

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

INDIANAPOLIS and INGELHEIM, Germany, Jan. 11, 2011 /PRNewswire/ --

- 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.

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

This press release contains forward-looking statements that are based on Lilly's and Boehringer Ingelheim's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products (including all of the compounds discussed in this press release) that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. In addition, there can be no guarantee that the companies will realize the financial and commercial results anticipated from this collaboration. Other risk factors that may affect Lilly's results can be found in the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. The companies undertake no duty to update forward-looking statements.

(Logo: http://photos.prnewswire.com/prnh/20070319/NYM004LOGO)

References:

- (1) The International Diabetes Federation Diabetes Atlas. Available at: http://www.diabetesatlas.org/content/some-285-million-people-worldwide-will-live-diabetes-2010. Accessed September 10, 2010.
- (2) Diabetes Statistics. American Diabetes Association. Available at: http://www.diabetes.org/diabetes-basics/diabetes-statistics/. Accessed September 10, 2010.
- (3) Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: http://www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html. Accessed September 10, 2010.
- (4) Saydah SH, Fradkin J and Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291:335-42.

SOURCE Eli Lilly and Company

News Provided by Acquire Media