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## **Boehringer Ingelheim and Eli Lilly and Company submit new drug application to FDA for empagliflozin, an investigational type 2 diabetes treatment**

### **Marketing application for the sodium glucose co-transporter-2 inhibitor follows completion of Phase III registration trials**

RIDGEFIELD, Conn. and INDIANAPOLIS, March 25, 2013 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) today announced that a New Drug Application (NDA) for the investigational sodium glucose co-transporter-2 (SGLT2) inhibitor empagliflozin\* was recently submitted to the Food and Drug Administration (FDA) in the United States for the treatment of type 2 diabetes mellitus (T2D) in adults.

Empagliflozin is a member of the SGLT2 inhibitor class of drugs being investigated for the reduction of blood glucose levels in adults with T2D. The emerging SGLT2 inhibitor class removes excess glucose through the urine by blocking glucose re-absorption in the kidney.

"We are excited to have submitted an application for a potential new treatment option that may help patients better manage their type 2 diabetes mellitus," said Christophe Arbet-Engels, MD, PhD, MBA, vice president, metabolic-clinical development and medical affairs, Boehringer Ingelheim. "Type 2 diabetes mellitus is a critical health issue facing the world today, and through the Boehringer Ingelheim and Lilly Diabetes Alliance, we are committed to developing new treatments to address patients with this disease."

Empagliflozin is being investigated in adults with T2D in a Phase III clinical trial program that plans to enroll more than 14,500 patients.[1] In total, this program comprises 12 multinational clinical trials, including a large cardiovascular outcome trial. Boehringer Ingelheim and Lilly plan to present detailed data disclosures for many of these studies at scientific medical meetings and in publications in 2013 and 2014.

#### **About Diabetes**

Approximately 25.8 million Americans[2] and an estimated 371 million people worldwide[3] have type 1 or type 2 diabetes. T2D is the most common type, accounting for an estimated 90 percent of all diabetes cases.[2] Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.[4] Diabetes was estimated to cost the U.S. \$245 billion in direct medical costs and reduced productivity in 2012.[5]

#### **Boehringer Ingelheim and Eli Lilly and Company**

In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance in the field of diabetes that centers on three pipeline compounds representing several of the largest treatment classes. This alliance leverages the companies' strengths as two of the world's leading pharmaceutical companies, combining Boehringer Ingelheim's solid track record of research-driven innovation and Lilly's innovative research, experience, and pioneering history in diabetes. 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](http://www.boehringer-ingelheim.com) or [www.lilly.com](http://www.lilly.com).

#### **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 145 affiliates and more than 44,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel medications of high therapeutic value for human and veterinary medicine.

As a central element of its culture, Boehringer Ingelheim pledges to act socially responsibly. Involvement in social projects, caring for employees and their families, and providing equal opportunities for all employees form the foundation of the global operations. Mutual cooperation and respect, as well as environmental protection and sustainability are intrinsic factors in all of Boehringer Ingelheim's endeavors.

In 2011, Boehringer Ingelheim achieved net sales of about \$17.1 billion (13.2 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 23.5% of its net sales.

For more information, please visit <http://us.boehringer-ingelheim.com> and follow us on Twitter at <http://twitter.com/boehringerus>.

## 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, IN, 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](http://www.lilly.com).

## About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we work to meet the diverse needs of people with diabetes through research and collaboration, a broad and growing product portfolio and our continued commitment to providing real solutions — from medicines to support programs and more — to make lives better.

For more information, visit [www.lillydiabetes.com](http://www.lillydiabetes.com).

*This press release contains forward-looking statements about empagliflozin\* for the treatment of type 2 diabetes. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that empagliflozin\* will prove to be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.*

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[1] Data on file, Boehringer Ingelheim Pharma GmbH & Co KG.

[2] Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.

[3] International Diabetes Federation. IDF Diabetes Atlas Poster. 2012 Update. 2012 (5th Edition).

[4] International Diabetes Federation. IDF Diabetes Atlas, 5th Edition: What is Diabetes?  
<http://www.idf.org/diabetesatlas/5e/what-is-diabetes>. Accessed on: March 22, 2012.

[5] American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. Diabetes Care. 2013. Mar 6. [Epub ahead of print]

\*Empagliflozin is an investigational compound. Its safety and efficacy have not yet been fully established.

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