Current Agreements

Dealdoc

Licensing, development and option agreement to co-market and co-develop insulin analogues (updated)

Eli Lilly
Boehringer Ingelheim

Jan 11 2011

Licensing, development and option agreement to co-market and co-develop insulin analogues (updated)

Companies:	Eli Lilly Boehringer Ingelheim
Announcement date:	Jan 11 2011
Amendment date:	Oct 29 2014
Deal value, US$m:	2381.4 : sum of upfront and milestone payments

Details

Announcement date:	Jan 11 2011
Amendment date:	Oct 29 2014
Industry sectors:	Bigpharma Pharmaceutical
Compound name:	LY2605541
Exclusivity:	Exclusive
Asset type:	Compound
Therapy areas:	Genitourinary » Chronic kidney disease (CKD) Metabolic » Diabetes
Technology types:	Antibodies » Monoclonal antibodies Biological compounds Drug delivery
Deal components:	Co-development Co-market Co-promotion Development Licensing Option
Stages of development:	Phase II Phase III

Financials

Deal value, US$m:	2381.4 : sum of upfront and milestone payments
Upfront, US$m:	391.2 : upfront payment
Milestones, US$m:	815.2 : Boehringer to receive success based regulatory milestone payments for linagliptin and BI10773 650.0 : Lilly to receive success based regulatory milestone payments on its two basal analogue insulins 525.0 : Lilly to receive in opt-in and success-based regulatory milestone payments n/d : Boehringer and Lilly to receive sales related milestone payments
Royalty rates, %:	50.0 : revenue share
Funding, US$m:	n/d : shared development costs n/d : shared commercialization costs

Termsheet

29 October 2014

In a move that will strengthen their alliance by enhancing efficiencies and enabling greater focus on product launches, Boehringer Ingelheim and Eli Lilly and Company are changing the operational and financial structure of their diabetes alliance in certain countries.

Under the revised agreement, 17 countries representing more than 90 percent of the alliance's anticipated market opportunity will continue their co-promotion work.

In all other countries, the companies will exclusively commercialize the respective molecules they brought to the alliance.

The changes will be implemented starting January 1, 2015.

The scope of the alliance will remain unchanged in the following 17 countries: United States, Germany, Italy, Spain, France, United Kingdom, Republic of Ireland, Portugal, Canada, Japan, China, Australia, New Zealand, South Korea, Taiwan, Brazil, and Mexico.

Boehringer Ingelheim and Lilly will exclusively commercialize the respective molecules they brought to the alliance in all other countries under revised financial terms that will include an upfront payment and ongoing payments paid to Lilly in lieu of commission payments in those markets.

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17 January 2013

Eli Lilly and Company and Boehringer Ingelheim International announced they will adjust the scope of their diabetes alliance with respect to LY2605541, Lilly’s novel basal insulin analog, with Lilly reassuming sole worldwide development and commercialization rights to LY2605541.

Lilly and Boehringer Ingelheim formed their diabetes alliance in January 2011, centering on four pipeline compounds representing several of the largest and most promising product classes.

It is one of the largest alliances among two pharmaceuticals companies ever in a single therapeutic area and aims to provide a broad portfolio of treatment options for patients with diabetes and their healthcare professionals.

While Lilly and Boehringer Ingelheim will continue to jointly develop and commercialize the other assets in the alliance, Boehringer Ingelheim elected to terminate the collaboration with Lilly with respect to LY2605541 given independent strategic portfolio considerations.

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11 January 2011

Eli Lilly and Boehringer Ingelheim have a global agreement to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development.

Included are Boehringer Ingelheim's two oral diabetes agents-linagliptin and BI10773-as well as Lilly's two basal insulin analogues-LY2605541 and LY2963016-as well as the option to co-develop and co-commercialize Lilly's anti-TGF-beta monoclonal antibody.

The agreement also includes an option for Boehringer Ingelheim to co-develop and co-commercialize another Lilly diabetes molecule, an anti-TGF-beta monoclonal antibody, which is currently in Phase II of clinical testing in patients with diabetes with chronic kidney disease.

Lilly will make an initial one-time payment to Boehringer Ingelheim of euro 300 million.

Boehringer Ingelheim will be eligible to receive up to a total of euro 625 million in success-based regulatory milestones for linagliptin and BI10773.

Lilly will be eligible to receive up to a total of $650 million in success-based regulatory milestones on its two basal analogue insulins.

Should Boehringer Ingelheim elect to opt-in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, Lilly would be eligible for up to $525 million in opt-in and success-based regulatory milestone payments.

The companies will share ongoing development costs equally.

Upon successful regulatory approval of any product resulting from the alliance, the companies will equally share in the product's commercialization costs and gross margin.

Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration.

Press Release

29 October 2014

Eli Lilly (LLY), Boehringer Ingelheim Corporation Revise Terms Of Diabetes Drugs Alliance

10/29/2014 7:03:40 AM

Boehringer Ingelheim and Lilly Revising Operational Structure of Diabetes Alliance in Certain Countries

Significant portion of alliance opportunity will remain unchanged; some countries will transition to exclusive promotion in 2015

INDIANAPOLIS and INGELHEIM, Germany, Oct. 29, 2014 /PRNewswire/ -- In a move that will strengthen their alliance by enhancing efficiencies and enabling greater focus on product launches, Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) are changing the operational and financial structure of their diabetes alliance in certain countries. Under the revised agreement, 17 countries representing more than 90 percent of the alliance's anticipated market opportunity will continue their co-promotion work. In all other countries, the companies will exclusively commercialize the respective molecules they brought to the alliance.

The changes will be implemented starting January 1, 2015.

The scope of the alliance will remain unchanged in the following 17 countries: United States, Germany, Italy, Spain, France, United Kingdom, Republic of Ireland, Portugal, Canada, Japan, China, Australia, New Zealand, South Korea, Taiwan, Brazil, and Mexico.

Under a revised agreement, Boehringer Ingelheim and Lilly will exclusively commercialize the respective molecules they brought to the alliance in all other countries under revised financial terms that will include an upfront payment and ongoing payments paid to Lilly in lieu of commission payments in those markets. Lilly plans to communicate the impact to its 2014 financial guidance in its third quarter Form 10-Q report to the U.S. Securities and Exchange Commission.

"Lilly and Boehringer Ingelheim have a highly successful alliance," said Enrique Conterno, president, Lilly Diabetes. "In less than four years, our companies have worked to develop and introduce several new important treatments for diabetes. The revised agreement will bring greater focus and clarity to our alliance and will benefit health care professionals, patients, and our companies. We look forward to continuing our important work together that makes life better for people with diabetes."

To date, three new treatments for diabetes have been launched by the alliance: Trajenta® (linagliptin), Jardiance® (empagliflozin), and Jentadueto® (linagliptin/metformin HCI). Additionally, the alliance's new insulin glargine product has been tentatively approved in the U.S. and approved in Europe. Other potential treatments, including fixed-dose combinations, continue being developed by the alliance.

"As our alliance continues to evolve, and with more medicines receiving approval by regulators, we have determined that enhancements are needed to reduce operational complexities in certain countries around the world," said Dr Ulrich Drees, corporate senior vice president, International Project Management, Boehringer Ingelheim. "By continuing our work under this revised model, our companies can better focus on the important task of delivering innovative solutions to patients."

Boehringer Ingelheim and Eli Lilly and Company

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in diabetes that centers on compounds representing several of the largest diabetes treatment classes. The alliance leverages the strengths of two of the world's leading pharmaceutical companies. By joining forces, the companies demonstrate commitment in the care of patients with diabetes and stand together to focus on patient needs. Find out more about the alliance at www.boehringer-ingelheim.com or www.lilly.com.

About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, Boehringer Ingelheim operates globally with 142 affiliates and a total of more than 47,400 employees. The focus of the family-owned company, founded in 1885, is researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine.

Taking social responsibility is an important element of the corporate culture at Boehringer Ingelheim. This includes worldwide involvement in social projects, such as the initiative "Making More Health" and caring for the employees. Respect, equal opportunities and reconciling career and family form the foundation of the mutual cooperation. In everything it does, the company focuses on environmental protection and sustainability.

In 2013, Boehringer Ingelheim achieved net sales of about 14.1 billion euros. R&D expenditure corresponds to 19.5% of its net sales.

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17 January 2013

Lilly reassumes sole worldwide development and commercialization rights for novel basal insulin analog

Announces it will begin remainder of pre-planned clinical trials for LY2605541

INDIANAPOLIS, IN, USA, and INGELHEIM, GERMANY– January 7, 2013 – Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim International GmbH announced today they will adjust the scope of their diabetes alliance with respect to LY2605541*, Lilly's novel basal insulin analog, with Lilly reassuming sole worldwide development and commercialization rights to LY2605541.

Lilly and Boehringer Ingelheim formed their diabetes alliance in January 2011, centering on four pipeline compounds representing several of the largest and most promising product classes. It is one of the largest alliances among two pharmaceuticals companies ever in a single therapeutic area and aims to provide a broad portfolio of treatment options for patients with diabetes and their healthcare professionals.

While Lilly and Boehringer Ingelheim will continue to jointly develop and commercialize the other assets in the alliance, Boehringer Ingelheim elected to terminate the collaboration with Lilly with respect to LY2605541 given independent strategic portfolio considerations.

"There is an excellent spirit of collaboration in our alliance with Lilly, and we are committed to the continued success in our partnership to develop and commercialize the other molecules within the alliance, including Trajenta® (linagliptin), empagliflozin and LY2963016, new insulin glargine product," said Dr. Ulrich Drees, Corporate Senior Vice President, International Project Management at Boehringer Ingelheim.

Lilly also announced plans for the 2013 and 2014 initiation of the remainder of the pre-planned clinical trials for LY2605541. In addition to supporting regulatory submissions, these studies will be conducted to evaluate safety, efficacy and differentiation of this novel basal insulin analog. These studies are in addition to the five ongoing IMAGINE clinical trials.

"We're encouraged by the pre-clinical, Phase I and II data we've seen for our novel basal insulin," said Gwen Krivi, Ph.D, vice president, Diabetes Product Development, Lilly Diabetes. "We look forward to sharing the Phase III data results of our novel basal insulin therapy with the medical community as early as 2014."

"Boehringer Ingelheim is an important partner in our strategy to provide a broad portfolio of diabetes medicines, and our diabetes alliance remains strong,"said Enrique Conterno, president of Lilly Diabetes. "There is no group of patients with whom Lilly has a deeper history than those impacted by diabetes. If approved, this basal insulin analog will be an important addition to the Lilly portfolio as we work to provide a broad portfolio of diabetes medicines to our customers."

If the Phase III trials for LY2605541 are successful, Lilly could submit its novel basal insulin analog to regulatory authorities as early as 2014, as previously communicated. About Diabetes An estimated 371 million people1 worldwide have type 1 and type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases. Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.2

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11 January 2011

Lilly and Boehringer Ingelheim Announce Strategic Alliance to Bring New Diabetes Treatments to Patients Worldwide

Major diabetes care agreement centers on four pipeline compounds representing several of the largest and most promising product classes.

Companies will jointly develop and commercialize a pipeline of oral diabetes agents and basal insulin analogues. The alliance also includes the option to co-develop and co-commercialize an anti-TGF-beta monoclonal antibody.

Boehringer Ingelheim's innovative late-stage diabetes pipeline drives its expansion into new therapeutic area, supplemented by two basal insulin analogues, currently under development from Lilly.

Agreement furthers Lilly's commitment to offer one of the broadest portfolios in diabetes care and provide together with Boehringer more options for people with diabetes, their health care providers and payers.

Boehringer Ingelheim will host a media event; Lilly will host an investor conference call today to discuss the content and benefits of the alliance.

11 January 2011

Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim today announced a global agreement to jointly develop and commercialize a portfolio of diabetes compounds currently in mid- and late-stage development. Included are Boehringer Ingelheim's two oral diabetes agents-linagliptin and BI10773-as well as Lilly's two basal insulin analogues-LY2605541 and LY2963016-as well as the option to co-develop and co-commercialize Lilly's anti-TGF-beta monoclonal antibody.

Linagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor discovered by Boehringer Ingelheim and being developed as an oral once-daily tablet for the treatment of Type 2 diabetes. It is currently under regulatory review in the U.S., Europe and Japan. Boehringer Ingelheim's BI10773, a sodium-dependent glucose co-transporter-2 (SGLT-2) inhibitor, began enrollment in Phase III clinical trials last year. It belongs to a new, emerging class of diabetes compounds that block tubular reabsorption of glucose in the kidney. Currently there are no SGLT-2 inhibitors approved for use.

Lilly's two basal insulin analogue candidates are expected to enter Phase III clinical testing in 2011. Lilly's two basal insulin analogue candidates are LY2605541, a structurally novel basal insulin analogue, and LY2963016, a new insulin glargine product. The agreement also includes an

option for Boehringer Ingelheim to co-develop and co-commercialize another Lilly diabetes molecule, an anti-TGF-beta monoclonal antibody, which is currently in Phase II of clinical testing in patients with diabetes with chronic kidney disease.

The alliance will leverage the collective scientific expertise and business capabilities of two leading research-driven pharmaceutical companies to address patient needs arising from the growing global diabetes epidemic.

"We are very excited about this new and extensive alliance with Boehringer Ingelheim, with whom we have partnered successfully in the past," said John C. Lechleiter, Ph.D., Lilly chairman and chief executive officer. "Working together, we will comprise one of the most robust diabetes pipelines in the pharmaceutical industry. For Lilly, this alliance expands our range of offerings for people with diabetes, strengthens our diabetes care capabilities and offers the prospect of near-term revenue opportunities as we address the upcoming loss of patent exclusivity for several of our products."

"Boehringer Ingelheim and Lilly have agreed to form a strategic alliance in diabetes at a time point when we at Boehringer Ingelheim are entering another new therapeutic area with innovative compounds out of our own research and development operations. This cooperation will give Boehringer Ingelheim and Lilly the combined benefits of Lilly's expertise in the diabetes market and two basal insulin analogues as well as Boehringer Ingelheim's rich and innovative late-stage pipeline." said Prof. Andreas Barner, Chairman of the Board of Managing Directors of Boehringer Ingelheim.

Under the terms of the agreement, Lilly will make an initial one-time payment to Boehringer Ingelheim of euro 300 million. Boehringer Ingelheim will be eligible to receive up to a total of euro 625 million in success-based regulatory milestones for linagliptin and BI10773. Lilly will be eligible to receive up to a total of $650 million in success-based regulatory milestones on its two basal analogue insulins. Should Boehringer Ingelheim elect to opt-in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, Lilly would be eligible for up to $525 million in opt-in and success-based regulatory milestone payments. The companies will share ongoing development costs equally. Upon successful regulatory approval of any product resulting from the alliance, the companies will equally share in the product's commercialization costs and gross margin. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration.

As a result of this transaction, Lilly expects 2011 earnings per share dilution in the range of $0.45-$0.50, including a charge of approximately $0.27 per share related to the one-time payment. Assuming a successful launch of linagliptin, Lilly anticipates progressively and significantly less dilution in 2012 and 2013, no dilution to slight accretion in 2014, and more significant accretion in 2015 and beyond. The 2011 financial impact of this transaction will be reflected in Lilly's 2011 financial guidance, which will be provided as part of the fourth quarter and full-year 2010 financial results announcement on January 27, 2011.

Lilly Conference Call and Webcast

Lilly will conduct a conference call with the investment community and media today at 10:00 a.m. EST to discuss today's announcement. Investors, media and the general public can access a live webcast of the conference call through the Webcasts & Presentations link that will be posted on Lilly's website at www.lilly.com. The webcast of the conference call will be available for replay through February 11, 2011.

Boehringer Ingelheim Press Conference and Webcast

Boehringer Ingelheim will host a web-enabled press conference in Frankfurt, Steigenberger Airport Hotel with the media today at 13:30 h CET to discuss today's announcement. Media not in attendance can access a live webcast of the press conference through this link: http://bit.ly/av-events. The webcast of the press conference will be available for replay through January 18, 2011.

About Diabetes

Diabetes affects an estimated 285 million adults worldwide and more than 24 million people in the U.S.(1,2) Approximately 90-95 percent of those affected have type 2 diabetes. Diabetes costs approximately $174 billion per year in direct and indirect medical expenses in the U.S.(3)

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen.(4)

About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally, with 142 affiliates in 50 countries and more than 41,500 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine. For more information on Boehringer Ingelheim, please see www.boehringer-ingelheim.com.

About Lilly Diabetes

For more than 85 years, Lilly has been a worldwide leader in pioneering industry-leading solutions to support people living with and treating diabetes. Lilly introduced the world's first commercial insulin in 1923, and remains at the forefront of medical and delivery device innovation to manage diabetes. Lilly is also committed to providing solutions beyond therapy - practical tools, education, and support programs to help

overcome barriers to success along the diabetes journey. At Lilly, the journeys of each person living with or treating diabetes inspire ours. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com. C-LLY

Filing Data

10K abstract - 2013

In January 2011, we and Boehringer Ingelheim entered into a global agreement to jointly develop and commercialize a portfolio of diabetes compounds. Included are Boehringer Ingelheim's two oral diabetes agents, linagliptin and empagliflozin. Subsequently in 2011, linagliptin was approved and launched in the U.S. (trade name Tradjenta), Japan (trade name TrazentaTM), Europe (trade name Trajenta®), and other countries. Empagliflozin is currently in Phase III clinical testing. Also included in the agreement were our new insulin glargine product and our novel basal insulin analog, both of which began Phase III clinical testing in the second half of 2011; and an option granted to Boehringer Ingelheim to co-develop and co-commercialize our anti-TGF-beta monoclonal antibody, which is currently in Phase II clinical testing. Subsequently in 2013, Boehringer Ingelheim elected to terminate our collaboration with respect to the novel basal insulin analog. Under the terms of the global agreement, we made an initial one-time payment to Boehringer Ingelheim of $388.0 million and recorded an acquired IPR&D charge, which was included as expense in the first quarter of 2011 and is deductible for tax purposes. In connection with the approval of linagliptin in the U.S., Japan, and Europe, in 2011 we paid $478.7 million in success-based regulatory milestones, all of which were capitalized as intangible assets and are being amortized to cost of sales. We may pay up to 300.0 million euro in additional success-based regulatory milestones for empagliflozin. We will be eligible to receive up to a total of $300.0 million in success-based regulatory milestones on our new insulin glargine product. Should Boehringer Ingelheim elect to opt in to the Phase III development and potential commercialization of the anti-TGF-beta monoclonal antibody, we would be eligible for up to $525.0 million in opt-in and success-based regulatory milestone payments. The companies share ongoing development costs equally. The companies also share in the commercialization costs and gross margin for any product resulting from the collaboration that receives regulatory approval. We record our portion of the gross margin as collaboration and other revenue, and we record our portion of the commercialization costs as marketing, selling, and administrative expense. Each company will also be entitled to potential performance payments on sales of the molecules they contribute to the collaboration. Revenue related to this collaboration was not material during the years ended December 31, 2012 and 2011.

Contract

Not available.