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## **Eli Lilly and Company and Boehringer Ingelheim announce new drug application filing in the U.S. for new insulin glargine product**

### **New Drug Application follows submission of Marketing Authorisation Application to the European Medicines Agency**

INDIANAPOLIS and RIDGEFIELD, Conn., Dec. 20, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim today announced that the U.S. Food and Drug Administration (FDA) has accepted the filing of the New Drug Application (NDA) for LY2963016, an investigational basal (long-acting) insulin.

LY2963016 is a new insulin glargine product developed for the treatment of patients with type 1 and type 2 diabetes. The NDA was filed through the 505(b)(2) regulatory pathway, which allows the FDA to reference their previous findings of safety and efficacy data for an already-approved insulin glargine product, in addition to the studies of LY2963016.

Lilly and Boehringer Ingelheim designed the comprehensive development program for LY2963016 in order to meet the regulatory standards of clinical and nonclinical safety, efficacy and quality. In addition to comparative pharmacokinetic and pharmacodynamic studies, the NDA submission includes results from Phase III studies that were conducted in patients with type 1 and type 2 diabetes, using a currently marketed insulin glargine product as the active comparator.

"The U.S. regulatory submission for our new insulin glargine product demonstrates our progress in bringing another option to the millions of Americans with diabetes who require long-acting insulin as an integral part of their treatment plan," said Gwen Krivi, Ph.D., vice president, Lilly Diabetes product development. "This submission of the NDA for this product helps us realize the goal of the Lilly-Boehringer Ingelheim Diabetes alliance, which is to leverage our combined expertise to develop important treatments for people with diabetes."

In July 2013, the companies announced the marketing authorisation application (MAA) for LY2963016 was accepted for review by the European Medicines Agency (EMA).

#### **About Diabetes**

Approximately 24.4 million Americans and an estimated 382 million people worldwide have type 1 or type 2 diabetes. Type 2 diabetes is the most common type, accounting for an estimated 85 to 95 percent of all diabetes cases. Diabetes is a chronic condition that occurs when the body either does not properly produce, or use, the hormone insulin.<sup>1</sup>

#### **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 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**

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation (Ridgefield, CT) and a member of the Boehringer Ingelheim group of companies.

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 140 affiliates and more than 46,000 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 has a demonstrated commitment to corporate social responsibility. 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 2012, Boehringer Ingelheim achieved net sales of about \$19.1 billion (14.7 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 22.5 percent of its net sales.

For more information please visit [www.us.boehringer-ingelheim.com](http://www.us.boehringer-ingelheim.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 organisations. 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 a 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).

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*This press release contains forward-looking statements about LY2963016 for the treatment of 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 commercialisation. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that LY2963016 will receive regulatory approval or 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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### **REFERENCES**

1. International Diabetes Federation. IDF Diabetes Atlas, 6th edn. Brussels, Belgium: International Diabetes Federation, 2013. <http://www.idf.org/diabetesatlas>. Accessed on December 18, 2013.

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