



Current Agreements

Dealdoc

Licensing and option agreement for diabetes compound BIM 51077 (terminated)

Roche

Ipsen

Oct 21 2003

Licensing and option agreement for diabetes compound BIM 51077 (terminated)

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|---------------------------|--|
| Companies: | Roche Ipsen |
| Announcement date: | Oct 21 2003 |
| Deal value, US\$m: | 300.0 : sum of upfront and milestone payments |

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Details

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|-------------------------------|---|
| Announcement date: | Oct 21 2003 |
| Termination date: | Feb 01 2011 |
| Industry sectors: | Bigbiotech Bigpharma Pharmaceutical |
| Therapy areas: | Metabolic » Diabetes |
| Technology types: | Small molecules Co-market |
| Deal components: | Licensing Termination |
| Stages of development: | Phase I |
| Geographic focus: | Worldwide |
| Excluded geography: | Asia » Japan Europe » France |

Financials

| | |
|---------------------------|--|
| Deal value, US\$m: | 300.0 : sum of upfront and milestone payments |
| Upfront, US\$m: | 11.6 : upfront payment |
| Milestones, US\$m: | 214.8 : based on successful clinical, manufacturing, regulatory and commercial milestones 70.6 : triggered by exercising option agreement 3.8 : triggered by closing of 2006 financial statement |
| Royalty rates, %: | n/d : royalty payments on worldwide sales |
| Funding, US\$m: | n/d : Roche will be responsible for all development costs |

Termsheet

21 October 2001

Roche and Ipsen have entered into a second agreement for Ipsen's diabetes compound BIM 51077.

BIM 51077 is a Glucagon-like-peptide-1 (GLP-1) analogue, currently in Phase I clinical studies for Type 2 diabetes.

Roche has been granted rights to all future compounds to be discovered or licensed by Ipsen in this class of drugs.

Roche will have exclusive rights to market and sell BIM 51077 worldwide, except in Japan where Roche will share co-marketing rights with Teijin and in France where Ipsen has the option to co-market. Roche will reimburse the development and formulation work undertaken by Ipsen and will be responsible for all future clinical development.

Ipsen will receive total payments of up to €202 million, consisting of €10 million in initial committed payments and additional payments contingent upon achievement of clinical, manufacturing, regulatory, and commercial milestones.

Additionally, Ipsen will receive royalties on worldwide sales.

19 July 2006

Roche is to exercise its option to exclusively licence, develop and market Ipsen's patented anti-diabetic drug BIM 51077.

This has triggered a payment to Ipsen of €56 million.

Roche will also make a payment of €3 million after the closing of Ipsen's 2006 financial statements.

Ipsen could receive total further payments of up to €170 million, contingent upon achievement of clinical, manufacturing, regulatory, and commercial milestones.

Ipsen will receive progressive royalties on any worldwide sales.

Roche is responsible for further developing and manufacturing of the product and will consequently hold the marketing authorisations.

Roche will fund 100% of the remaining development of BIM 51077, except with respect to Japan where expenses will be shared 50% between Roche and Teijin.

Press Release

Roche acquires rights to diabetes compound from Ipsen

21 October 2003

Basel -- October 21, 2003 -- Roche and Ipsen today announced that the two companies have entered into a second agreement, following the one concluded December 2002, this time for Ipsen's diabetes compound BIM 51077. BIM 51077 is a Glucagon-like-peptide-1 (GLP-1) analogue, currently in Phase I clinical studies for Type 2 diabetes. In addition to BIM 51077 itself, Roche has been granted rights to all future compounds to be discovered or licensed by Ipsen in this class of drugs.

According to the terms of the first agreement entered in December 2002, Roche already has worldwide rights, excluding Europe, to market Ipsen's homocamptothecin class of compounds, a promising group of anticancer agents with lead compounds in development, such as diflomotecan and BN 80927.

"BIM 51077 is a very promising compound that will further strengthen our position in the diabetes market, with proven products such as Xenical," stated William M. Burns, Head of the Pharmaceutical Division at Roche, "We are very pleased to build upon our relationship with Ipsen. After just ten months of entering into our first collaboration, we have identified a further opportunity for collaboration. Working closely with partners and building upon existing relationships is a key business strategy for Roche."

"We are delighted to be working once again with Roche. This agreement reflects our corporate strategy to actively search for new alliances and partnerships, particularly with quality partners, and confirms the quality of our research," said Jean-Luc Bélingard, Ipsen's President and CEO.

Terms of the Agreement

Under the terms of the agreement, Roche will have exclusive rights to market and sell BIM 51077 worldwide, except in Japan where Roche will share co-marketing rights with Teijin and in France where Ipsen has the option to co-market. Roche will reimburse the development and formulation work undertaken by Ipsen and will be responsible for all future clinical development. Ipsen will receive total payments of up to €202 million, consisting of €10 million in initial committed payments and additional payments contingent upon achievement of clinical, manufacturing, regulatory, and commercial milestones. Additionally, Ipsen will receive royalties on worldwide sales.

About BIM 51077

BIM 51077, a compound discovered by Ipsen Research and Development, is a GLP-1 receptor agonist, a new class of compounds under study for the treatment of Type 2 diabetes. Diabetic patients produce less insulin than non-diabetics, and clinical studies suggest that GLP-1 receptor agonists can increase insulin to near normal levels. GLP-1 incretin hormone is secreted naturally in response to food intake and acts to stimulate insulin production, suppress glucagon secretion, and slow gastric emptying in order to restore and sustain physiological blood glucose levels. The structure of BIM 51077 was optimized to provide extended duration of action while retaining the potency of the endogenous hormone.

Ipsen's Active Search for New Alliances and Partnerships

Ipsen's strategy for development is based on two main pillars: the high quality of its research and an active search for new alliances and partnerships. This new agreement with Roche reflects such strategy, validates the quality of the new molecules discovered by Ipsen's researchers and confirms the Ipsen development model. Since January 2002, Ipsen has signed ten major licensing, research development and other partnership agreements and thus demonstrated its ability to form and develop alliances and partnerships with the leading pharmaceutical and biotech companies. The Group intends to continue this strategy in the future in order to enrich its product portfolio in its four targeted disease areas. These agreements help the Company to secure access to complementary technologies to those it already has, and at the same time provide new opportunities for international distribution, particularly in the United States and Japan.

19 July 2006

Roche exercises its option to license Ipsen's anti-diabetic medicine for type 2 diabetes

July 19, 2006 - Further to the agreement signed in October 2003, Roche announced today its decision to exercise its option to exclusively licence, develop and market Ipsen's patented anti-diabetic drug BIM 51077. This GLP-1 medicine has shown a good efficacy signal and latest data from phase I and II clinical studies showed potential to be more conveniently administered than existing members of the class, which would facilitate patient compliance. Roche has been granted worldwide rights, except in Japan where these rights are shared with Teijin (Ipsen's Japanese partner), and in France where Ipsen may elect to retain co-marketing rights.

"Our decision to in-license this anti-diabetic medicine adds a very promising compound to our metabolic disease portfolio and also complements our diagnostics activities in diabetes" said Peter Hug, Global Head of Pharma Partnering for Roche. "Our continued collaboration with Ipsen, based on our respective complementary strengths, has the potential to deliver treatments that will make a difference in patients' lives."

Jean-Luc Bélingard, Chairman and CEO of the Ipsen Group said "We are delighted that Roche, a world-class group with a strong commitment to the diagnosis and treatment of diabetes, decided to exercise its option to develop and market BIM 51077. It shows once again that Ipsen is a reference partner in the industry, able to deliver first-in-class products through its differentiated and unique R&D. We are very excited about BIM 51077's prospects and believe that Roche is uniquely placed to successfully market this product".

Roche's decision is supported by the phase I and II results obtained with BIM 51077, a glucagon-like peptide-1 (GLP-1) analogue, and partly presented at the American Diabetes Association (ADA) scientific meeting in Washington D.C. this year. These data showed that this anti-diabetic compound exhibited an efficacy and safety profile in line with the GLP-1 class of incretins and was compatible with Ipsen's proprietary controlled delivery systems which upon subcutaneous administration could deliver over a period of one day, one week or two weeks. Phase II study, to confirm the efficacy and safety of this compound in a sustained release formulation, will start early 2007.

Terms of the agreement

The exercise of this option by Roche has triggered a payment to Ipsen of €56 million. Roche will also make a payment of ca.€3 million after the closing of Ipsen's 2006 financial statements.

Ipsen could receive total further payments of up to €170 million, contingent upon achievement of clinical, manufacturing, regulatory, and commercial milestones. Additionally, Ipsen will receive progressive royalties on any worldwide sales.

As of the date of exercise of the option, Roche is fully responsible for further developing and manufacturing of the product and will consequently hold the marketing authorisations. Roche will fund 100% of the remaining development of BIM 51077, except with respect to Japan where expenses will be shared 50% between Roche and Teijin.

TERMINATION - FEBRUARY 2011

2 February 2011

Taspoglutide

Roche has informed the Group on its decision to return taspoglutide to Ipsen. Roche's decision is based on the analysed data stemming from the root cause analysis carried-out on both nausea and hypersensitivity.

According to the agreements signed with Roche in 2003 and 2006, Ipsen is entitled to the full body of data generated by Roche. Ipsen will thoroughly assess the available data to determine potential further partnership opportunities. Given the level of required investment, the Group does not intend to clinically develop taspoglutide on its own.

Roche's decision to return taspoglutide to Ipsen triggers the accelerated recognition in 2010 of the deferred revenues corresponding to the taspoglutide milestones cashed-in but not recognized in Ipsen's profit and loss account by the end of June 2010, amounting to a non-recurring, non-cash profit of c.41 million euros after tax.

Filing Data

Not available.

Contract

Not available.