Current Agreements

Dealdoc

Licensing agreement for Sym004 (terminated)

Merck KGaA
Symphogen

Sep 06 2012

Licensing agreement for Sym004 (terminated)

Companies:	Merck KGaA Symphogen
Announcement date:	Sep 06 2012
Deal value, US$m:	622 : sum of upfront, clinical development, regulatory, sales milestones and royalties

Details

Announcement date:	Sep 06 2012
Termination date:	Jan 29 2015
Industry sectors:	Bigpharma Biotech Pharmaceutical
Compound name:	Sym004
Asset type:	Compound
Therapy areas:	Oncology » Colorectal cancer Oncology » Head and neck cancer Antibodies Antibodies » Monoclonal antibodies
Technology types:	Biological compounds Radio/Chemo-therapy Small molecules
Deal components:	Licensing Termination
Stages of development:	Phase I Phase II
Geographic focus:	Worldwide

Financials

Deal value, US$m:	622 : sum of upfront, clinical development, regulatory, sales milestones and royalties
Upfront, US$m:	25.1 : sum of upfront payment
Milestones, US$m:	283 : sum of clinical development and regulatory milestones 313.9 : sales performance milestones
Royalty rates, %:	n/d : royalties on net worldwide sales

Termsheet

January 2015

Merck KGaA is conducting an ongoing assessment of its pipeline assets and has decided to return the rights of Sym004 to Symphogen for further development.

The decision to return the rights is not related to any new safety or efficacy findings regarding Sym004.

The regained Sym004 product rights provide Symphogen with a valuable opportunity to retain the value of this attractive clinical candidate, an investigational antibody mixture targeting the epidermal growth factor receptor (EGFR), currently in Phase 2b and 1b trials.

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26 June 2013

Symphogen has received a milestone payment from Merck KGaA related to the successful achievement of specific development objectives for Sym004, an investigational antibody mixture targeting the epidermal growth factor receptor.

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6 September 2012

Symphogen announced that an exclusive worldwide license agreement was signed with Merck KGaA, Darmstadt, Germany, for Sym004, an investigational antibody mixture targeting the epidermal growth factor receptor (EGFR).

Sym004 is currently being evaluated in a Phase I/II trial for the treatment of patients with advanced KRAS wild-type metastatic colorectal cancer (mCRC) who have previously progressed on treatment with standard chemotherapy and a marketed anti-EGFR monoclonal antibody.

Under the agreement, Symphogen will receive from Merck an upfront payment of € 20 million.

Symphogen is also eligible to receive up to € 225 million for clinical development and regulatory milestones, € 250 million in potential combined sales performance milestones and royalties on net worldwide sales.

In exchange, Merck will gain exclusive worldwide rights to develop and commercialize Sym004.

Press Release

January 2015

Symphogen Regains Rights to Sym004

Announces Organizational Changes

COPENHAGEN, Denmark--(BUSINESS WIRE)--Symphogen, a private biopharmaceutical company developing recombinant antibody mixtures, announced today several new corporate initiatives that reposition the company to focus on its proprietary pipeline of clinical oncology programs. The announcements address the regained rights to Sym004, a novel antibody mixture currently in a Phase 2b program, and a prioritization of the company's discovery activities in immuno-oncology.

Symphogen's collaborative partner, Merck KGaA, is conducting an ongoing assessment of its pipeline assets and has decided to return the rights of Sym004 to Symphogen for further development. The decision to return the rights is not related to any new safety or efficacy findings regarding Sym004.

The regained Sym004 product rights provide Symphogen with a valuable opportunity to retain the value of this attractive clinical candidate, an investigational antibody mixture targeting the epidermal growth factor receptor (EGFR), currently in Phase 2b and 1b trials.

In addition to Sym004, Symphogen expects to bring its Pan-HER multi-targeting antibody mixture into clinical development in 2015. Pan-HER is a mixture of six humanized full-length monoclonal antibodies targeting EGFR, HER2 and HER3, all validated targets for cancer treatment that effectively induces simultaneous down-modulation of all three targets and prevents compensatory receptor up-regulation. Symphogen's research has demonstrated that simultaneous targeting of three receptors provides broader efficacy, than targeting a single receptor or any combination of two receptors in the HER family. Symphogen also has, in late preclinical development, an mAb mixture program against the receptor tyrosine kinase c-MET, which is expected to enter the clinic in 2016. Symphogen's early discovery activities will now be focused on the development of multi-targeting programs in the immuno-oncology area.

"We are pleased to have regained the rights to this attractive product candidate and look forward to rapidly moving forward its clinical development in areas of high unmet medical needs. The return of this mature program allows Symphogen, effectively and efficiently, to transition into a clinical company. With more than €70 million in cash to execute its strategy, the rights to an advancing clinical program, and several pipeline programs being readied for development, we can harvest the productivity of our research efforts and move the company forward with an eye toward commercial oncology opportunities," said Kirsten Drejer, PhD, Chief Executive Officer of Symphogen.

Organizational Changes

Symphogen also announced today that Symphogen Inc. is opening a Clinical Development Unit in New Jersey, US, under the leadership of Head of Corporate R&D, Chief Medical & Scientific Officer Dr. Ivan Horak.

Additionally, Dr. Esper Boel has joined the company as Chief Technology Officer to lead Symphogen's antibody discovery activities in Denmark, including Immuno-Oncology projects. Prior to joining Symphogen, Dr. Boel served as Corporate Vice President for the Biotechnology unit in

Novo Nordisk's international R&D organization. Dr. Boel has extensive experience in biopharmaceutical R&D management, and has served as Board member/consultant for high-profile antibody based companies including Xencor Inc. and Innate Pharma SA, and he has (co)authored more than 70 original research articles and reviews.

About Sym004

Sym004 is comprised of two antibodies that are not only designed to block ligand binding, receptor activation and downstream signaling but are also thought to elicit removal of the EGFR receptors from the cancer cell surface by inducing EGFR internalization and degradation.

Sym004 was the subject of data presentations at the 2013 and 2014 ASCO Annual Meetings in Chicago, IL. At these meetings, reported Phase 2 proof-of-concept data in squamous cell carcinoma of the head & neck (SCCHN) and in metastatic colorectal cancer signaled clinical activity and were supportive of the proposed mechanism of action. Merck KGaA, through its biopharmaceutical business, Merck Serono, initiated new clinical studies evaluating Sym004, an investigational antibody mixture targeting the epidermal growth factor receptor (EGFR). The trials are a Phase 2b study in patients with metastatic colorectal cancer (mCRC) and a Phase 1b study in patients with Non-Small Cell Lung Cancer (NSCLC). In addition, a Japanese Phase 1 study, which started in 2013, is currently recruiting patients with Esophageal Cancer. Also in 2014, Symphogen received three milestone payments from Merck for achieving certain agreed goals in the collaboration, including the initiation of new mCRC and NSCLC clinical trials.

About Symphogen A/S

Symphogen is developing next-generation antibody therapeutics for the treatment of cancer and is dedicated to bringing truly innovative oncology products to the market. The company has advanced the frontier of antibody discovery by creating well-characterized antibody mixtures that address multiple oncology targets in a single drug product. The company has matured its pipeline and has currently brought two product candidates into the clinic. The company's productive technology suite - capable of identifying, selecting and manufacturing optimal antibody mixtures – fuels Symphogen's innovative pipeline.

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26 June 2013

Symphogen Receives Milestone Payment in Merck KGaA Sym004 Collaboration

2013 ASCO Annual Meeting

COPENHAGEN, Denmark--Symphogen, a private biopharmaceutical company developing recombinant antibody mixtures, announced today that it has received a milestone payment from Merck KGaA, Darmstadt, Germany, related to the successful achievement of specific development objectives for Sym004, an investigational antibody mixture targeting the epidermal growth factor receptor (EGFR).

“This payment substantially enhances the financial position of Symphogen and demonstrates our commitment to assisting Merck KGaA to advance this promising program.”

Out-licensed world-wide by Symphogen to Merck in September 2012, Sym004 was the subject of two data presentations at the 2013 ASCO Annual Meeting in Chicago, IL, earlier this month. Specifically, Sym004 reported Phase 2 proof-of-concept data in squamous cell carcinoma of the head & neck (SCCHN) and in metastatic colorectal cancer that signaled clinical activity and were supportive of the anticipated mixture’s mechanism of action.

“We are pleased to achieve meaningful progress so early in our collaboration,” said Kirsten Drejer, Chief Executive Officer of Symphogen. “This payment substantially enhances the financial position of Symphogen and demonstrates our commitment to assisting Merck KGaA to advance this promising program.”

About SYM004 Sym004 is comprised of two antibodies that are not only designed to block ligand binding, receptor activation and downstream signaling but are also thought to elicit removal of the EGFR receptors from the cancer cell surface by inducing EGFR internalization and degradation. As of 21 May 2013, 105 patients have been treated with Sym004 in clinical trials.

Sym004 was out-licensed to Merck KGaA in 2012 following phase 2 clinical data in late stage cancer patients.

About Symphogen A/S Symphogen is developing next-generation antibody therapeutics for the treatment of cancer and is dedicated to bringing truly innovative oncology products to the market. The company has advanced the frontier of antibody discovery by creating well characterized antibody mixtures that address multiple oncology targets in a single drug product. The company has matured its pipeline and has currently brought two product candidates into the clinic. The company’s productive technology suite - capable of identifying, selecting and manufacturing optimal antibody mixtures – fuels Symphogen’s innovative pipeline. In total, the company has raised € 249 million in equity capital from premier international investors including Novo, Essex Woodlands Health Ventures and PKA, and employs 95 people, most of who are based at Symphogen’s facilities in Copenhagen.

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6 September 2012

Symphogen Grants Exclusive Worldwide License of Phase II Oncology Drug Candidate Sym004 to Merck KGaA

A novel investigational antibody mixture targeting the epidermal growth factor receptor (EGFR)

Symphogen will host a conference call today (Thursday 6 September 2012) to discuss the announcement at 11:30 CET/ 10:30 BST, details on how to access this call and the accompanying presentation are below

COPENHAGEN, Denmark--(BUSINESS WIRE)--Symphogen A/S, a private biopharmaceutical company developing recombinant antibody mixtures, a class of antibody therapeutics under investigation for the treatment or prophylaxis of serious human diseases such as cancer or infectious and autoimmune diseases, today announced that an exclusive worldwide license agreement was signed with Merck KGaA, Darmstadt, Germany, for Sym004, an investigational antibody mixture targeting the epidermal growth factor receptor (EGFR). Sym004 is currently being evaluated in a Phase I/II trial for the treatment of patients with advanced KRAS wild-type metastatic colorectal cancer (mCRC) who have previously progressed on treatment with standard chemotherapy and a marketed anti-EGFR monoclonal antibody. In addition, a single-arm, open-label Phase II trial in patients with squamous cell carcinoma of the head and neck (SCCHN) who have failed anti-EGFR–based therapy is currently ongoing.

Under the agreement, Symphogen will receive from Merck an upfront payment of € 20 million. Symphogen is also eligible to receive up to € 225 million for clinical development and regulatory milestones, € 250 million in potential combined sales performance milestones and royalties on net worldwide sales. In exchange, Merck will gain exclusive worldwide rights to develop and commercialize Sym004.

“We believe that Merck is uniquely well positioned to develop Sym004 based on its deep knowledge of the EGFR area,” said Kirsten Drejer, Chief Executive Officer of Symphogen. “This transaction further validates the antibody mixture approach as a highly attractive option.”

“Sym004 further strengthens our early development pipeline by adding a product that is thought to act via a proposed synergistic mechanism of action not previously studied, but more specifically, it has the potential to become a key asset complementing our already highly successful Erbitux franchise,” commented Dr. Susan Jane Herbert, Head of Global Business Development and Strategy for Merck Serono. “This collaboration once again reflects our strong commitment to fighting cancer and to providing new treatment options to patients.”

Sym004 is comprised of two antibodies that are not only designed to block ligand binding, receptor activation and downstream signaling but are also thought to elicit removal of the EGFR receptors from the cancer cell surface by inducing EGFR internalization and degradation.1

As of July 2012, 88 patients have been treated with Sym004 in clinical trials. The adverse events from the preliminary clinical data include diarrhea, skin rash, mucosal inflammation, nausea, infusion-related reaction and hypomagnesemia. Exposure data from the patients, after weekly repeated infusions, do not indicate an anti-drug antibody response.

About Symphogen

Symphogen is developing antibody therapeutics (monoclonal, monoclonal mixtures and polyclonal) to help people with serious diseases and significant unmet medical needs. With its proprietary Symplex™ discovery, SymSelect™ lead selection and Sympress™ manufacturing platforms, the company captures the diversity and specificity of the natural immune response in rationally designed recombinant antibody mixtures. Symphogen is maturing a diversified pipeline of internal and partnered products across multiple indications including cancer, autoimmune and infectious disease. Symphogen is a private biopharmaceutical company headquartered in Copenhagen, Denmark, with a US subsidiary in Princeton, New Jersey. For more information, please visit www.symphogen.com.

About Merck Serono

Merck Serono is the biopharmaceutical division of Merck KGaA. With headquarters in Darmstadt, Germany, Merck Serono offers leading brands in 150 countries to help patients with cancer, multiple sclerosis, infertility, endocrine and metabolic disorders as well as cardiovascular diseases. In the United States and Canada, EMD Serono operates as a separately incorporated subsidiary of Merck Serono.

Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. We have an enduring commitment to deliver novel therapies in our core focus areas of neurodegenerative diseases, oncology and rheumatology.

About Merck

Merck is a global pharmaceutical and chemical company with total revenues of €10.3 billion in 2011, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

Filing Data

Not available.

Contract

Not available.