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CHMP Recommends Lilly and Boehringer Ingelheim's Investigational New Insulin Glargine Product for Approval in the European Union

First biosimilar insulin to receive CHMP positive opinion in the EU

INDIANAPOLIS and RIDGEFIELD, Conn., June 27, 2014 /PRNewswire/ -- The Committee for Medicinal Products for Human Use (CHMP) today issued a positive opinion recommending approval for the investigational compound LY2963016, a new insulin glargine product, for the treatment of type 1 and type 2 diabetes. The new insulin glargine product from Eli Lilly and Company (NYSE: LLY) and Boehringer Ingelheim is the first biosimilar insulin recommended for approval in the European Union (EU).

Lilly/BI's insulin glargine is a basal insulin, which is intended to provide long-lasting blood sugar control between meals and at night, an integral part of glycemic control.¹ It has the same amino acid sequence as Lantus[®] (insulin glargine) and was filed through the European Medicines Agency's (EMA) biosimilar pathway.

As the term is a regulatory designation, Lilly/BI's insulin glargine is considered a biosimilar in some regions, including Europe, but not in others, including the United States.

"The CHMP's recommendation brings us a step closer to providing an important new option for the millions of patients in the EU who need basal insulin to help manage their diabetes," said Enrique Conterno, president, Lilly Diabetes. "This first-ever biosimilar insulin to receive a positive CHMP recommendation underscores Lilly and Boehringer Ingelheim's commitment to providing physicians and patients high-quality diabetes medicines, along with expertise and support tools they need to help manage the disease."

The CHMP's recommendation is based on the companies' non-clinical and clinical development program, which included pharmacokinetic and pharmacodynamic studies, as well as Phase III studies in patients with type 1 and type 2 diabetes. The European Commission's final decision is expected in approximately two months. If approved for marketing authorisation, Lilly/BI's insulin glargine would be the fourth diabetes product in the Lilly-Boehringer Ingelheim Diabetes Alliance to receive regulatory approval in the EU.

Lilly has been manufacturing insulin since 1923, and remains committed to innovation in insulin therapy, introducing many insulin products and delivery devices in the last nine decades. This history gives Lilly extensive expertise, insights and knowledge in the insulin space, enabling it to provide high quality medicine to diabetes patients worldwide.

About Diabetes

Approximately 29 million Americans² and an estimated 382 million people worldwide have type 1 or type 2 diabetes.³ 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.³

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 Pharmaceuticals Inc.

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 142 affiliates and more than 47,400 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.

Social responsibility is a central element of Boehringer Ingelheim's culture. 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 2013, Boehringer Ingelheim achieved net sales of about \$18.7 billion (14.1 billion euro). R&D expenditure in the Prescription Medicines business corresponds to 19.5% of its net sales.

For more information please visit <http://www.us.boehringer-ingelheim.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 are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research and collaboration, a broad and growing product portfolio and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and <http://newsroom.lilly.com/social-channels>.

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This press release contains forward-looking statements about LY2963016, an investigational compound that is being studied for type 1 and 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 LY2963016 will receive regulatory approvals 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.

Lantus® is a registered trademark of Sanofi.

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REFERENCES

1. Inzucchi SE, Bergenstal RM, et al. Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach. *Diabetes Care* June 2012 vol. 35 no. 6 1364-1379.
2. Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services; 2014.
3. International Diabetes Federation. *IDF Diabetes Atlas, 6th edn*. Brussels, Belgium: International Diabetes Federation, 2013. <http://www.idf.org/diabetesatlas>. Accessed on December 18, 2013.

Lilly



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