Current Agreements

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Amendment to licensing and option agreement for RDX5791

AstraZeneca
Ardelyx

Dec 23 2013

Amendment to licensing and option agreement for RDX5791

Companies:	AstraZeneca Ardelyx
Announcement date:	Dec 23 2013
Amendment date:	Dec 23 2013
Deal value, US$m:	n/d
Related contracts:	Licensing and option agreement for RDX5791

Details

Announcement date:	Dec 23 2013
Amendment date:	Dec 23 2013
Start date:	Dec 23 2013
Industry sectors:	Bigpharma Pharmaceutical
Compound name:	tenapanor (AZD1722 and RDX5791)
Exclusivity:	Exclusive
Asset type:	Compound
Therapy areas:	Gastrointestinal » Inflammatory bowel disease Gastrointestinal » Symptoms » Constipation Genitourinary » Chronic kidney disease (CKD)
Technology types:	Small molecules
Deal components:	Co-promotion Licensing Option
Stages of development:	Phase II
Geographic focus:	Worldwide North America » United States

Financials

Deal value, US$m:	n/d

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

AMENDMENT NUMBER ONE

TO

LICENSE AGREEMENT

BY AND BETWEEN

ASTRAZENECA AB

AND

ARDELYX, INC.

DECEMBER 23, 2013

AMENDMENT NUMBER ONE TO LICENSE AGREEMENT

This Amendment Number One to License Agreement ("Amendment One") is entered into as of the 23rd day of December, 2013 (the "Amendment One Effective Date") by and between AstraZeneca AB (publ), a Swedish corporation with corporate identity no. 556011-7482 and a place of business at 431 83 Molndal, Sweden ("AstraZeneca") and Ardelyx, Inc. a Delaware corporation having its principal place of business at 34175 Ardenwood Boulevard, Fremont, California United States of America 94555 ("Ardelyx"). Ardelyx and AstraZeneca are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

Whereas, AstraZeneca and Ardelyx are parties to that certain License Agreement dated as of October 4, 2012 (the "Agreement"), establishing a license and collaboration between the Parties for the further development and commercialization of RDX5791 (known as of the Amendment One Effective Date as AZD1722) and its back-up compounds.

Whereas, the Parties desire to amend certain terms and conditions of the Agreement in the manner set forth in this Amendment One.

Now Therefore, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1. DEFINITIONS

1.1 Capitalized Terms. Capitalized terms not defined in this Amendment One shall have the meaning assigned in the Agreement.

1.2 Ardelyx [***] Patents. The definition of Ardelyx [***] Patents shall be revised to read in full as follows:

"Ardelyx [***] Patents shall mean Patents (i) [***], (ii) that cover or claim inventions necessary or useful to Develop, Manufacture or Commercialize any Licensed Compound or Licensed Product, and (iii) with respect to which AstraZeneca has not exercised the Exclusion Option."

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.3 Licensed Patents. The definition of Licensed Patents shall be revised to read in full as follows:

"Licensed Patents shall mean (i) all of the Listed Patents, (ii) [***], and (iii) all Ardelyx Sole Invention Patents; provided that in the case of (ii) and (iii) above, such Patents (a) cover or claim any Licensed Compound or Licensed Product, or (b) cover or claim any invention necessary or useful for the Exploitation of Licensed Compounds or Licensed Products; and provided, further that prior to the Amendment One Effective Date, [***] shall not be Licensed Patents. Licensed Patents exclude Ardelyx [***] Patents."

1.4 New Definitions. The following shall be added as new defined terms in Section 1.1 of the Agreement:

"Constipation Related Disorder Indication Demonstration of Decision to Proceed" shall have the meaning assigned in Section 5.2(a)(iii)."

“Demonstration of Decision to Proceed” shall mean the Constipation Related Disorder Indication Demonstration of Decision to Proceed and the Other Indications Demonstration of Decision to Proceed.”

“International Co-ordinating Investigator” shall mean an external (i.e. not employed by AstraZeneca or its Affiliates) physician assigned by or on behalf of AstraZeneca or its Affiliates with the responsibility for the coordination of investigators at different centres participating in a multicentre Clinical Trial for a Licensed Product. AstraZeneca agrees to provide Ardelyx with written notice of the designation of each International Co-ordinating Investigator so assigned by AstraZeneca prior to the end of the Notification Period, and written notice of any change to such designation within five (5) days of such change being made. “

“Other Indications Demonstration of Decision to Proceed” shall have the meaning assigned in Section 5.2(a)(ii).”

“[***] Patents” shall mean the following United States Provisional Patent Applications: [***], and any such Patents claiming priority to such Patents.”

“Planned Phosphate 2b Clinical Trial” means the Phase 2b Clinical Trial (No. D5613C00001) of the Lead Licensed Compound in hyperphosphatemia in patients with ESRD that is – as of the Amendment One Effective Date – planned to be conducted by or on behalf of AstraZeneca.

The Parties acknowledge and agree that for the purposes of this Agreement the Planned Phosphate 2b Clinical Trial, as currently (as of the Amendment One

Effective Date) proposed to be designed, shall not be deemed to constitute a Phase 3 Clinical Trial. However, the Parties further acknowledge and agree that the Planned Phosphate 2b Clinical Trial may be deemed to constitute a Phase 3 Clinical Trial solely in the event that (a) the design of the Planned Phosphate 2b Clinical Trial, as manifested by a subsequent (i.e. following the Amendment One Effective Date) submission to the applicable Regulatory Health Authority, is modified in any material respect, including, without limitation, a material extension of the treatment duration of the Planned Phosphate 2b Clinical Trial, such that the Planned Phosphate 2b Clinical Trial can actually be used as a pivotal study for purposes of seeking Regulatory Approval or (b), following completion of the Planned Phosphate 2b Clinical Trial, AstraZeneca seeks and obtains confirmation from the Regulatory Health Authority that the Planned Phosphate 2b Clinical Trial can be used as a pivotal study for purposes of seeking Regulatory Approval, where such confirmation shall be deemed to have been obtained when (but not before) (i) the first meeting with the Regulatory Health Authority that is convened for the purpose of discussing the end of the Planned Phosphate 2b Clinical Trial has occurred, and (ii) the minutes of such meeting prepared by the Regulatory Health Authority confirm concurrence by the Regulatory Health Authority that the Planned Phosphate 2b Clinical Trial can be used as a pivotal study for the purposes of seeking Regulatory Approval.

ARTICLE 2. SECTION 2.9(e) OF THE AGREEMENT

Section 2.9(e) of the Agreement shall be deleted in its entirety and replaced with the following:

“(e) With respect to the Listed Patents and [***], Ardelyx covenants that for the duration of the Term, neither Ardelyx nor any of it Affiliates shall directly or indirectly (i) seek to [***], or [***] any rights to, any [***], (ii) grant any [***] in respect of the [***]; or (iii) seek to [***] unless expressly permitted by this Agreement.”

ARTICLE 3. SECTION 5.2 OF THE AGREEMENT

Section 5.2 of the Agreement shall be deleted in its entirety and replaced with the following:

“Section 5.2 AstraZeneca’s Option During the Notification Period.

(a) At any time following the Amendment One Effective Date and prior to [***]

[***] (the “Notification Period”), AstraZeneca may either,

(i) terminate this Agreement in its entirety effective thirty (30) days after having provided written notice of termination to Ardelyx, which termination shall be an AZ Triggered Termination subject to the provisions of Section 14.3. Notwithstanding the termination of this Agreement under this Section 5.2(a)(i), or any other termination at will under Section 14.2(b), AstraZeneca shall remain obligated to reimburse Ardelyx for its Development Expenses incurred in connection with its performance of the IBS-C Study, whether incurred prior to or on or after the effective date of such termination, up to a maximum amount of [***]; or

(ii) demonstrate its decision to proceed with Clinical Development of a Licensed Product for any indication other than a Constipation Related Disorder Indication, and pay the amount set forth in Section 9.2(b) of this Agreement, with such demonstration of its decision to so proceed being deemed to have been made at the earlier to occur of [***]; (the earlier to occur of (X), (Y) and (Z) being an "Other Indications Demonstration of Decision to Proceed"); it being agreed that no event or circumstance other than (X), (Y) or (Z) as per this Section 5.2(a)(ii) or a notification pursuant to Section 5.2(a)(iv), occurring within the Notification Period, shall trigger an obligation for AstraZeneca to pay the amount set forth in Section 9.2(b)); or

(iii) demonstrate its decision to proceed with Clinical Development of a Licensed Product for a Constipation Related Disorder Indication, and pay the amount set forth in Section 9.2(c) of this Agreement, with such demonstration of its decision to so proceed being deemed to have been made at the earlier to occur of [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***] (the earlier to occur of (X), (Y) and (Z) being a "Constipation Related Disorder Indication Demonstration of Decision to Proceed"); it being agreed that no event or circumstance other than (X), (Y) or (Z) as per this Section 5.2(a)(iii), occurring within the Notification Period, shall trigger an obligation for AstraZeneca to pay the amount set forth in Section 9.2(c); or

(iv) notify Ardelyx in writing, such notice given in accordance with Section 17.4 and expressly referencing this Section 5.2(a)(iv), of its decision to make the payment under Section 9.2(b).

(b) If prior to the end of the Notification Period, a Demonstration of Decision to Proceed has not occurred under subsections (ii) or (iii) of Section 5.2(a); AstraZeneca has not provided Ardelyx with the written notification described in subsection (iv) of Section 5.2(a); or AstraZeneca has not terminated this Agreement under subsection (i) of Section 5.2(a), then this Agreement shall be deemed terminated by AstraZeneca in its entirety upon the expiry of the Notification Period, and the consequences set forth in subsection (i) of Section 5.2(a) shall apply. Furthermore and for the avoidance of doubt, if an Other Indications Demonstration of Decision to Proceed occurs, then Section 4.4 shall not be construed to require AstraZeneca to use Commercially Reasonable Efforts to pursue Development of Licensed Products for a Constipation Related Disorder Indication for so long as AstraZeneca pursues any indication that is not a Constipation Related Disorder Indication.

(c) For the avoidance of doubt, this Section 5.2 sets out AstraZeneca's options during the Notification Period and AstraZeneca's obligations to make certain payment upon the occurrence of the relevant triggering event as set forth in this Section 5.2 and Section 9.2. However, this Section 5.2 is not intended, and shall not be construed to, limit in any way AstraZeneca's ability to Exploit the Licensed Compounds or Licensed Product or otherwise exercise the License and other rights granted to it under this Agreement during the Term."

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE 4. SECTION 9.2 OF THE AGREEMENT

Section 9.2 of the Agreement shall be deleted in its entirety and replaced with the following:

"Section 9.2 Additional Payments.

(a) Within five (5) days of the Amendment One Effective Date, AstraZeneca shall pay to Ardelyx a nonrefundable, one-time amount of fifteen million U.S. dollars (U.S. $15,000,000), against an invoice received by AstraZeneca from Ardelyx fulfilling the requirements set forth in Section 9.12, which invoice may be sent on or after the Amendment One Effective Date. The payment pursuant to this Section 9.2(a) shall not be creditable against any other payments AstraZeneca is obligated to make to Ardelyx under the Agreement or this Amendment One.

(b) Following [***], AstraZeneca shall pay Ardelyx a nonrefundable, one-time amount of twenty million U.S. dollars (U.S. $20,000,000); provided, however, that if at such time as a payment is due under this Section 9.2(b), [***], then the amount due under this Section 9.2(b) shall be reduced to ten million U.S. dollars (U.S. $10,000,000). Payment under this Section 9.2(b) shall be made to Ardelyx within [***] after AstraZeneca's receipt of an invoice from Ardelyx (fulfilling the requirements set forth in Section 9.12) following such [***]. The payment pursuant to this Section 9.2(b) shall not be creditable against any other payments that AstraZeneca is obligated to make to Ardelyx under this Agreement or this Amendment One.

(c) Following [***], AstraZeneca shall pay Ardelyx a nonrefundable, one-time payment of ten million U.S. dollars (U.S. $10,000,000); provided, however, that if at such time as a payment is due under this Section 9.2(c), [***], then no additional payment shall be due under this Section 9.2(c). Payment under this Section 9.2(c) shall be made to Ardelyx within [***] after AstraZeneca's receipt of an invoice from Ardelyx (fulfilling the requirements set forth in Section 9.12) following such [***]. The payment pursuant to this Section 9.2(c) shall not be creditable against any other payments that AstraZeneca is obligated to make to Ardelyx under this Agreement or this Amendment One.

(d) If (i) within a period of [***] after the end of the Notification Period, [***], (ii) [***], and (iii) [***], then AstraZeneca shall pay Ardelyx a

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nonrefundable, one-time payment of ten million U.S. dollars (U.S. $10,000,000) within [***] after AstraZeneca's receipt of an invoice from Ardelyx (fulfilling the requirements set forth in Section 9.12) following such [***]. The payment pursuant to this Section 9.2(d) shall not be creditable against any other payments that AstraZeneca is obligated to make to Ardelyx under this Agreement or this Amendment One."

ARTICLE 5. SECTION 11.4(d) OF THE AGREEMENT

Section 11.4(d) of the Agreement shall be deleted in its entirety and replaced with the following:

"(d) Other than as described in Section 11.4(e) and 11.4(f) below, after the Effective Date, the Party prosecuting patent applications and maintaining Patents pursuant to this Section 11.4 shall be solely responsible for all costs and expenses associated with the filing, prosecution and maintenance of such Patents. For the avoidance of doubt, Ardelyx is responsible for all costs and expenses incurred prior to the Amendment One Effective Date in filing [***]."

ARTICLE 6. SECTION 14.3(c) OF THE AGREEMENT

Section 14.3(c) of the Agreement shall be amended to add [***] such that those subsections shall each read in full as follows:

[***]

[***]

ARTICLE 7. MISCELLANEOUS

7.1 Governing Law. This Amendment One shall be governed by and interpreted under the laws of the State of Delaware, without giving effect to any conflict of law provision that would otherwise result in the application of the laws of any State or jurisdiction other than the State of Delaware.

7.2 Entire Agreement. This Amendment One, together with the Agreement, constitutes the entire agreement between the Parties with respect to

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the subject matter of the Agreement. The Agreement together with this Amendment One supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement, as amended by this Amendment One. Each Party confirms that it is not relying on any statements, representations, warranties or covenants of any person (whether a Party to this Agreement or not) except as specifically set out in the Agreement as hereby amended. Nothing in this Amendment is intended to limit or exclude any liability for fraud. The Parties hereby agree that subject to the modifications specifically stated in this Amendment One, all terms and conditions of the Agreement shall remain in full force and effect.

7.3 Counterparts. This Amendment One may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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

ARDELYX, INC. ASTRAZENECA (PUBL)

By:

/s/ Michael Raab

By:

/s/ Marcus Schindler

Name:

Michael Raab

Name:

Marcus Schindler

Title:

CEO

Title:

VP, Head of CVM