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# U.S. Food and Drug Administration Issues Complete Response Letter for Empagliflozin

## Boehringer Ingelheim and Lilly are committed to working with the FDA

RIDGEFIELD, Conn. and INDIANAPOLIS, March 5, 2014 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (Lilly; NYSE: LLY) today announced the U.S. Food and Drug Administration (FDA) has issued a complete response letter for the New Drug Application (NDA) of the investigational sodium glucose co-transporter-2 (SGLT2) inhibitor empagliflozin.

The complete response letter referenced previously observed deficiencies at a Boehringer Ingelheim facility where empagliflozin will be manufactured. The FDA stated these deficiencies need to be resolved before the approval of the application. The FDA has not asked Boehringer Ingelheim to complete any new clinical trials to support the approval of the application.

Boehringer Ingelheim and Lilly are committed to working with the FDA to make empagliflozin available to adults with type 2 diabetes and submitting a response to the complete response letter as soon as possible.

Empagliflozin is a member of the sodium glucose co-transporter-2 (SGLT2) inhibitor class of compounds, and is 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 by the kidney.

The U.S. NDA was based on results from one of the largest clinical registration programs in its class, comprised of more than 10 multinational clinical trials and more than 13,000 people with type 2 diabetes (T2D).

**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.[1]

**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 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 or 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.

**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.

**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.

*This press release contains forward-looking statements about empagliflozin, an investigational compound that is being studied for 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 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.*

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**References**

1. International Diabetes Federation. Diabetes Atlas, 6th Edition. 2013.

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