for the Cardiometabolic Indications if XOMA does not exercise the Cardiometabolic Indications Option before expiration thereof. Except for those clinical studies commenced prior to the Effective Date and unless otherwise agreed by the Parties, Servier shall be the sponsor of all clinical studies of the Product performed in the Licensed Territory, and XOMA (or its licensee) shall be the sponsor of all clinical studies performed in the Retained Territory; provided that if XOMA does not exercise the Cardiometabolic Indications Option before expiration thereof, Servier’s designee shall be the sponsor of all clinical studies performed in the Retained Territory for the Product in any Cardiometabolic Indication. To the extent a Party for a given clinical trial requires that the other Party conduct some part of such trial or interact with Regulatory
4.2 Ownership of Regulatory Dossier. Servier will own all Regulatory Materials for the Product in the Licensed Territory, and XOMA will own all Regulatory Materials for the Product in the Retained Territory, for all indications. Following the Pre-Exercise Period, where XOMA has not exercised the Cardiometabolic Indications Option, and upon the sublicense by Servier, if any, of the rights to the Product in such indications in the Retained Territory to a Third Party, XOMA shall be obligated at such time to assign over to such Third Party, upon request, any such Regulatory Materials for the Product for the Cardiometabolic Indications. XOMA will also manage and control the drug master file for the Licensed Antibody, to which Servier shall have full access and the right to reference for the exercise of its licenses to the Product.

4.3 Regulatory Rights, Diligence and Responsibilities. Servier shall use Diligent Efforts to prepare and file all necessary Regulatory Materials for the Product with Regulatory Authorities and to seek Regulatory Approval for the Product in the Lead Cardiometabolic Indications and in Behçet's Uveitis in the Major European Countries, and shall be responsible for preparing and filing all necessary Regulatory Materials for the Product with Regulatory Authorities and seeking Regulatory Approval for the Product in all other indications in the Licensed Territory, in each case as relevant, in accordance with the Global Research and Development Plans. XOMA shall be responsible for preparing and filing all necessary Regulatory Materials for the Product with Regulatory Authorities and seeking Regulatory Approval for the Product in the Retained Territory in all indications other than the Cardiometabolic Indications and, upon exercise of the Cardiometabolic Indications Option, in the Cardiometabolic Indications in the Retained Territory, in accordance with the Global Research and Development Plans. Each Party shall keep the other Party informed of regulatory developments relating to the Product in its respective territory through regular reports at the JDC meetings. Each Party shall send Regulatory Materials (in the case of Servier for the EMA) in draft form to the other Party and give the latter a reasonable period of time (not exceeding [*] days) to comment on such drafts of Regulatory Materials. Each Party shall notify the other Party of any Regulatory Materials (other than routine correspondence) submitted to or received from any Regulatory Authorities respectively in the Retained Territory for XOMA and in the Major European Countries for Servier and shall provide the other Party with copies thereof. Each Party shall provide the other Party with reasonable advance notice of all meetings, conferences, and discussions scheduled with any Regulatory Authority (in the case of Servier for the EMA) concerning the Product, and shall consider in good faith any input from the other Party in preparing for such meetings, conferences or discussion. Unless prohibited by applicable Laws, XOMA shall have the right to attend any such meetings, conferences or discussions of Servier with EMA. If XOMA elects not to or cannot attend such meetings, conferences or discussions, Servier shall provide written summaries of such meetings, conferences or discussions in English as soon as practicable after the conclusion thereof. Following the last Phase 2 Clinical Trial for Type 2 diabetes, as determined by the JDC, XOMA agrees to schedule and attend an End of Phase 2 Meeting with the FDA with respect to the anticipated Phase 3 clinical program for Type 2 diabetes, should the data warrant, Servier will have the option, but not the obligation, to have representatives of Servier present at such meeting.

4.4 Rights of Reference; Use of Data.

(a) Promptly after the Effective Date, XOMA shall work with Servier to facilitate the timely transfer of the XOMA Know-How related to the Product (other than the XOMA Know-How related to Manufacturing, which is covered by Section 6.8). Such transfer shall occur in a manner and following a reasonable schedule to be established by the JSC. XOMA shall provide access to Servier to copies of relevant material, Information, reports and data, including pre-clinical data, clinical data, and any data that have been provided to Regulatory Authorities for the purpose of obtaining Regulatory Approval. Except with respect to Unsponsored Work, each Party shall make available to the other Party all data and results generated under any Global Research and Development Plan and, for use in complying with safety reporting obligations in its territory, all data generated under any Unsponsored Work or Territory-Specific Work; and each Party shall have the right to cross reference, file or incorporate by reference any Regulatory Materials filed by the other Party (or for which the other Party has a right of reference and a right to transfer such right of reference to such first Party) for the Product in order to support regulatory filings that such Party is permitted to make under this Agreement for the Product and to enable such Party to fulfill its obligations and exploit its rights under this Agreement to Develop, Manufacture (subject to Article 6), or Commercialize the Product. Each Party shall, upon written request by the other Party (or its Affiliate or licensee), provide to the requesting Party and to any specified Regulatory Authority a letter, in the form reasonably required by the requesting Party, acknowledging that the requesting Party has the right of reference to any such Regulatory Materials for all purposes consistent with the Development and Commercialization of Product in the applicable country. Further, each Party shall ensure that any other party to which such Party assigns any such Regulatory Materials agrees in writing that the other Party has the above rights of reference, and to provide to such other Party (or its Affiliate or licensee) and to any specified Regulatory Authority a letter, in the form reasonably required by the requesting Party, acknowledging that the requesting Party has the right of reference to any such Regulatory Materials for all such purposes.

(b) During the Term, on a regular basis, each Party shall present reports at JDC meetings on its activities under the Global Research and Development Plans and all regulatory activities with respect to Products in its territory, at a level of detail to be agreed by the JDC; provided, however, that any such presentation shall include at least a summary of the resulting data from all studies conducted by a Party with respect to the Product.
5. Commercialization

5.1 Overview. Servier shall have sole control and responsibility for the Commercialization of Products in the Licensed Territory and shall bear all costs and expenses associated with the Commercialization of Products in the Licensed Territory; and XOMA shall have sole control and responsibility for the Commercialization of Products in the Retained Territory and shall bear all costs and expenses associated with the Commercialization of Products in the Retained Territory; provided, however that following the Pre-Exercise Period, if XOMA does not exercise the Cardiometabolic Indications Option, Servier (or its sublicensee) shall have the right to initiate a recall or withdrawal of a Product for the Cardiometabolic Field in the Retained Territory. In the event of any recall or withdrawal, such Party shall take any and all necessary action to implement such recall or withdrawal in accordance with applicable Laws, with assistance from the other Party as reasonably requested by the deciding Party. The costs of any such recall or withdrawal shall be borne solely by the deciding Party in the applicable territory and field.

5.2 Sales and Distribution. It is understood that as between the Parties, the Commercializing Party shall be solely responsible for handling all returns, order processing, invoicing and collection, distribution, and receivables for Products in the applicable territory and indication.

5.3 Ex-Territory Sales. Neither Party shall engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located outside its territory or accept orders for Products from or sell Products into such other Party’s territory for its own account or for the Commercializing Party’s account, and if such other Party receives any order for Products in the Commercializing Party’s territory, it shall refer such orders to the Commercializing Party for acceptance or rejection.

5.4 Commercialization Plan for Licensed Territory. Servier shall pursue Commercialization of the Product in the Licensed Territory, in accordance with its normal business practices for its internal products at a similar stage. Servier shall deliver an initial Commercialization plan to XOMA no later than [*] months prior to the anticipated date of the first filing of the first MAA for the Product in the Licensed Territory (the “Commercialization Plan”). After the establishment of the initial Commercialization Plan, Servier shall prepare updates and amendments to such Commercialization Plan at least annually and deliver such updated Commercialization Plan to XOMA no later than October 31st of each calendar year.

5.5 Trademarks. Servier shall have the right to brand the Products in the Licensed Territory using trademarks and trade names it determines appropriate for the Products, which may vary by country or within a country (“Product Marks”). Each Party shall not, and shall ensure that its Affiliates and sublicensees will not, make any use of the trademarks or house marks of the other Party or its Affiliates or licensees (including their corporate names) or any trademark confusingly similar thereto. Servier shall own all rights in the Product Marks and shall register and maintain the Product Marks in the Retained Territory (if XOMA does not exercise the Cardiometabolic Indications Option) and other countries it determines reasonably necessary at its own cost and expense. XOMA shall have the right to brand the Products in the Retained Territory in the Remaining Field, and, in the event that XOMA exercises the Cardiometabolic Indications Option, in the Cardiometabolic Indications, using trademarks and trade names it determines appropriate for the Products at XOMA’s cost and expense. Following the Pre-Exercise Period, if XOMA does not exercise the Cardiometabolic Indications Option, Servier shall have the right to convey to any sublicensee in the Retained Territory the right to brand the Products for the Cardiometabolic Indications, subject to coordination with and the approval of XOMA, not to be unreasonably withheld, to ensure that no confusion arise in the Retained Territory with respect to Products for use in the Remaining Field and those for use in the Cardiometabolic Indications.

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(c) All preclinical, non-clinical, analytical, manufacturing, and clinical data and associated reports disclosed by one Party to the other under this Agreement, other than Unsponsored Work or Territory-Specific Work, may be used by the receiving Party subject to the terms of this Agreement solely for the purpose of Developing, seeking and obtaining Regulatory Approval and Commercializing the Product in its respective territory and field. Each Party shall have the right to share any and all such data and other Regulatory Materials received from the other Party with its Affiliates and any Third Party sublicensees or licensees in its respective territory solely for the purpose of Developing, seeking and obtaining Regulatory Approval and Commercializing the Product in its respective territory and field. Access to and use of such pre-clinical and clinical data are given by each Party to the other Party without cost (except as otherwise provided herein) on an “as is” basis without any warranty of any kind. Each receiving Party accepts all risk and liability in relation to the use of the data received from the other Party and shall indemnify and hold harmless the Party providing such data from any Third Party’s claim(s) based upon such data as provided in Article 13.
5.6 Commercial Diligence. During the Term, Servier shall use Diligent Efforts to Commercialize the Products throughout the Licensed Territory [*], including in [*] of the Major European Countries, in the Cardiometabolic Field and in the Remaining Field. Without limiting the generality of the foregoing, Servier [*], including in [*] of the Major European Countries, in Behçet’s Uveitis, in each Lead Cardiometabolic Indication pursuant to Section 3.8(a). After the Pre-Exercise Period, if XOMA does not exercise the Cardiometabolic Indications Option, Servier shall include in any sublicense agreement with respect to the Retained Territory, that such sublicensee [*] to Commercialize the Product in the U.S. and Japan in each Lead Cardiometabolic Indication and each additional Cardiometabolic Indication agreed pursuant to Section 3.8(a), in each case provided that it receives Regulatory Approval in such countries. To the extent Servier determines not to apply for Regulatory Approval, for and/or launch the Product [*], it shall promptly notify XOMA and terminate this Agreement with respect to such Significant Markets in accordance with Section 11.2.

5.7 Standards of Conduct. Each Party shall in all respects comply with all applicable Laws and applicable guidelines concerning the advertising, sales and marketing of prescription drug products in Commercializing Products under this Agreement, including without limitation the Foreign Corrupt Practices Act of 1977, as amended (“FCPA”) and any applicable local anti-bribery laws.

5.8 Limitations and Protections in Retained Territory in Event of No Option Exercise. Following the Pre-Exercise Period and where XOMA does not exercise or allows to lapse the Cardiometabolic Indications Option, the following shall apply thereafter:

(a) Limitations on Development.

(ii) Except as expressly approved in advance in writing by the Parties, neither Servier, nor any of its Affiliates or sublicensees shall, directly or through any Third Party, sponsor, conduct or cause to be conducted, otherwise assist in, supply any Licensed Antibody or Product for use in connection with, fund or otherwise support any human clinical trial (including without limitation any investigator sponsored studies) using such Licensed Antibody or Product for any indication or use in the Retained Territory, in the Remaining Field.

(b) Limitations on Commercialization Activities

(i) Subject to any applicable law, Servier and its sublicensees (and their respective Affiliates) shall not knowingly promote or sell (or encourage or facilitate the sale of) (a) any Product for use in the Remaining Field in the Retained Territory. Servier and its sublicensees (and their respective Affiliates) shall not provide funding to or otherwise support continuing education programs for sales representatives and/or medical professionals in which information is provided about the use of any Product for use in the Remaining Field in the Retained Territory.

(c) Tracking of Sales of Product. Should XOMA not exercise the Cardiometabolic Indications Option, the Parties agree to discuss, through the JSC and/or JEC, potential mechanisms to be put in place with respect to the tracking of sales of the Product as between the Cardiometabolic Indications and the Remaining Field in the Retained Territory.

(d) Each of Servier and XOMA shall ensure that any license or sublicense agreement it enters into with respect to the Retained Territory include the foregoing obligations.

6. Manufacturing

6.1 Overview. The Manufacture of Product shall be overseen and coordinated by the Joint Manufacturing Committee and conducted pursuant to the Manufacturing Plan. In general and subject to the terms of this Agreement, (a) XOMA shall be primarily responsible for conducting the CMC Activities, (b) XOMA shall be responsible for Manufacturing Bulk Drug Substance for clinical and commercial use for the Licensed Territory and the Retained Territory, (c) Servier shall be responsible for Manufacturing finished Product from such Bulk Drug Substance for sale of Products in the Licensed Territory, and (d) where XOMA does not exercise its Cardiometabolic Indications Option, Servier, or at Servier’s choice XOMA (for a period not to exceed [*] years from First Commercial Sale in the Retained Territory) or a Third Party designated by Servier, shall be responsible for Manufacturing finished Product from such Bulk Drug Substance for sale of Products in the Cardiometabolic Field in the Retained Territory.

6.2 Manufacturing Plan. XOMA shall prepare and propose to the JMC for discussion purposes a detailed plan for CMC Activities, including process development and scale-up, Manufacture of Bulk Drug Substance, Manufacture of finished Product from Bulk Drug Substance, and any
other matters related to the Manufacture of the Product, as well as a quarter-by-quarter budget for such activities (including direct costs, external costs, costs of raw materials, capital improvements required in connection therewith, and the like), such a detailed plan will be submitted for approval to the JSC (the “Manufacturing Plan”). The Manufacturing Plan will include only those capital expenditures by XOMA that are fully dedicated to the production of Bulk Drug Substance, and will provide allocations of costs for those costs that are shared between Bulk Drug Substance and other products of XOMA. An initial Manufacturing Plan for Development of the Product for Behçet’s Uveitis for calendar year 2011 is attached to this Agreement as Exhibit 6.2. The Parties, through the JMC, shall make good faith efforts to review such initial Manufacturing Plan and agree upon any revisions, amendments or additions thereto, for the Product for Behçet’s Uveitis and the Lead Cardiometabolic Indications for the subsequent [*] years, and have it approved by the JSC within [*] days after the Effective Date. On an annual basis, the JMC shall have prepared by XOMA and shall propose any amended or revised Manufacturing Plan for approval by the JSC by no later than [*] of each year, the budget for which shall govern the activities to be conducted during the following calendar year to enable appropriate scale up activity and financial planning.

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6.3 Future Planning. Promptly after the Effective Date, the Parties through the JMC shall discuss a mutually beneficial arrangement for the harmonized Manufacture of Bulk Drug Substance for Commercialization and Development use by Servier, consistent with the following principles, and amend the Manufacturing Plan to reflect such arrangement:
(a) Maintain quality control standards and uniform specifications for the Bulk Drug Substance and finished Product;
(b) Enable speed to market for initial launch and subsequent indications;
(c) Mitigate risks to ensure the uninterrupted supply of Bulk Drug Substance and finished Product.
(d) Minimize XOMA Manufacturing Costs.

6.4 CMC Activities. XOMA shall be responsible for the performance of CMC Activities for Bulk Drug Substance, including associated regulatory activities, in accordance with the Manufacturing Plan. Prior to XOMA’s exercise of the Cardiometabolic Indications Option and thereafter if XOMA does not exercise such option, Servier shall reimburse XOMA for all documented costs incurred by XOMA in performing such activities in accordance with the Manufacturing Plan and the budget contained therein, as provided in Article 3. If XOMA exercises the Cardiometabolic Indications Option, XOMA shall reimburse certain of these costs as provided in Section 8.5, and the Parties shall thereafter share such costs for the Cardiometabolic Field as provided in Section 3.4(d).

6.5 Supply of Bulk Drug Substance. Until such time as Servier may establish a second source of Bulk Drug Substance as contemplated in Section 6.7, Servier, its Affiliates and sublicensees shall purchase exclusively from XOMA, and XOMA shall Manufacture and supply exclusively to Servier or its Affiliates or sublicensees, subject to the terms of this Article 6, and to the terms of the Supply Agreement (as defined below), all Bulk Drug Substance required by Servier, its Affiliates and sublicensees for Development use and for Commercial use.

(a) Clinical Use. Bulk Drug Substance for clinical use by Servier will be supplied either as finished Product in vials or as Bulk Drug Substance, at Servier’s option. Manufacture and supply of Bulk Drug Substance will be included within CMC Activities under the Manufacturing Plan, and all related costs will be included in CMC Costs under Section 6.4.

(b) Commercial Use.

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(i) XOMA’s manufacture and supply of Bulk Drug Substance to Servier for commercial use will be governed by a supply agreement, containing commercially reasonable terms mutually agreed by the Parties, including terms for sales forecasting, inventory builds and safety stock requirements, an initial version of which will be negotiated and entered into within [*] days after the Effective Date (the “Initial Supply Agreement”). At a time to be determined by the JMC, and reasonably sufficiently in advance of the anticipated First Commercial Sale of a Product, the Parties will amend the Initial Supply Agreement to reflect then-available relevant Information (as amended, the “Supply Agreement”). XOMA will supply Bulk Drug Substance to Servier for commercial use at a price equal to [*]% of the XOMA Manufacturing Costs for such Bulk Drug Substance.

(ii) For the avoidance of doubt, no cost or expense shall be counted more than once in calculating XOMA’s actual Manufacturing costs or the XOMA Manufacturing Costs even if such cost or expense falls into more than one of the cost categories that comprise such cost. The Parties agree that each shall use its good faith efforts to reduce the XOMA Manufacturing Costs, including, where appropriate, the procurement of raw materials by using Servier’s internal procurement infrastructure.

(c) Existing Inventory. Servier shall only purchase from XOMA, and XOMA shall sell to Servier, XOMA’s existing inventory of phase 2 clinical materials and XOMA’s existing inventory of phase 3 clinical materials that are necessary and suitable for the performance of clinical studies by
6.6 Manufacture of Finished Product. For all Product sold by or on behalf of Servier, except for the Products sold in the Retained Territory (which is discussed under Section 6.1), XOMA shall be responsible for final Manufacture of the finished Product from Bulk Drug Substance, including fill and finish and packaging, at Servier's expense; provided that upon Servier's request, XOMA shall arrange for a Third Party selected and approved by Servier to conduct final Manufacture of the Product for Servier from Bulk Drug Substance supplied by XOMA, including fill and finish and packaging, at Servier's expense. Where Servier requests that XOMA be responsible for final Manufacture of finished Product from Bulk Drug Substance for sale in the Retained Territory, the Parties shall discuss the terms and conditions of such final Manufacture at such time.

6.7 Manufacturing Facilities. XOMA shall ensure that (a) prior to the first filing of an MAA for the Product with the EMA, there is at least one facility qualified to manufacture Bulk Drug Substance for MAA submission to the EMA and (b) prior to the filing of an MAA for the first Major Cardiometabolic Indication for the Product with the EMA, there is a second facility qualified to manufacture Bulk Drug Substance for MAA submission to the EMA; provided that, where upon timely request by Servier, such second Bulk Drug Substance manufacturing facility is to be located in the EU and owned by Servier or by a Third Party contract manufacturer selected by Servier (the “Servier Facility”), the costs and expenses of qualifying and constructing such Servier Facility shall be borne by Servier; and provided further, that where Servier does not so request, XOMA shall establish such second facility outside the EU, at its own expense. In connection with such request by Servier regarding the Servier Facility, the Parties shall discuss in good faith and cooperate with respect to the transfer of XOMA Know-How related to the Manufacture of Bulk Drug Substance and Product to the Servier Facility pursuant to Section 6.8.

6.8 Transfer of XOMA Know-How and Manufacturing Technology.

(a) At Servier’s request and expense, and on a schedule determined by the JMC, XOMA shall disclose (and provide copies, as applicable) to either Servier or the Third Party manufacturer selected by Servier under Section 6.7, all XOMA Know-How necessary or useful to enable Servier or such Third Party manufacturer (as appropriate) to Manufacture Bulk Drug Substance. For clarity, nothing in this Section 6.8 with respect to XOMA’s obligation to transfer XOMA Know-How to Servier shall limit XOMA’s right to use any such XOMA Know-How to fulfill XOMA’s obligations to Manufacture and supply Bulk Drug Substance to Servier under this Agreement or the Supply Agreement. In addition, XOMA shall make available to Servier, on a reasonable consultation basis, advice of its technical personnel as may reasonably be requested by Servier in connection with such transfer of XOMA Know-How. [*]

(b) Servier and/or its Third Party manufacturer shall use the XOMA Know-How transferred under Section 6.8(a) solely for the purpose of Manufacturing Bulk Drug Substance and finished Products in accordance with the terms and conditions of this Agreement, and for no other purpose.

(c) Servier acknowledges and agrees that XOMA may condition its agreement to transfer any XOMA Know-How to a Third Party manufacturer on the execution of a confidentiality agreement between such Third Party manufacturer and XOMA that contains terms substantially equivalent to those of Article 10.

6.9 Audits.

(a) XOMA shall maintain, for at least [*] years from the date of creation, accurate records and accounts of costs of Manufacturing the Bulk Drug Substance in order to allow Servier to determine the accuracy of the calculation of XOMA Manufacturing Costs. Upon the written request of Servier and not more than once in any calendar year, XOMA shall permit an independent certified public accounting firm of internationally recognized standing, selected by Servier and reasonably acceptable to XOMA and under binder of confidentiality, to have access during normal business hours to such of the records of XOMA as may be reasonably necessary to verify the accuracy of such calculations hereunder for any year ending not more than [*] months prior to the date of such request. The accounting firm shall disclose to Servier only whether the records are correct or not and the specific details concerning any discrepancies. The findings of such inspection shall be XOMA's Confidential Information for the purposes of Article 10; provided that Servier shall have the right to disclose such findings to any sublicensee or Affiliate in accordance with Article 10.

(b) If such accounting firm concludes that Servier has overpaid for the Bulk Drug Substance supplied during such period, XOMA shall refund Servier the amount overpaid within [*] days after the receipt of such accounting firm’s written report so concluding. If such accounting firm concludes that additional amounts were owed by Servier for the for the Bulk Drug Substance supplied during such period, Servier shall pay the additional amounts to XOMA within [*] days after the receipt of such accounting firm’s written report so concluding. Any such audit of records shall be at Servier's expense; provided that in the event such audit discloses an overpayment of more than [*] percent ([*]%) between the amounts paid and the amounts due to XOMA, XOMA shall pay the expense of such audit.
6.10 Quality Agreement. In connection with the negotiation of the Supply Agreement, the Parties also shall enter into a separate quality agreement setting forth the responsibilities of the quality organizations of each Party with respect to the cGMP manufacture of the Product (the “Quality Agreement”). In the event of any conflict or inconsistency between the Quality Agreement and this Agreement, the Quality Agreements shall govern with respect to matters related to quality, and this Agreement shall govern with respect to all other matters.

6.11 Safety Data Exchange Agreement. As soon as reasonably practicable after the Effective Date, but in no event later than 90 days thereafter, the pharmacovigilance departments of both Parties shall meet and agree on a safety data exchange agreement (“Safety Data Exchange Agreement”) which when executed shall be incorporated herein as Exhibit 6.11.

7. Licenses and Related Rights

7.1 Licenses to Servier.

(a) License Grant. Subject to the terms and conditions of this Agreement and the agreements set forth on Exhibit 7.1(a), XOMA hereby grants Servier:

(i) a co-exclusive (with XOMA) royalty free license, with the right to sublicense as provided in Section 7.1(c), under the XOMA Technology to (A) Develop Products in the Cardiometabolic Field and in the Remaining Field in the Licensed Territory (subject to the last sentence of Section 4.1., and to Section 3.3.(b) above), and (B) in the Cardiometabolic Field in the Retained Territory, subject to earlier termination in the event of XOMA’s exercise of the Cardiometabolic Indications Option, solely in accordance with the Global Research and Development Plans and/or this Agreement;

(ii) an exclusive, royalty-bearing license, with the right to sublicense as provided in Section 7.1(c), under the XOMA Technology to use, sell, offer for sale, distribute, import, export and otherwise Commercialize Products in (A) the Remaining Field and the Cardiometabolic Field in the Licensed Territory during the Term and (B) the Cardiometabolic Field in the Retained Territory, during the Term, but subject to earlier termination in the event of XOMA’s exercise of the Cardiometabolic Indications Option; and

(iii) an exclusive, worldwide, royalty-free license under the XOMA Technology, with the right to sublicense as provided in Section 7.1(c), to make and have made finished Product from Bulk Drug Substance supplied by XOMA, (A) in the Remaining Field in the Cardiometabolic Field in the Licensed Territory and (B) for use in the Development or Commercialization of Products in the Cardiometabolic Field in the Retained Territory, until such time as and subject to XOMA’s exercise of the Cardiometabolic Indications Option. In addition, XOMA hereby grants Servier a license to manufacture or have manufactured Bulk Drug Substance (X) solely for use in the Development or Commercialization of Products in and for the Licensed Territory, and (Y) for use in the Development or Commercialization of Products solely in the Cardiometabolic Field in the Retained Territory, until such time as and subject to XOMA’s exercise of the Cardiometabolic Indications Option, all as and to the extent provided in Sections 6.7 and 6.8.

(b) XOMA Retained Rights. It is understood that at all times XOMA and its Affiliates retain (i) the exclusive right to Develop and Commercialize the Product in the Remaining Field in the Retained Territory, (ii) the right to practice the XOMA Technology as and to the extent needed in connection with its activities under this Agreement in fulfillment of its obligations hereunder, (iii) the right to Manufacture Bulk Drug Substance in the Licensed Territory and the Retained Territory and (iv) the right to use and practice the XOMA Technology outside the scope of the licenses granted to Servier in Section 7.1(a).

(c) Sublicense Rights.

(i) Servier shall have the right to grant sublicenses of the licenses granted to it under Section 7.1(a)(i)(A), Section 7.1(a)(i)(A), and Section 7.1(a)(ii)(A) and 7.1(a)(ii)(X) to any of its Affiliates. Servier shall have the right to grant sublicenses of the licenses granted to it under Section 7.1(a)(i)(A), Section 7.1(a)(i)(A), and Section 7.1(a)(iii)(A) to any Third Parties with the prior written consent of XOMA, not to be unreasonably withheld;

(ii) Servier shall have the right to grant sublicenses of the licenses granted to it under Section 7.1(a)(i)(B), 7.1(a)(ii)(B) and Section 7.1(a)(ii)(B) to any of its Affiliates. Servier shall have the right to grant sublicenses of the licenses granted to it under Section 7.1(a)(i)(B), 7.1(a)(ii)(B), Section 7.1(a)(iii)(B), and 7.1(a)(iii)(Y) to any Third Parties with the prior written consent of XOMA, not to be unreasonably withheld, but only in the event XOMA does not exercise its Cardiometabolic Indications Option; for clarity, where XOMA does not exercise such option at the Early Option Exercise Date, Servier shall have no right to sublicense such rights until after the Late Option Exercise Date;

provided that in the case of Third Parties: (w) Servier shall provide XOMA with prior written notice with respect to any such sublicense, and a redacted copy thereof, (x) Servier shall remain responsible for the compliance with this Agreement by such sublicensee(s), (y) each such sublicense agreement shall be consistent with the terms and conditions of this Agreement, and (z) Servier shall require, in substance, any sublicense of XOMA Technology in the Cardiometabolic Field in the Retained Territory to defend, indemnify and hold harmless the XOMA Indemnities from any and all damages or other amounts payable to a Third Party claimant, to the extent resulting from Claims against them that arise from or are based on: (A) the use of XOMA Technology in connection with the Development, Manufacture or Commercialization of the
7.2 Licenses to XOMA.

(a) License Grant. Subject to the terms and conditions of this Agreement, Servier hereby grants XOMA:

(i) a non-exclusive, royalty-free license, with the right to sublicense as provided in Section 7.2(b), under the Servier Technology to Develop Products in the Cardiometabolic Field (subject to XOMA’s exercise of the Cardiometabolic Indications Option) and in the Remaining Field solely in accordance with the Global Research and Development Plans and/or this Agreement;

(ii) a non-exclusive, royalty-free license, with the right to sublicense as provided in Section 7.2(b), under the Servier Technology to use, sell, offer for sale, distribute, import, export and otherwise Commercialize Products in (A) the Remaining Field in the Retained Territory during the Term and (B) upon XOMA’s exercise of the Cardiometabolic Indications Option, the Cardiometabolic Field in the Retained Territory; and

(iii) a non-exclusive, worldwide license under the Servier Technology to Manufacture Bulk Drug Substance and Product.

(b) Sublicense Rights. XOMA shall have the right to grant sublicenses of the license granted to it under Section 7.2(a) to any of its Affiliates. XOMA shall have the right to grant sublicenses of the license granted to it under Section 7.2(a) to any Third Parties, with the prior written consent of Servier, which shall not be unreasonably withheld: (i) XOMA shall provide Servier with prior written notice with respect to any such sublicense, (ii) XOMA shall remain responsible for the compliance with this Agreement by such sublicensee(s), and (iii) each such sublicense agreement shall be consistent with the terms and conditions of this Agreement.

(c) Exclusive Rights Option. Should XOMA desire to convert any of the licenses granted under Section 7.2(a) from non-exclusive to exclusive, upon reasonable written notice to Servier, the Parties shall negotiate in good faith the terms upon which Servier will grant such exclusive rights.

7.3 Negative Covenants.

(a) Servier covenants that it will not, and will not permit any of its Affiliates or sublicensees to, use or practice any XOMA Technology outside the scope of the license granted to it under Section 7.1 above. XOMA covenants that it will not, and will not permit any of its Affiliates or sublicensees to, use or practice any Servier Technology outside the scope of the license granted to it under Section 7.2 above.

(b) XOMA agrees that during a period of [*] years following the First Commercial Sale of the Product in the Licensed Territory, it shall not, itself or through one or more Affiliates or Third Parties, sell, offer for sale, distribute, promote or market any Competing Product (x) for use in any indication in the Licensed Territory, and (y) in the event of expiration of the Cardiometabolic Indications Option without exercise by XOMA, in the Retained Territory for use in any Cardiometabolic Indication.

(c) Servier agrees that during a period of [*] years following the First Commercial Sale of the Product by or on behalf of XOMA in the Retained Territory, it shall not, itself or through one or more Affiliates or Third Parties, sell, offer for sale, distribute, promote or market any Competing Product (x) for use in any indication in the Licensed Territory, (y) for use in any indication in the Retained Territory if XOMA exercises the Cardiometabolic Indications Option, or (z) for use in any indication, other than Cardiometabolic Indications, in the Retained Territory, in the event of expiration of the Cardiometabolic Indications Option without exercise by XOMA.

(d) Sections 7.3(b) and 7.3(c) shall survive termination of this Agreement as follows:

(i) Upon early termination of this Agreement by Servier under Section 11.2 (whether in its entirety or in a given country or region) or by XOMA under Section 11.4 , Section 7.3(c) shall survive (in the terminated country/region(s) or, if the Agreement is terminated in its entirety, in the Licensed Territory and Retained Territory ) until the earlier of (A) [*] years following the First Commercial Sale of the Product in the Retained Territory by or on behalf of XOMA, or (B) [*] years following the effective date of such termination. However, in the event of such termination, XOMA’s obligations under Section 7.3(b) shall terminate in the terminated country/region(s) or in the Licensed Territory in its entirety, as applicable.

(ii) Upon termination of this Agreement by Servier under Section 11.3 , Servier’s obligations under Sections 7.3(c) and XOMA’s obligations under Section 7.3(b) shall terminate in the terminated region(s) or in the Licensed Territory and Retained Territory in their entirety, as applicable.

(iii) Upon termination of this Agreement by Servier under Section 11.4 , XOMA’s obligations under Section 7.3(b) shall survive until the earlier of (A) [*] years following the First Commercial Sale of the Product in the Licensed Territory, or (B) [*] years following the effective date of
termination; and Servier’s obligations under Section 7.3(c) shall terminate.

(iv) Upon termination of this Agreement by XOMA under Section 11.5, Servier’s obligations under Section 7.3(c) shall survive in the terminated jurisdiction(s) until the earlier of (A) [*] years following the First Commercial Sale of the Product by or on behalf of XOMA in the Retained Territory, or (B) [*] years following the effective date of termination; and Section 7.3(b) shall terminate in the terminated jurisdiction(s).

7.4 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

8. PAYMENTS

8.1 Notification, Payment and Invoicing. Any and all amounts payable by a Party to the other Party under this Agreement shall be invoiced as follows:

- by XOMA to LES LABORATOIRES SERVIER, 22 rue Garnier, 92200 Neuilly sur Seine, France, VAT FR08085480796, to the attention of [*].

- by Servier to XOMA Ireland Limited, 26 Upper Pembroke Street, Dublin 2, Ireland, VAT IE 6327875R, to the attention of [*].

Unless otherwise indicated below, payment shall be made within [*] days of receipt of the corresponding invoice. Each Party shall inform the other Party promptly and no later than within [*] days of the occurrence of an event triggering a payment obligation on the informing Party.

8.2 Upfront Payment. Within ten (10) business days after the Effective Date and the date of receipt of the invoice, Servier shall pay to XOMA a one-time, non-refundable and non-creditable upfront cash payment of Fifteen Million Dollars ($15,000,000).

8.3 Cash Advance to XOMA. Servier shall provide to XOMA an advance of funds in the total amount of up to fifteen million euro (€15,000,000), in accordance with a separate loan agreement to be entered into by and between the Parties contemporaneous with this Agreement (the “Loan Agreement”).

8.4 Phase 3 Initiation Milestone. Regardless of whether XOMA has at such time exercised the Cardiometabolic Indications Option, Servier shall make a one-time, non-refundable and non-creditable milestone payment to XOMA of Twenty Million Dollars ($20,000,000) within [*] days after the Initiation of the first Phase 3 Clinical Trial for the Product by or on behalf of Servier in and for the Licensed Territory in Type 2 diabetes and receipt of the corresponding invoice.

8.5 XOMA Payments on Option Exercise. XOMA shall be obligated to make the applicable following payments to Servier upon exercise of the Cardiometabolic Indications Option:

<table>
<thead>
<tr>
<th>Early Option Exercise</th>
<th>Late Option Exercise</th>
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<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Reimbursement of CMC Costs Incurred Prior to Exercise for CMC Activities for Cardiometabolic Indications – Percent of Total Costs Incurred [<em>]% [</em>]%</td>
<td></td>
</tr>
<tr>
<td>Reimbursement of Development Costs Incurred Prior to Exercise for Clinical Studies for Cardiometabolic Indications – Percent of Total Costs Incurred [<em>]% [</em>]%</td>
<td></td>
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</tbody>
</table>

XOMA shall pay the Option Exercise amount for patent and know-how access within [*] days of exercise of the option and receipt of the corresponding invoice. Subject to Article 3, as of the date of exercise of the option, XOMA shall be obligated to reimburse Servier for XOMA’s share (as determined above) of the CMC Costs and Development Costs incurred by Servier prior to the option exercise date (the “Reimbursable Costs”) in accordance with the following schedule: (A) for the Early Option Exercise, during the period from the date of option exercise until the [*] anniversary of such date, no payments would be owed, but commencing with the first calendar [*] after the [*] anniversary, and for the [*] calendar [*] thereafter, XOMA would be obligated to pay [*] of the total Reimbursable Costs within [*] days following the end of such calendar [*] and receipt of the corresponding invoice; and (B) for the Late Option Exercise, during the period from the date of option exercise until the [*] month anniversary of such date, no payments would be owed, but commencing with the first calendar [*] after such [*] month anniversary, and for the [*] calendar [*] thereafter, XOMA would be obligated to pay [*] of the total Reimbursable Costs within [*] days following the end of such calendar [*] and receipt of the corresponding invoice. Following exercise of the option, the ongoing CMC Costs and Development Costs for the Cardiometabolic Indications shall be handled as provided in Article 3.
8.6 Milestone Payments if XOMA Exercises the Cardiometabolic Indications Option.

(a) General. If XOMA exercises the Cardiometabolic Indications Option, Servier shall make one-time, non-refundable and non-creditable milestone payments to XOMA within [*] days after the achievement of each applicable milestone event by Servier or its Affiliates or sublicensees as provided below and receipt of the corresponding invoice.

(b) Development and Regulatory Milestones for Major Cardiometabolic Indications. The following milestone payments shall be payable to XOMA for one or more Products to achieve the following milestone events:

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation of the first Phase 3 Clinical Trial for each of the first [<em>] Major Cardiometabolic Indications other than Type 2 diabetes €[</em>]</td>
<td></td>
</tr>
<tr>
<td>Acceptance for filing of MAA by EMA for each of the first [<em>] Major Cardiometabolic Indications €[</em>]</td>
<td></td>
</tr>
<tr>
<td>Regulatory Approval by EMA (centralized) for each of the first [<em>] Major Cardiometabolic Indications €[</em>]</td>
<td></td>
</tr>
</tbody>
</table>

For clarity, the maximum total amount payable under this Section 8.6(b) if all milestones are achieved would be €[*]. Whether a Cardiometabolic Indication is a Major Cardiometabolic Indication shall be determined by Servier in good faith, in consultation with XOMA. To the extent XOMA disagrees, in good faith, with any determination by Servier that an indication is not a Major Cardiometabolic Indication, the Parties shall attempt to resolve such dispute by good-faith negotiations between the Executive Officers and if not resolved within [*] days after notice of XOMA’s disagreement, Servier shall have the final say and shall not be required to pay the foregoing milestones with respect to such Cardiometabolic Indication. Rather, in such a case, Servier shall be required to pay milestones as provided under Section 8.6(c) below, up to the limits provided in such section; it being understood that the maximum number of Cardiometabolic Indications for which Servier would owe milestones under this Section 8.6(b) and Section 8.6(c), in the aggregate, is [*]. Further, if Net Sales of the Product for such Cardiometabolic Indication in the Licensed Territory achieve at least [*] euros (€[*]) during any annual period starting on October 1st, then Servier shall so notify XOMA and the amounts set forth above (i.e., an aggregate of [*] euros (€[*])) minus such amounts as were previously paid to XOMA pursuant to Section 8.6(c), if any, shall thereafter be due and owing within [*] days of receipt of invoice from XOMA.

(c) Development and Regulatory Milestones for Non-Major Cardiometabolic Indications. Servier shall pay the following milestone payments to XOMA for one or more Products, for each of the first [*] Indications in the Cardiometabolic Field which are not determined to be Major Cardiometabolic Indications, to achieve the designated milestone event within [*] days of the achievement of each such milestone event and receipt of the corresponding invoice:

<table>
<thead>
<tr>
<th>Milestone Event Payment</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance for filing of MAA by EMA €[*]</td>
<td></td>
</tr>
<tr>
<td>Regulatory Approval by EMA €[*]</td>
<td></td>
</tr>
</tbody>
</table>

(d) Sales Milestones. Servier shall make the following one-time, non-refundable and non-creditable sales milestone payments to XOMA when the aggregate Net Sales of all Products in the Licensed Territory first reach the thresholds specified below in any [*]-month period. Such payments shall be made no later than [*] days after the end of the period in which each such sales milestone event is achieved and receipt of the corresponding invoice.

<table>
<thead>
<tr>
<th>Threshold for Aggregate Net Sales in the Licensed Territory</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>€[*]</td>
<td></td>
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<tr>
<td>€[*]</td>
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<td>€[*]</td>
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<td>€[*]</td>
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<td>€[*]</td>
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</tbody>
</table>
To the extent more than one sales threshold is reached in any given [*]-month period, then the applicable milestone payment for each such achievement shall be due and owing with respect to such period. If during the Pre-Exercise Period any sales milestone becomes due in accordance with this Section 8.6(c) such amount shall be due and owing. If following the Pre-Exercise Period, however, the Cardiometabolic Indications Option is not exercised, the Net Sales milestones then due and owing thereafter are only those set forth below under Section 8.8(c) and not those listed above; provided that any amounts paid as of such time under the above schedule shall be credited against the first Net Sales milestone owed under Section 8.8(c). For example, should the payment of €[*] have been paid, and XOMA does not exercise the Cardiometabolic Indications Option, and subsequently Servier achieves worldwide Net Sales of $[*], the payment owed would be $[*] minus €[*].

8.7 Regulatory Milestones for Remaining Field Indications. Irrespective of whether XOMA exercises the Cardiometabolic Indications Option, Servier shall pay the following milestone payments to XOMA, within [*] days of the achievement of the applicable milestone event and receipt of the corresponding invoice, for one or more Products to achieve the following milestones for each of the first [*] Indications in the Remaining Field, other than Behçet’s Uveitis, to achieve the designated milestone event:

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance for filing of MAA by EMA</td>
<td>€[*]</td>
</tr>
<tr>
<td>Regulatory Approval by EMA</td>
<td>€[*]</td>
</tr>
</tbody>
</table>

No development or regulatory milestone payments will be due for Behçet’s Disease. For clarity, the maximum total amount payable under this Section 8.7 is €[*]. As used in this Article 8, “Indication” means an indication for the Product that is the subject of a separate MAA or supplemental MAA or any new indication requiring an amendment to the MAA.

8.8 Development and Regulatory Milestone Payments if XOMA Does Not Exercise the Cardiometabolic Indications Option.

(a) General. If XOMA does not exercise the Cardiometabolic Indications Option, Servier shall make one-time, non-refundable and non-creditable development and regulatory milestone payments to XOMA within [*] days after the achievement of each applicable milestone event by Servier or its Affiliates or sublicensees as set forth below and receipt of the corresponding invoice.

(b) Major Cardiometabolic Indications Field. The following milestone payments shall be payable to XOMA for achievement of the following milestones by one or more Products:

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation of the first Phase 3 Clinical Trial for each of the first [*] Major Cardiometabolic Indications other than Type 2 diabetes</td>
<td>€[*]</td>
</tr>
<tr>
<td>Acceptance for filing of MAA by FDA for each of the first [*] Major Cardiometabolic Indications</td>
<td>€[*]</td>
</tr>
<tr>
<td>Acceptance for filing of MAA by EMA for each of the first [*] Major Cardiometabolic Indications</td>
<td>€[*]</td>
</tr>
<tr>
<td>Filing of MAA with MHLW for each of the first [*] Major Cardiometabolic Indications</td>
<td>€[*]</td>
</tr>
<tr>
<td>Regulatory Approval by FDA for each of the first [*] Major Cardiometabolic Indications</td>
<td>€[*]</td>
</tr>
<tr>
<td>Regulatory Approval by EMA for each of the first [*] Major Cardiometabolic Indications</td>
<td>€[*]</td>
</tr>
<tr>
<td>Regulatory Approval by MHLW for each of the first [*] Major Cardiometabolic Indications</td>
<td>€[*]</td>
</tr>
</tbody>
</table>

For clarity, the maximum total amount payable under this Section 8.6(b) shall be €[*].

(c) Sales Milestones. Servier shall make the following one-time, non-refundable and non-creditable sales milestone payments to XOMA when the aggregate worldwide Net Sales of all Products first reach the thresholds specified below in any [*]-month period. Such payments shall be made no later than [*] days after the end of the period in which each such sales milestone event is achieved and receipt of the corresponding invoice.

<table>
<thead>
<tr>
<th>Threshold for Aggregate Annual Worldwide Net Sales Milestone Payment</th>
<th></th>
</tr>
</thead>
</table>
To the extent more than one sales threshold is reached in any given year, then the applicable milestone payment for each such achievement shall be due and owing with respect to such year.

8.9 Royalty Payments.

(a) Royalties in Licensed Territory. Subject to the other applicable terms of this Section 8.7, and regardless of whether XOMA exercises the Cardiometabolic Indications Option, Servier shall pay to XOMA quarterly non-refundable, non-creditable royalties on Net Sales of Products in the Licensed Territory during such quarter, on a Product-by-Product and a country-by-country basis, as calculated by multiplying the total Net Sales of such Product in such country during such quarter by the applicable royalty rate as determined in the following royalty rate table. As used herein, “Daily Cost of Treatment” for a particular Product in a country means the average Net Sales per unit of the Product for such country in a specific calendar quarter (converted to Euros), divided by the number of days between each use of such Product as specified in the label for such Product in the country (e.g., per unit Net Sales divided by 30 for a Product labeled to be administered once per month).

<table>
<thead>
<tr>
<th>Daily Cost of Treatment Royalty Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than or equal to [*] [*]%</td>
</tr>
<tr>
<td>Greater than [*] and less than or equal to [*] [*]%</td>
</tr>
<tr>
<td>Greater than [*] and less than or equal to [*] [*]%</td>
</tr>
<tr>
<td>Greater than [*] [*]%</td>
</tr>
</tbody>
</table>

In addition, Servier shall pay to XOMA (to the extent applicable) the following additional quarterly non-refundable, non-creditable royalties on Net Sales of Products in the Licensed Territory during such quarter, depending upon the Purchase Cost Ratio (as defined below) of such Product for the quarter, on a Product-by-Product and country-by-country basis, such royalties to be calculated by multiplying the applicable royalty rate set forth in the royalty rate table below by the total Net Sales of the Product in such country during such quarter. As used herein, “Purchase Cost” means, with respect to a particular Product for commercial sale in a particular country during a calendar quarter, the actual total amount paid by Servier to XOMA for its purchase of the amount of Bulk Drug Substance actually contained in such Product sold in such quarter (i.e., the XOMA Manufacturing Cost for such amount of Bulk Drug Substance purchased, plus [\*]% of such cost). As used herein, “Purchase Cost Ratio” means, with respect to a particular Product for commercial sale in a particular country during a calendar quarter, the Purchase Cost for such Product divided by the average Net Sales per unit of such Product sold in the country during such quarter, expressed as a percentage.

<table>
<thead>
<tr>
<th>Purchase Cost Ratio for a Product Additional Royalty Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than [*]% but greater than or equal to [*] [*]%</td>
</tr>
<tr>
<td>Less than [*]% but greater than or equal to [*] [*]%</td>
</tr>
<tr>
<td>Less than [*]% of Net Sales per unit [*]%</td>
</tr>
</tbody>
</table>

The Parties agree that if any factors affecting the profitability of the Product in the Licensed Territory change materially during the Term, the Parties will meet and discuss in good faith possible modifications to the royalty scheme for the Product in the Licensed Territory set forth in this Section 8.7(b) in light of such changing factors.

(b) Royalties in Retained Territory. Subject to Section 8.9(c) and 8.9(d), if XOMA does not exercise the Cardiometabolic Indications Option, in addition to royalties under Section 8.9(a), Servier shall pay to XOMA non-refundable, non-creditable royalties on Net Sales of Products by Servier, its Affiliates and sublicensees for use in the Cardiometabolic Indications in the Retained Territory, as calculated by multiplying the applicable royalty rates set forth in the royalty rate table below by the corresponding amount of incremental Net Sales in the Retained Territory of all Products in a calendar year (the “Total Annual Net Sales”).

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Net Sales of all Products in Retained Territory Royalty Rate

For that portion of Total Annual Net Sales less than $[*] [*]%
For that portion of Total Annual Net Sales greater than or equal to $[*] but less than $[*] [*]%
For that portion of Total Annual Net Sales greater than or equal to $[*] but less than $[*] [*]%
For that portion of Total Annual Net Sales greater than or equal to $[*] but less than $[*] [*]%
For that portion of Total Annual Net Sales equal to or greater than $[*] [*]%

(c) Royalty Term. Royalties under this Section 8.9 with respect to a particular Product and country will be payable for so long as such Product is sold in such country.

(d) Royalty Adjustments.

(i) Third Party Royalty Offset. If, after the Effective Date, Servier or its sublicensee or designee: (A) is required, as agreed by the Parties in good faith, or absent such agreement, in the reasonable opinion of an independent expert selected by the Parties, to obtain a license from any Third Party under patent rights controlled by such Third Party in order to make, have made, use, sell, offer for sale or import a Licensed Antibody and/or a Product in any country, and pursuant to such license is required to pay a royalty or a lump sum payment to the Third Party based on sales of the Product containing such Licensed Antibody in such country, or (B) is required by any court of competent jurisdiction, due to infringement of patent rights controlled by such Third Party in any country(ies), to pay such a royalty to such a Third Party based on sales of such Product in such country(ies), then Servier may deduct from the milestones payments or royalties that would otherwise be due to XOMA on Net Sales resulting from the sales of such Product in such country in a calendar quarter the amount paid by Servier to such Third Party with respect to the sale of such Product for such country during such calendar quarter; provided that in no event shall the operation of this Section reduce the royalties or milestones payment due to XOMA for any Product below [*] percent ([*]%) of the amount that otherwise would have become due under this Agreement for such country.

(ii) Biosimilar Competition. On a country by country basis, following expiration of all XOMA Patents and Servier Collaboration Patents claiming a particular Product and the first commercial sale of a Biosimilar Product to such Product in such country, if, during any calendar quarter, the unit volume of sales of all such Biosimilar Product(s) in such country during such quarter are more than [*] percent ([*]%) of the total unit volume of sales of (i) all such Biosimilar Products plus (ii) such Product’s unit volume of sales in such country, then the royalty rates under Section 8.9(a) or (b), as applicable, shall be reduced by [*] percent ([*]%) in any given calendar quarter with respect to the sales such Product in such country.

(e) Royalty Reports and Payments. Within [*] days following the end of each calendar [*] following the First Commercial Sale of a Product by Servier or its Affiliate or sublicensee anywhere in the Licensed Territory or Retained Territory, Servier shall provide XOMA with a report containing the following information for the applicable calendar quarter, on a Product-by-Product basis: (i) gross sales and Net Sales of Product consolidated in Euros, (ii) a calculation of the royalty payment due on such sales, including a calculation of the Purchase Cost used in the determination of such royalty, (iii) an accounting of the number of units and prices for the Product sold, grouped by the Daily Cost of Treatment in the countries in the Licensed Territory, (iv) the adjustment, if any, made in accordance with the terms of Section 8.9(d), as well as any other details reasonably requested by XOMA.

8.10 Payment Method. All payments due under this Agreement to XOMA shall be made by bank wire transfer in immediately available funds to an account designated by XOMA. All royalty payments arising from Net Sales in the Licensed Territory shall be made in Euros. All other payments, including any royalties arising from sales in the Retained Territory in the Cardiometabolic Indications, shall be made either in Dollars or in Euros as indicated in the corresponding section of this Agreement or as agreed by the Parties.

8.11 Late Payment. If either Party fails to make any payment due to the other Party under this Agreement, then interest shall accrue on a daily basis at the rate equal to one month LIBOR (for payment in Dollars) or EURIBOR (for payments in Euros) plus [*] basis points per annum, or at the maximum rate permitted by applicable Law, whichever is the lower.

8.12 Foreign Exchange. Conversion of sales recorded in local currencies to Euros shall be performed in a manner consistent with Servier’s normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

8.13 Records; Inspection. Servier shall, and shall ensure that its Affiliates and sublicensee(s) will, keep complete, true and accurate books of account and records for the purpose of determining the payments to be made under this Agreement. Such books and records shall be kept for at least [*] years following the end of the calendar year to which they pertain. Such records shall be open for inspection during such period by independent accountants, solely for the purpose of verifying payment statements hereunder. Such inspections shall be made no more than [*] each calendar year, on reasonable notice during normal business hours. Any unpaid amounts (plus interest as set forth in Section 8.11) that are
8.14 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Servier to XOMA under this Agreement. Servier agrees that under current bilateral income tax Treaty between France and Ireland, payments made by Servier to XOMA under this Agreement are not subject to withholding tax in France. To the extent Servier is required to deduct and withhold taxes on any payment to XOMA, Servier shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to XOMA an official tax certificate or other evidence of such withholding sufficient to enable XOMA to claim such payment of taxes. XOMA shall provide Servier, who shall complete any required portions of, any tax forms that may be reasonably necessary in order for Servier not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, including Forms 5000-EN and 5003-EN. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. Servier shall require its sublicensees to cooperate with XOMA in a manner consistent with this Section 8.14(b).

(c) Taxes Resulting From Servier Action. If Servier is required to make a payment to XOMA that is subject to a deduction or withholding of tax, then (i) if such withholding or deduction obligation arises as a result of any action by Servier, including any assignment or sublicense, or any failure on the part of Servier or its Affiliate to comply with applicable Laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a ‘Servier Withholding Tax Action’), then the sum payable by Servier (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that XOMA receives a sum equal to the sum that it would have received had no such Servier Withholding Tax Action occurred, and (ii) otherwise, the sum payable by Servier (in respect of which such deduction or withholding is required to be made) shall be made to XOMA after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the proper Governmental Authority in accordance with applicable Laws.

(d) Other Taxes. Each Party shall be solely responsible for the payment of Value Added Tax, custom duties, registration duties, transfer taxes, stamp duties and any other taxes or duties imposed to it in relation with the payments made under this Agreement.

(e) XOMA Obligations. The provisions of subsections (b) and (c) above shall apply mutatis mutandis to XOMA where XOMA is the paying Party.

9. INTELLECTUAL PROPERTY

9.1 Ownership of Inventions. Each Party shall own all inventions, whether or not patentable, made solely by its or its Affiliates’ own employees, agents, or independent contractors in the course of conducting its or its Affiliates’ activities under this Agreement, together with all intellectual property rights therein (“Sole Inventions”). The Parties shall jointly and equally own any inventions, whether or not patentable, that are made jointly by employees, agents, or independent contractors of each Party or its Affiliates in the course of conducting its or its Affiliates’ activities under this Agreement, together with all intellectual property rights therein (“Joint Inventions”). Inventorship shall be determined in accordance with U.S. patent laws. All Patents claiming patentable Sole Inventions (but not Joint Inventions) shall be referred to herein as “Sole Invention Patents”. All Patents claiming patentable, jointly owned Joint Inventions shall be referred to herein as “Joint Invention Patents”. Except to the extent either Party is restricted by the licenses granted to the other Party or its Affiliates under this Agreement, each Party and its Affiliates shall be entitled to practice and exploit the Joint Inventions and the Joint Invention Patents without the duty of accounting or seeking consent from the other Party.

9.2 Disclosure. Each Party shall promptly disclose to the other Party all Sole Inventions and Joint Inventions, including any invention disclosures or other similar documents, submitted to it by its or its Affiliates’ employees, agents or independent contractors describing inventions that are either Sole Inventions or Joint Inventions, and all Information relating to such inventions to the extent necessary for the preparation, filing and prosecution of any Patent with respect to such invention. Upon the disclosure of a Joint Invention or Sole Invention pursuant to this Section 9.2, the Parties shall promptly discuss such Joint Invention or Sole Invention and (a) confirm its status as either a Joint Invention or a Sole Invention in light of the ownership principles set forth in Section 9.1 and (b) determine whether to file a patent application claiming such Joint Invention or Sole Invention; provided that the Party owning such Sole Invention shall nonetheless have the right to file for such patent application.

9.3 Patent Prosecution.
(a) Budget. Within [*] days after the Effective Date, and at the beginning of each calendar quarter thereafter, each Party shall provide to the other Party a reasonably detailed budget setting forth its estimated costs and expenses for the subsequent six (6)-month period for the preparation, filing, prosecution and maintenance of all Patents whose costs and expenses such other Party is (or may be) responsible for under this Section 9.3. At either Party’s request, the Parties shall promptly discuss such budget(s), and the providing Party shall provide any additional Information as the other Party may reasonably request.

(b) XOMA Patents and Joint Invention Patents.

(i) Licensed Territory. Except as otherwise provided in this Section 9.3(b)(i), XOMA shall be solely responsible for the preparation, filing, prosecution and maintenance of the XOMA Patents in its own name, and Joint Invention Patents in the name of Servier and XOMA, in the Licensed Territory, using patent counsel reasonably acceptable to Servier. The Parties shall discuss and confer with respect to the overall patent strategy with respect to the XOMA Patents and any Joint Invention Patents in the Licensed Territory. XOMA shall keep Servier advised of the status of all communications and actual and prospective filings and submissions regarding the XOMA Patents and Joint Invention Patents in the Licensed Territory, and shall give Servier a reasonable opportunity (but in no event less than ten (10) business days) to review and comment on any such communications, filings, filing date and submissions proposed to be sent to any patent office. XOMA shall incorporate all reasonable comments of Servier before making any substantive filing or submission related to the XOMA Patents or Joint Invention Patents in the Licensed Territory, provided that such comments are obtained at least [*] business days prior to the deadline for filing. If XOMA no longer wishes to maintain or prosecute any XOMA Patent or Joint Invention Patent in the Licensed Territory, then XOMA shall give reasonable notice to Servier, and thereafter, Servier may, upon written notice to XOMA, prosecute and maintain such XOMA Patent or Joint Invention Patent in its own name, and XOMA shall execute all required documents in order to assign to Servier such XOMA Patent or XOMA’s interest in such Joint Invention Patent, at XOMA’s expense. Servier shall be solely responsible for all costs and expenses incurred by XOMA or its Affiliates after the Effective Date and associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the XOMA Patents and Joint Invention Patents in the Licensed Territory. Notwithstanding the foregoing, if Servier no longer desires to retain its license under any XOMA Patent or Joint Invention Patent in the Licensed Territory, and desires to cease payment of the costs of prosecution and maintenance thereof, it shall have the right to terminate such license to such Patent, and terminate reimbursement to XOMA of such costs, upon [*] days written notice; provided that with respect to any such Joint Invention Patent, Servier shall execute all required documents in order to assign to XOMA Servier’s interest in such Joint Invention Patent, at Servier’s expense.

(ii) Retained Territory.

(1) XOMA shall have the sole authority and control over the preparation, filing, prosecution and maintenance of the XOMA Patents in its own name, and Joint Invention Patents in the name of XOMA and Servier, in the Retained Territory, at XOMA’s sole cost and expense, provided that XOMA shall update Servier from time to time on the status of such Patent prosecution and maintenance efforts; provided, however, that if the Cardiometabolic Indications Option expires without exercise thereof by XOMA, Section 9.3(b)(ii)(2) below shall apply to the XOMA Patents and Joint Invention Patents in the Retained Territory, and not this Section 9.3(b)(ii)(1).

(2) After expiration of the Cardiometabolic Indications Option without exercise thereof by XOMA, except as otherwise provided in this Section 9.3(b)(ii)(2), XOMA shall be solely responsible for the preparation, filing, prosecution and maintenance of the XOMA Patents and Joint Invention Patents in the Retained Territory, using patent counsel reasonably acceptable to Servier. The Parties (including any sublicensee of Servier) shall discuss and confer with respect to the overall patent strategy with respect to the XOMA Patents and any Joint Invention Patents in the Retained Territory. XOMA shall keep Servier advised of the status of all communications and actual and prospective filings and submissions regarding such XOMA Patents and Joint Invention Patents in the Retained Territory, and shall give Servier a reasonable opportunity (but in no event less than [*] business days) to review and comment on any such communications, filings and submissions proposed to be sent to any patent office. With respect to those XOMA Patents and Joint Invention Patents in the Retained Territory that are relevant to the Cardiometabolic Field (e.g., that claim the use of the Licensed Antibody to treat a Cardiometabolic Indication) (the “XOMA Retained Territory Cardiometabolic Patents”), XOMA shall incorporate all reasonable comments of Servier before making any substantive filing or submission related to such Patents, provided that such comments are obtained at least [*] business days prior to the deadline for filing. For all other XOMA Patents and Joint Invention Patents in the Retained Territory, XOMA shall consider Servier’s comments in good faith. If XOMA no longer wishes to maintain or prosecute any XOMA Patent or Joint Invention Patent in the Retained Territory, then XOMA shall give reasonable notice to Servier, and thereafter, Servier may, upon written notice to XOMA, prosecute and maintain such XOMA Patent or Joint Invention Patent in its own name and at its sole expense, and XOMA shall execute all required documents in order to assign to Servier such XOMA Patent or XOMA’s interest in such Joint Invention Patent, at XOMA’s expense. Servier shall be responsible for [*]% of all costs and expenses incurred by XOMA or its Affiliates after the expiration of the Cardiometabolic Indications Option, associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the XOMA Retained Territory Cardiometabolic Patents, and XOMA shall be responsible for [*]% of such costs and expenses. XOMA shall be solely responsible for all costs and expenses incurred by XOMA or its Affiliates associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all XOMA Patents and Joint Invention Patents in the Retained Territory that are not XOMA Retained Territory Cardiometabolic Patents.
(c) Servier Patents.

(i) Licensed Territory. Servier shall have sole authority and control over the preparation, filing, prosecution and maintenance of the Servier Patents in the Licensed Territory, at Servier’s sole cost and expense, provided that Servier shall update XOMA from time to time on the status of such Patent prosecution and maintenance efforts in the Licensed Territory.

(ii) Retained Territory. Except as otherwise provided in this Section 9.3(c)(ii), Servier shall be solely responsible for the preparation, filing, prosecution and maintenance of the Servier Patents in the Retained Territory, using patent counsel reasonably acceptable to XOMA. The Parties (including any sublicensee of Servier) shall discuss and confer with respect to the overall patent strategy with respect to the Servier Patents in the Retained Territory. Servier shall keep XOMA advised of the status of all communications and actual and prospective filings and submissions regarding the Servier Patents, and shall give XOMA a reasonable opportunity (but in no event less than ten (10) business days) to review and comment on any such communications, filings and submissions proposed to be sent to any patent office. Servier shall incorporate all reasonable comments of XOMA before making any substantive filing or submission related to the Servier Patents in the Retained Territory, provided that such comments are obtained at least [*] business days prior to the deadline for filing. If Servier no longer wishes to maintain or prosecute any Servier Patent in the Retained Territory, then Servier shall give reasonable notice to XOMA, and thereafter, XOMA may, upon written notice to Servier, prosecute and maintain such Patent in its own name, and Servier shall execute all required documents in order to assign to XOMA such Patent, at Servier’s expense. XOMA shall be solely responsible for all costs and expenses incurred by Servier or its Affiliates associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the Servier Patents in the Retained Territory. Notwithstanding the foregoing, if the Cardiometabolic Indications Option expires without exercise thereof by XOMA, then (A) for those Servier Patents in the Retained Territory that are relevant to the Remaining Field (e.g., that claim the use of the Licensed Antibody to treat a Remaining Field Indication) (the “Servier Retained Territory Remaining Field Patents”), XOMA shall be responsible for [*]% of all costs and expenses incurred by Servier or its Affiliates after the expiration of the Cardiometabolic Indications Option, associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the Servier Retained Territory Remaining Field Patents, and Servier shall be responsible for [*]% of such costs and expenses, and (B) for all other Servier Patents in the Retained Territory, Servier shall be solely responsible for all costs and expenses incurred by Servier or its Affiliates after the expiration of the Cardiometabolic Indications Option, associated with the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of such Patents, and Servier shall not be obliged to incorporate all reasonable comments of XOMA with respect thereto, but shall consider XOMA’s comments in good faith.

(d) Patent Term Extension. XOMA and Servier shall cooperate with each other and shall use Diligent Efforts in obtaining patent term extension (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country.

(e) Data Exclusivity. With respect to data exclusivity periods (such as those periods listed in the Biologics Price Competition and Innovation Act of 2009 and the Patient Protection and Affordable Care Act, as amended, or foreign equivalents of such laws), Servier shall use Diligent Efforts consistent with its obligations under applicable Laws (including any applicable consent order) to seek, maintain and enforce all such data exclusivity periods available for the Products in the Licensed Territory and, if XOMA does not exercise the Cardiometabolic Indications Option, in the Retained Territory.

(f) Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts provide above in this Section 9.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.4 Enforcement of Patents.

(a) Notification and Dispute Resolution. If either Party becomes aware of any existing or threatened infringement of any XOMA Patents, Joint Invention Patents or Servier Patents, which infringing activity involves the manufacture, use, import, offer for sale or sale of any Product in the Licensed Territory or the Retained Territory (a “Product Infringement”), it shall promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken with respect to such Product Infringement. The Parties (including any sublicensee of Servier) shall discuss and confer with respect to the overall strategy with respect to any Patent litigation strategy under this section 9.4 with respect to a XOMA Patent or Joint Invention Patent in the Licensed Territory (and Retained Territory, with respect to the Cardiometabolic Field in the event of failure by XOMA to exercise the Cardiometabolic Indications Option), or Servier Patents, except with respect to those Servier Patents listed under section 9.3(c)(ii)(B) in the event of failure by XOMA to exercise the Cardiometabolic Indications Option, or Joint Invention Patent in the Retained Territory; any disputes arising with respect to such strategy or litigation tactics shall be submitted for resolution to an independent patent counsel approved by both Parties for resolution, pursuant to an expedited procedure, so as not to prejudice the proposing Party’s response or action.
(b) XOMA Patents and Joint Invention Patents.

(i) Licensed Territory. XOMA shall have the first right, but shall not be obligated, to bring an infringement action against any person or entity engaged in a Product Infringement of the XOMA Patents and Joint Invention Patents in the Licensed Territory, at XOMA’s cost and expense. If XOMA does not desire to bring such an action or to continue to pursue such action with respect to any such Patent (or to settle or otherwise secure the abatement of such Product Infringement), it shall so notify Servier prior to the earlier of: (A) [*] days following XOMA’s receipt or delivery of the notice under Section 9.4(a), or (B) [*] days before the deadline, if any, set forth in the applicable Laws for the filing of such actions, in which event Servier shall have the right to bring and control any such action, at its own expense and by counsel of its own choice. In addition, to the extent Servier does not so notify XOMA within a reasonable time to allow Servier to bring such action, XOMA shall bring such action on behalf of, under the direction of, and at the expense of, Servier.

(ii) Retained Territory. XOMA shall have the first right, but shall not be obligated, to bring an infringement action against any person or entity engaged in a Product Infringement of the XOMA Patents and Joint Invention Patents in the Retained Territory, at XOMA’s cost and expense. If the Cardiometabolic Indications Option expires without XOMA’s exercise thereof, and if XOMA does not desire to bring such an action or to continue to pursue such action with respect to any such Patent (or to settle or otherwise secure the abatement of such Product Infringement), it shall so notify Servier prior to the earlier of: (A) [*] days following XOMA’s receipt or delivery of the notice under Section 9.4(a), or (B) [*] days before the deadline, if any, set forth in the applicable Laws for the filing of such actions, in which event, Servier shall have the right to bring and control any such action, at its own expense and by counsel of its own choice. In addition, to the extent XOMA does not so notify Servier within a reasonable time to allow Servier to bring such action, XOMA shall bring such action on behalf of, under the direction of, and at the expense of, Servier.

(c) Servier Patents. Servier shall have the first right, but shall not be obligated, to bring an infringement action against any person or entity engaged in any infringement of the Servier Patents in the Licensed Territory or the Retained Territory, at Servier’s cost and expense. If Servier does not desire to bring such an action or to continue to pursue such action with respect to any such Patent (or to settle or otherwise secure the abatement of such Product Infringement) it shall so notify XOMA prior to the earlier of: (i) [*] days following Servier’s receipt or delivery of the notice under Section 9.4(a), or (ii) [*] days before the deadline, if any, set forth in the applicable Laws for the filing of such actions, in which event XOMA shall have the right to bring and control any such action, at its own expense and by counsel of its own choice. In addition, to the extent Servier does not so notify XOMA within a reasonable time to allow XOMA to bring such action, Servier shall bring such action on behalf of, under the direction of, and at the expense of, XOMA.

(d) Cooperation. Each Party shall provide to the enforcing Party under this Section 9.4 reasonable assistance in such enforcement, at such enforcing Party’s request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party’s comments on any such efforts, subject to Section 9.4(a). To the extent that the non-enforcing Party owns or controls the Patent being enforced, it shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party. Neither Party shall have the right to settle any patent infringement litigation under this Section 9.4 without the prior written consent of such other Party, such consent not to be unreasonably withheld or delayed.

(e) Expenses and Recoveries. The enforcing Party bringing a claim, suit or action under Section 9.4(b) or 9.4(c) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be allocated as follows: (i) in the case of any recovery for a Product Infringement of a XOMA Patent or Joint Invention Patent in the Licensed Territory, [*] percent ([*]%) to Servier and [*] percent ([*]%) to XOMA, (ii) in the case of any recovery for a Product Infringement of a(XOMA Patent or Joint Invention Patent in the Retained Territory, one hundred percent (100%) retained by XOMA, but, where XOMA does not exercise the Cardiometabolic Indications Option, and such recovery relates to a Product Infringement in the Cardiometabolic Field, [*] percent ([*]%) to Servier and [*] percent ([*]%) to XOMA, (iii) in the case of any recovery for a Product Infringement of a Servier Patent in the Licensed Territory, one hundred percent (100%) retained by Servier, and (iv) in the case of any recovery for a Product Infringement of a Servier Patent in the Retained Territory, [*] percent ([*]%) to XOMA and [*] percent ([*]%) to Servier or, where XOMA does not exercise the Cardiometabolic Indications Option, and such recovery relates to a Product Infringement in the Cardiometabolic Field, one hundred percent (100%) to Servier.

9.5 Patent Oppositions and Other Proceedings.

(a) If a XOMA Patent or Joint Invention Patent in the Licensed Territory becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof, then XOMA shall have the first right, but not the obligation, to control such defense at its own expense using counsel of its own choice. If XOMA decides that it does not wish to defend against such action, it shall notify Servier reasonably in advance of all applicable deadlines, and Servier shall thereafter have the right, but not the obligation, to assume defense of such action at its own expense.
shall reasonably consider and seek to accommodate any timely comments of XOMA with respect thereto.

Agreement or any other agreement between the Parties or their Affiliates.

counsel in such defense, it would be at its own cost and expense. Servier shall keep XOMA fully informed of such claim and its defense, and

those permitted by this Agreement or in connection with exercising such Party’s or its Affiliates’ rights and/or fulfilling their obligations under this

sentence, XOMA, against any such claim or assertion in the Licensed Territory, at its sole expense. To the extent XOMA engages separate

Agreement or otherwise agreed in writing by the Parties; and (c) not use such other Party’s Confidential Information for any purpose except

Confidential Information to any Third Party without prior written consent of the other Party, except to the extent expressly authorized by this

notify Servier reasonably in advance of all applicable deadlines, and Servier shall thereafter have the right, but not the obligation, to assume
defense of such action with respect to such Patent at its own expense.

c) If a Servier Patent becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, action for
declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof, then Servier shall have the
first right, but not the obligation, to control such defense at its own expense using counsel of its own choice. If Servier decides that it does not
wish to defend against such action with respect to a Servier Patent in the Retained Territory, it shall notify XOMA reasonably in advance of all
applicable deadlines, and XOMA shall thereafter have the right, but not the obligation, to assume defense of such action at its own expense.

(d) The Party controlling any defense under this Section 9.5 (other than XOMA under Section 9.5(b) in the Retained Territory, or Servier under
Section 9.5(c) in the Licensed Territory) shall permit the non-controlling Party to participate in the proceedings to the extent permissible under
applicable Laws and to be represented by its own counsel at the non-controlling Party’s expense. Notwithstanding any of the foregoing, the Party
controlling any infringement action pursuant to Section 9.4 shall also have the sole right to control the response to any attack on the validity, title,
or enforceability of a Patent that is asserted by the alleged infringer(s) as a counterclaim or affirmative defense in such action, subject to Section
9.6. Neither Party shall have the right to settle any proceeding under this Section 9.5 with respect to any XOMA Patent or Joint Invention Patent
without the prior written consent of such other Party, such consent not to be unreasonably withheld or delayed.

(e) The Parties (including any sublicensee of Servier) shall discuss and confer with respect to the overall strategy with respect to any Patent
litigation strategy under this Section 9.5 with respect to a XOMA Patent or Joint Invention Patent in the Licensed Territory (and Retained
 Territory, with respect to the Cardiometabolic Field in the event of failure by XOMA to exercise the Cardiometabolic Indications Option), or
Servier Patents or Joint Invention Patent in the Retained Territory; any disputes arising with respect to such strategy or litigation tactics shall be
submitted for resolution to an independent patent counsel approved by both Parties for resolution, pursuant to an expedited procedure, so as not
to prejudice the proposing Party’s response or action.

9.6 Patents Licensed From Third Parties. Each Party’s rights under this Article 9 with respect to the prosecution, maintenance and enforcement
of any XOMA Background Patent that is licensed by XOMA or its Affiliates from a Third Party or any New Servier Patent that is licensed by
Servier or its Affiliates from a Third Party, shall be subject to the rights of such Third Party to prosecute, maintain and enforce such Patent.

9.7 Patent Marking. Servier and its Affiliates and sublicensees shall mark Products marketed and sold by Servier or its Affiliates or sublicensee
hereunder with appropriate patent numbers or indices, where required by applicable Laws; provided, however, that Servier shall only be required
to mark such Product to the extent such markings or such notices would affect recoveries of damages or equitable remedies available under
applicable Laws with respect to infringements of patents in the applicable jurisdiction.

9.8 Infringement of Third Party Rights. If any Product used or sold by Servier or its Affiliates or sublicensees becomes the subject of a Third
Party’s claim or assertion of infringement of such Third Party’s intellectual property rights in any jurisdiction, Servier shall promptly notify XOMA,
and the Parties shall agree on and enter into a “common interest agreement” wherein the Parties agree to their shared, mutual interest in the
outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course
of action. Unless agreed otherwise by the Parties, Servier shall be solely responsible for defending itself and, except as provided in the next
sentence, XOMA, against any such claim or assertion in the Licensed Territory, at its sole expense. To the extent XOMA engages separate
counsel in such defense, it would be at its own cost and expense. Servier shall keep XOMA fully informed of such claim and its defense, and
shall reasonably consider and seek to accommodate any timely comments of XOMA with respect thereto.

10. CONFIDENTIALITY

10.1 Confidentiality Obligations. The Parties agree that during the Term and for a period of [*] years thereafter, a Party receiving Confidential
Information of the other Party shall: (a) use Diligent Efforts to maintain in confidence such Confidential Information (but not less than those
efforts as such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value); (b) not disclose such
Confidential Information to any Third Party without prior written consent of the other Party, except to the extent expressly authorized by this
Agreement or otherwise agreed in writing by the Parties; and (c) not use such other Party’s Confidential Information for any purpose except
those permitted by this Agreement or in connection with exercising such Party’s or its Affiliates’ rights and/or fulfilling their obligations under this
Agreement or any other agreement between the Parties or their Affiliates.
10.2 Exceptions. The obligations in Section 10.1 shall not apply with respect to any portion of the other Party’s Confidential Information that the receiving Party can show by competent written proof:

(a) was known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party;
(b) was generally available to the public or otherwise part of the public domain, at the time of disclosure by the other Party;
(c) becomes generally available to the public or otherwise part of the public domain after the disclosure by the other Party, other than through any act or omission of the receiving Party in breach of this Agreement;
(d) is subsequently disclosed to the receiving Party by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or
(e) is subsequently independently developed by employees or contractors of the receiving Party who had no access to or knowledge of the other Party’s Confidential Information.

10.3 Authorized Disclosure. A Party may disclose to a Third Party the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances; provided that notice of any such disclosure shall be provided as soon as practicable to the other Party:

(a) filing or prosecuting Patents in accordance with Section 9.3;
(b) complying with the requirement of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of Products;
(c) prosecuting or defending litigation as contemplated by this Agreement;
(d) disclosure to its or its Affiliates’ employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its or its Affiliates’ obligations or exercising its or its Affiliates’ rights under this Agreement or any other agreement between the Parties or their Affiliates; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;
(e) disclosure to any bona fide potential or actual investor, Acquirer or merger partner or other potential or actual financial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; provided, however, that where such potential Acquirer or merger partner is at such time a competitor of Servier in the Licensed Territory, i.e., a company clinically developing or commercializing in the Licensed Territory a product in one or several indications where the Product is being developed or is planned to be developed by Servier (and, where XOMA has not exercised the Cardiometabolic Indications Option, the same applies in the Retained Territory), XOMA shall prior to such disclosure obtain Servier’s approval with respect to such disclosure; or
(f) complying with applicable Laws, including regulations promulgated by applicable security exchanges, court orders or administrative subpoenas or orders.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party’s Confidential Information pursuant to Sections 10.3(c) or (f), such Party shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to assist the other Party, at such other Party’s expense, in obtaining a protective order preventing or limiting the required disclosure.

10.4 Publicity; Terms of Agreement.

(a) Each Party shall have the right to make its own public announcement of the execution of this Agreement in accordance with its internal policies and legal requirements, provided the other Party agrees with the content of such public announcement, except to the extent any such content of such announcement is required by applicable Law or the exchange on which such Party’s securities are traded, as determined by such Party’s counsel.

(b) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, except that in the case of a press release or governmental filing required by law, regulation or stock exchange rules, the disclosing Party shall provide the other Party with such advance notice.
notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release or governmental filing shall provide its comments, if any, within [*] business days after receiving the press release for review. Further, Servier agrees that XOMA has the right to issue a press release with respect to the occurrence of the following events under this Agreement, provided that Servier is afforded a reasonable opportunity (but not more than [*] business days) to review the content of such press release prior to its release: (i) filing and/or approvals of any regulatory applications; (ii) initiation and summary results of a clinical trial; (iii) the receipt, and, where deemed material, the amount, of each milestone payment received under this Agreement; and (iv) commercial launch of a Product in a country or region in the Retained Territory or in the Licensed Territory (to the extent agreed by Servier that such launch has occurred). Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment thereto that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 10.4, provided such information remains accurate as of such time.

(c) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission (“SEC”) or other Governmental Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party and permitted by such Governmental Authority. In the event of any such filing, each Party will provide the other Party with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party’s comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

10.5 Technical Publications. Neither Party may publish peer reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement, without the opportunity for prior review and coordination by the other Party, except to the extent required by applicable Laws. A Party seeking publication shall provide the other Party the opportunity to review and comment on any proposed publication which relates to the Product at least [*] days prior to its intended submission for publication. The other Party shall provide the Party seeking publication with its comments in writing, if any, within [*] days after receipt of such proposed publication. The Party seeking publication shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party’s request to remove any and all of such other Party’s Confidential Information from the proposed publication. In addition, the Party seeking publication shall delay the submission for a period up to [*] days in the event that the other Party can demonstrate reasonable need for such delay, including the preparation and filing of a patent application. If the other Party fails to provide its comments to the Party seeking publication within such [*]-day period, such other Party shall be deemed not to have any comments, and the Party seeking publication shall be free to publish in accordance with this Section 10.5 after the [*]-day period has elapsed. The Party seeking publication shall provide the other Party with a copy of the manuscript at the time of the submission. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications as scientifically appropriate.

10.6 Equitable Relief. Each Party acknowledges that its breach of this Article 10 could cause irreparable harm to the other Party, which might not be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 10 by the other Party.

11. TERM AND TERMINATION

11.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 11, shall remain in effect on a Product-by-Product basis, for so long as Servier is developing or selling such Product in any country in the Licensed Territory and, where XOMA does not exercise the Cardiometabolic Indications Option, the Retained Territory (the “Term”).

11.2 Unilateral Termination by Servier. Notwithstanding the above, Servier shall be permitted to terminate the Agreement with respect to the EU or in its entirety or, with respect to countries outside the EU only, on a country-by-country basis, without cause and without damages due by Servier to XOMA, its Affiliates, licensees or sub-licensees on account of such termination, upon [*] days prior written notice to XOMA (it being understood that Servier shall at all times remain liable for all costs incurred by it under this Agreement during such notice period).

11.3 Termination for Safety or Public Health Reasons. Notwithstanding Section 11.2, if Servier determines that a safety or public health issue has arisen which is demonstrated by clinically relevant events which are documented and which relate to the Licensed Antibody or the Product, it shall immediately notify XOMA, and it shall be permitted to terminate the Agreement with respect to the EU or in its entirety or, with respect to countries outside the EU only, on a country-by-country basis, promptly, but in any event within [*] days of Servier’s determination of such issue.

11.4 Termination for Material Breach. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such
11.5 Termination for Patent Challenge. XOMA shall have the right to terminate this Agreement immediately upon written notice to Servier if Servier or its Affiliates or sublicensees (directly or indirectly, individually or in association with any other person or entity) challenge the validity, enforceability or scope of any XOMA Patent anywhere in the Licensed Territory or Retained Territory; provided that such termination right shall be for the country of the challenged Patent only or, for a challenged Patent in a member state of the European Patent Organisation, for all such member states.

11.6 Effects of Termination of the Agreement. Upon any early termination of this Agreement, in its entirety or on a country-by-country or EU basis:

(a) Termination of License to Servier. All licenses granted to Servier under Section 7.1 shall terminate, but in the case of termination on a country-by-country or EU basis, solely to the extent such licenses relate to those countries so terminated.

(b) Servier License. Other than termination on the basis of a public health and safety reason under Section 11.3, or termination by Servier on the basis of a material breach of the Agreement by XOMA under section 11.4, or except where Servier can reasonably demonstrate that Commercializing the Product in the terminated country(ies) is detrimental to Servier’s sales in the non-terminated countries, Servier hereby grants to XOMA, effective only in the event of such termination and upon the request of XOMA, an exclusive, irrevocable license (with the right to grant sublicenses through multiple tiers) under the Servier Technology to research, Develop, make, have made, use, sell, offer for sale, import and otherwise Commercialize the Products in such terminated country(ies), which shall bear royalties at a rate equal to the lower of (x) 4% of Net Sales (defined mutatis mutandis with the definition in Section 1.74) in any country in which a Product has received Regulatory Approval prior to the effective date of termination, or 2% of Net Sales (defined mutatis mutandis with the definition in Section 1.74) in any country in which a Product has not received Regulatory Approval prior to the effective date of termination, or (y) such royalty rate as was then being paid by Servier as of the time of such termination.

(c) Regulatory Materials; Data. Other than termination on the basis of a public health and safety reason under Section 11.3, or termination by Servier on the basis of a material breach of the Agreement by XOMA under Section 11.4 (provided that in such case Servier, upon XOMA’s request, would agree to discuss in good faith such a transfer of such materials and approvals), or except where Servier can reasonably demonstrate that Commercializing the Product in the terminated country(ies) is detrimental to Servier’s sales in the non-terminated countries, effective only in the event of such termination Servier hereby transfers to XOMA, at XOMA’s costs, the Regulatory Materials, and Regulatory Approvals, and the related data relating to the Product in such terminated country.

(d) Transition Assistance. Promptly upon request by XOMA, but in no event commencing later than [*] days after the effective date of termination, Servier shall provide such assistance, at no cost to XOMA, as may be reasonably necessary or useful for XOMA to commence or continue Developing, Manufacturing or Commercializing the Product in the terminated country(ies), to the extent Servier is then performing or having performed such activities, including transferring or amending as appropriate, upon request of XOMA, any agreements or arrangements with Third Party vendors to Develop, Manufacture, distribute, sell or otherwise Commercialize the Product in such terminated country(ies). To the extent that any such contract between Servier and a Third Party is not assignable to XOMA, Servier shall reasonably cooperate with XOMA to arrange to continue to provide such services for a reasonable time after termination.

(e) Remaining Inventories. If this Agreement is terminated in a given country, XOMA shall have the right, upon its request, to obtain from Servier, at cost, any or all of the inventory of Products (or components thereof) held by Servier as of the date of such termination (that are not committed to be supplied to any Third Party or sublicensee, in the ordinary course of business, as of the date of termination), XOMA shall notify Servier within [*] days after the date of termination whether XOMA elects to exercise such right.

(f) Assignment of Patents by Servier. With respect to any or all of those XOMA Patents and Joint Invention Patents in the terminated countries, or in all countries if this Agreement is terminated in its entirety, that were assigned by XOMA to Servier under Section 9.3(b), upon XOMA’s request, Servier shall assign to XOMA (i) all of its right, title and interest in such XOMA Patents and (ii) a one-half interest in such Joint Invention Patents, in each case on commercially reasonable terms to be negotiated by the Parties in good faith upon such termination.

(g) Assignment of Patents by XOMA. With respect to any or all of those Servier Patents and Joint Invention Patents in the terminated countries, or in all countries if this Agreement is terminated in its entirety, that were assigned by Servier to XOMA under Section 9.3(c), upon Servier’s request, XOMA shall assign to Servier (i) all of its right, title and interest in such Servier Patents and (ii) a one-half interest in such Joint Invention Patents, in each case on commercially reasonable terms to be negotiated by the Parties in good faith upon such termination.
11.7 Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Sections 6.9, 6.11, 7.3 (as and to the extent provided therein), 8.11, 8.13, 9.1, 10.1, 10.2, 10.3, 10.4, 10.6, 11.6, 11.7, 12.5, 15.4, 15.5, 15.7, 15.8, 15.9, 15.10, 15.11 and 15.12 and Articles 1, 13 and 14.

12. REPRESENTATIONS AND WARRANTIES AND COVENANTS

12.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing, if applicable, under the Laws of the jurisdiction in which it is incorporated.

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

12.2 Additional Representations and Warranties of XOMA. XOMA represents and warrants to Servier that, as of the Effective Date:

(a) Title; Encumbrances. It has sufficient legal and/or beneficial title, ownership or license, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind, of the XOMA Technology to grant the licenses to Servier as purported to be granted pursuant to this Agreement.

(b) Sufficiency. The XOMA Background Patents are all of the Patents owned or Controlled by XOMA or its Affiliates as of the Effective Date that claim the composition, manufacture or use of a Licensed Antibody and/or Product. To XOMA’s and its Affiliates' knowledge, none of the Development, Manufacture, or Commercialization of the Product as it exists as of the Effective Date, interferes with, infringes, misappropriates or otherwise violates any intellectual property rights of any Third Party in a manner that would reasonably result in a material adverse effect on the marketability of the Product.

(c) Pending or Threatened Proceedings. To XOMA’s and its Affiliates’ knowledge, [*] there is no claim, investigation, suit, action or proceeding pending against XOMA or its Affiliates before or by any governmental entity or arbitrator that (i) relates to the Licensed Antibody and the XOMA Background Patents or (ii) prevents the execution of this Agreement.

(d) Intellectual Property Proceedings. To XOMA’s and its Affiliates’ knowledge, the XOMA Background Patents are valid and enforceable. Neither XOMA nor any of its Affiliates have received any written communication alleging that any of the XOMA Background Patents are unpatentable, invalid or unenforceable or are subject to interference, reexamination, reissue, revocation, opposition, appeal or other administrative proceeding.

(e) Regulatory Data. XOMA has disclosed or made available to Servier in writing (i) any and all study reports, data and information provided to any Regulatory Authority, and (ii) all filings and correspondence between XOMA and its Affiliates and any Regulatory Authority, in the case of both (i) and (ii) relating to the Licensed Antibody.

(f) Due Diligence Data. To XOMA’s and its Affiliates’ knowledge, [*] the documents containing the technical information and Know-How disclosed or made available to Servier prior to the Effective Date are true and accurate copies of what they purport to be in all material respects. XOMA has made available to Servier all information in its (or its Affiliates’) possession or control relating to the Licensed Antibody and the Development, Manufacture and Commercialization of the Licensed Antibody or the Product, that XOMA believes, [*] is material to the marketability of the Product in the Licensed Territory.

(g) Notice of Infringement or Misappropriation. Neither XOMA nor its Affiliates have received any written notice from any Third Party asserting or alleging that any research or development of the Licensed Antibody or Licensed Product by XOMA or its Affiliates prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party.

12.3 Additional Representations and Warranties of Servier. Servier represents and warrants to XOMA that, as of the Effective Date, to Servier’s knowledge, it does not own or Control any Patents covering or claiming the manufacture, use, sale, offer for sale, or import of any Licensed Antibody.

12.4 Mutual Covenants.

(a) No Debarment. In the course of the Development of Products, neither Party nor its Affiliates shall use any employee or consultant who has been debarred by any Regulatory Authority, or, to such Party’s or its Affiliates’ knowledge, is the subject of debarment proceedings by a
13. INDEMNIFICATION AND LIMITATION OF LIABILITY

13.1 Indemnification by Servier. Servier shall defend, indemnify, and hold XOMA and its Affiliates and their respective officers, directors, employees, and agents (the “XOMA Indemnitees”) harmless from any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation incurred by such XOMA Indemnitees, all to the extent resulting from claims, suits, proceedings or causes of action brought by such Third Party (“Claims”) against such XOMA Indemnitees that arise from or are based on: (a) the Development, Manufacture or Commercialization of the Product by or on behalf of Servier or its Affiliates or its or their sublicensees (excluding in all cases XOMA or its Affiliates) in the Licensed Territory; (b) the breach of any of Servier’s obligations under this Agreement, including Servier’s representations and warranties set forth herein; (c) the willful misconduct or gross negligence of any Servier Indemnitee; or (d) the use by Servier of the Licensed Territory of pre-clinical and clinical data and information supplied by XOMA to Servier under Section 4.4(c), except in the case of XOMA’s fraud or willful misconduct (it being understood that Servier’s defense obligations shall remain in effect). The foregoing indemnity obligation shall not apply to any Claim to the extent that such Claim arises from or is based on any activity set forth in Section 13.2(b) or (c).

13.2 Indemnification by XOMA. XOMA shall defend, indemnify, and hold Servier and its Affiliates and their respective officers, directors, employees, and agents (the “Servier Indemnitees”) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys’ fees and costs of litigation incurred by such Servier Indemnitees, all to the extent resulting from Claims against such Servier Indemnitees that arise from or are based on (a) the Development, Manufacture or Commercialization of the Product by or on behalf of XOMA or its Affiliates or its or their sublicensees (excluding in all cases Servier, its Affiliates or its sublicensees) in the Retained Territory; (b) the breach of any of XOMA’s obligations under this Agreement, including XOMA’s representations and warranties set forth herein; (c) the willful misconduct or gross negligence of any XOMA Indemnitee; or (d) the use by XOMA in the Retained Territory of pre-clinical and clinical data and information supplied by Servier to XOMA under Section 4.4(c), except in the case of Servier’s fraud or willful misconduct (it being understood that XOMA’s defense obligations shall remain in effect). The foregoing indemnity obligation shall not apply to any Claim to the extent that such Claim arises from or is based on any activity set forth in Section 13.1(b) or (c).

13.3 Conditions to Indemnification. The Party claiming indemnity under this Article 13 (the “Indemnified Party”) shall give written notice to the Party from whom indemnity is being sought (the “Indemnifying Party”) promptly after learning of such Claim, provided that the failure to promptly provide such notice shall not relieve the Indemnifying Party of any of its indemnification obligations hereunder except to the extent that the Indemnifying Party’s defense of the relevant Claim is prejudiced by such failure. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnified Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 13.

13.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.
13.5 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold. Each Party shall provide the other Party with evidence of such insurance upon request and shall provide the other Party with written notice at least [*] days prior to the cancellation, non-renewal or material changes in such insurance. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this Article 13.

14. Dispute Resolution.

14.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party’s rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expeditious manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

14.2 Internal Resolution; Mediation. With respect to all disputes arising between the Parties under this Agreement, including, without limitation, any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [*] days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers (or their designees) for attempted resolution by good faith negotiations within [*] days after such notice is received, including at least one (1) in person meeting of the Executive Officers within [*] days after such notice is received. If the Executive Officers of the Parties are not able to resolve such disputed matter within [*] days and either Party wishes to pursue the matter, the Parties agree to submit the disputed matter for non-binding mediation (with the understanding that the role of the mediator shall not be to render a decision but to assist the Parties in reaching a mutually acceptable resolution), using a mutually agreed upon mediator selected from [*]. in [*], for a period of not more than [*] days.

14.3 Binding Arbitration. If the Parties are unable to resolve a dispute relating to any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement and such disputed matter is not resolved by non-binding mediation under Section 14.2 within [*] days and either Party wishes to pursue the matter, each such dispute, controversy or claim, subject to Section 14.4, shall be finally resolved by binding arbitration administered by the International Chamber of Commerce ("ICC") pursuant to its Dispute Resolution Rules then in effect, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

   (a) The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business. Within [*] days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [*] days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be [*], and all proceedings and communications shall be in English.

   (b) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damage. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration, unless the arbitrators determine that a Party has incurred unreasonable expense due to vexatious or bad faith position taken by the other Party, in which event, the arbitrators may make an award of all or any portion of such expenses so incurred.

   (c) Reasons for the arbitrators’ decisions should be complete and explicit, including reasonable determinations of law and fact. The written reasons should also include the basis for any damages awarded and a statement of how the damages were calculated. Such a written decision shall be rendered by the arbitrators following a full comprehensive hearing, no later than [*] months following the selection of the arbitrators under Section 14.3(a).

   (d) Except to the extent necessary to confirm an award or as may be required by applicable Laws, neither Party nor any arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.

14.4 Patent Disputes. Notwithstanding Section 14.3, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent covering the manufacturing, use, importation, offer for sale or sale of a Product shall be submitted to a court of competent jurisdiction in the country in which such Patent was granted.
15. MISCELLANEOUS

15.1 Entire Agreement; Amendments. This Agreement, including the Exhibits hereto and the Supply Agreement, Quality Agreement, and Safety Data Exchange Agreement contemplated hereunder, and the Loan Agreement, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Rights in Bankruptcy. All licenses granted under this Agreement by Servier or XOMA are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101(34A) of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property (including all Information related to such intellectual property and rights of reference with respect to Regulatory Approvals), and same, if not already in their possession, shall be promptly delivered to them (a) upon any such commencement of a bankruptcy proceeding upon their written request therefore, unless the Party subject to such proceeding continues to perform all of its obligations under this Agreement, or (b) if not delivered or granted under (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefore by the non-subject Party.

15.3 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (as defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, “force majeure” shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

15.4 Notices. Any notices given under this Agreement shall be in writing, addressed to the Parties at the following addresses, and delivered by person, by facsimile (with receipt confirmation), or by FedEx or other reputable courier service. Any such notice shall be deemed to have been given: (a) as of the day of personal delivery; (b) one (1) day after the date sent by facsimile service; or (c) on the day of successful delivery to the other Party confirmed by the courier service. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

If to XOMA: XOMA Ireland Limited
26 Upper Pembroke Street
Dublin 2
Ireland
Attention: Company Secretary
FAX: 353 1 637 3989

With copies (which shall not constitute notice) to:
A & L Goodbody
North Wall Quay
IFSC
Dublin 1
Attention: Seamus O’Croinin
FAX: 353 1 649 2649

If to Servier: LES LABORATOIRES SERVIER
15.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party’s consent to its Affiliates, including in connection with any re-domiciling of such Party or its Affiliates, or to a Third Party successor to substantially all of the business of such Party to which this Agreement relates (such Third Party, an “Acquiror”), whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

15.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

15.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.8 Severability. If any of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.9 No Waiver. Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

15.10 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

15.11 Governing Law. Resolution of all disputes, controversies or claims arising out of, relating to or in connection with this Agreement or the performance, enforcement, breach or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of [*], without regard to conflicts of law rules.

15.12 Construction of this Agreement. Except where the context otherwise requires, wherever used, the use of any gender shall be applicable to all genders, and the word “or” is used in the inclusive sense. When used in this Agreement, “including” means “including without limitation”. References to either Party include the successors and permitted assigns of that Party. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The Parties have each consulted counsel of their choice regarding this Agreement and have jointly prepared this Agreement, and, accordingly, no provisions of this Agreement shall be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, then the terms of this Agreement shall govern. The official text of this Agreement and any Exhibits hereto, any notice given or accounts or statements required by this Agreement, and any dispute proceeding related to or arising hereunder, shall be in English. In the event of any dispute concerning the construction or meaning of this Agreement, reference shall be made only to this Agreement as written in English and not to any other translation into any other language.

15.13 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be an original and all of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which
shall be binding when sent.

[Signature page follows.]

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In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their proper officers as of the Effective Date.

Les Laboratoires Servier XOMA Ireland Limited

By: By:
Name: [*] Name: [*]
Title: [*] Title: [*]

By:
Name: [*]
Title: [*]

Institut de Recherches Servier

By:
Name: [*]
Title: [*]

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Exhibits

Exhibit 1.88 Product Specifications
Exhibit 1.116 XOMA Background Patents as of Effective Date
Exhibit 1.119 XOMA Know-How as of Effective Date
Exhibit 3.3(a) Initial Behçet's Development Plan
Exhibit 3.4(a) Initial T2D Development Plan
Exhibit 3.6(a) FTE Rates
Exhibit 6.2 Initial Manufacturing Plan
Exhibit 6.11 Safety Data Exchange Agreement
Exhibit 7.1(a) Third Party Agreements

Exhibit 1.88
Product Specifications

[*]

Exhibit 1.116
XOMA Background Patents as of Effective Date

**FAMILY 1**

**Title:** IL-1-BETA BINDING ANTIBODIES AND FRAGMENTS THEREOF

**Inventors:** Linda Masat; Mary Haak-Frendscho; Gang Chen; Arnold Horwitz; Marina Roell

**COUNTRY APP. NO. FILE DATE PATENT/PUBLICATION**

- US Provisional 60/692,830 06/21/05
- PCT PCT/US06/024261 06/21/06 WO07/002261
- US 11/472,813 06/21/2006 7,531,166
- US 12/218,914 07/18/2008 7,582,742
- US 12/463,741 05/11/2009 7,744,865
- US 12/463,844 05/11/2009 7,744,866
- US 12/464,323 05/12/2009 2010-0055110A1
- US 12/464,381 05/12/2009 2010-0061998A1
- Australia 2006 262179 06/21/2006 AU2006262179 A1
- Brazil PI0612273-6 06/21/2006 BRPI0612273 A2
- Canada 2,612,760 06/21/2006 CA2612760 A1
- China 2006 80026551.9 06/21/2006 CN101228188 A
- Europe: 06773749.4 06/21/2006 1899378
- Austria 06773749.4 06/21/2006 1899378
- Belgium 06773749.4 06/21/2006 1899378
- Bulgaria 06773749.4 06/21/2006 1899378
- Cyprus 06773749.4 06/21/2006 1899378
- Czech Republic 06773749.4 06/21/2006 1899378
- Denmark 06773749.4 06/21/2006 1899378
- Estonia 06773749.4 06/21/2006 E004059
- Finland 06773749.4 06/21/2006 1899378
- France 06773749.4 06/21/2006 1899378
- Germany 06773749.4 06/21/2006 60 2006 010 072.8-08
- Greece 06773749.4 06/21/2006 1899378
- Hungary 06773749.4 06/21/2006 E007716
- Iceland 06773749.4 06/21/2006 1899378
- Ireland 06773749.4 06/21/2006 1899378
- Italy 06773749.4 06/21/2006 73749BE/2009
Title: METHODS FOR TREATMENT OF IL-1BETA RELATED DISEASES
FAMILY 4
Title: METHODS FOR THE TREATMENT OF RHEUMATOID ARTHRITIS
Inventors: Alan M. Solinger, Alexander Owyang
COUNTRY APP. NO. FILE DATE PATENT/PUBLICATION
US Provisional 61/059,711 06/05/08
US Provisional 61/095,232 09/08/08
Canada PCT/US09/46441 12/06/2010
Australia PCT/US09/46441 To be filed by 01/06/11
Europe PCT/US09/46441 To be filed by 01/06/11

FAMILY 5
Title: METHODS FOR TREATING OR PREVENTING IL-1BETA RELATED DISEASES
Inventors: Patrick J. Scannon, Alan M. Solinger, Robert J. Bauer
COUNTRY APP. NO. FILE DATE PATENT/PUBLICATION
US Provisional 61/094,842 09/05/08
US Provisional 61/121,451 12/10/08

FAMILY 6
Title: METHODS FOR IMPROVEMENT OF BETA CELL FUNCTION
Inventors: Patrick J. Scannon, Alan M. Solinger, Robert J. Bauer
COUNTRY APP. NO. FILE DATE PATENT/PUBLICATION
US Provisional 61/094,857 09/05/08
US Provisional 61/121,486 12/10/08

FAMILY 7
Title: CARDIOVASCULAR RELATED USES OF IL-1BETA ANTIBODIES AND BINDING FRAGMENTS THEREOF
Inventors: Patrick J. Scannon, Alan M. Solinger, Jeffrey D. Feldstein
COUNTRY APP. NO. FILE DATE PATENT/PUBLICATION
US Provisional 61/182,679 05/29/09
US Provisional 61/252,571 10/16/09
US Provisional 61/313,001 03/11/10
Exhibit 1.119
XOMA Know-How as of Effective Date

Exhibit 3.3(a)
Initial Behçet’s Development Plan

Exhibit 3.4(a)
Initial T2D Development Plan

Exhibit 3.6(a)
FTE Rates
2010 Budgeted Rates
Quality $ [*]
Pilot Plant $ [*]
Analytical Development $ [*]
PAM $ [*]
Manufacturing $ [*]
Formulation Development $ [*]
Materials Mgmt $ [*]
Clinical Development $ [*]
Regulatory Affairs $ [*]
Bioanalytical Development $ [*]
NonClinical Safety Evaluation $ [*]
Pharmacokinetics $ [*]

Exhibit 6.2
Initial Manufacturing Plan
[*]
Exhibit 6.11
Safety Data Exchange Agreement

Exhibit 7.1(a)
Third Party Agreements

- Non-Exclusive XOMA License Agreement by and between XOMA Corporation (the predecessor in interest of XOMA Ltd.) and Genentech, Inc., effective as of December 30, 1998.1

- [*]

- License Agreement by and between the University of Zurich and XOMA (US) LLC, effective as of April 11, 2007.3

1 Assigned to XOMA Technology Ltd. pursuant to an Assignment and Assumption Agreement between XOMA Ltd. and XOMA Technology Ltd., effective as of May 31, 1999.

2 [*]

3 Assigned to XOMA Technology Ltd. pursuant to an Assignment and Assumption Agreement between XOMA (US) LLC and XOMA Technology Ltd., effective as of December 30, 2010.