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Type 2 diabetes: Boehringer Ingelheim and Eli Lilly and Company announce resubmission of New Drug Application for empagliflozin to FDA

-- No additional clinical trials requested by the FDA

RIDGEFIELD, Conn. and INDIANAPOLIS, June 17, 2014 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) and Eli Lilly and Company (NYSE: LLY) today announced the resubmission of a New Drug Application (NDA) for the investigational sodium glucose co-transporter-2 (SGLT2) inhibitor empagliflozin for the treatment of adults with type 2 diabetes (T2D) to the U.S. Food and Drug Administration (FDA). The Class 1 resubmission follows a complete response letter issued by the FDA that referenced previously observed deficiencies at a Boehringer Ingelheim facility where empagliflozin will be manufactured. The FDA did not ask Boehringer Ingelheim to complete any new clinical trials to support the approval of the application.

"We are very pleased to move forward with resubmission of the empagliflozin NDA following a FDA inspection of the Boehringer Ingelheim facility referenced in the complete response letter," said Paul Fonteyne, president and chief executive officer, Boehringer Ingelheim Pharmaceuticals, Inc. "We believe in the potential of empagliflozin and hope to provide another treatment option in the near future to adults with type 2 diabetes."

Empagliflozin is an investigational SGLT2 inhibitor being studied for the reduction of blood glucose levels in adults with diabetes. The SGLT2 inhibitor class removes excess glucose through the urine by blocking glucose re-absorption in the kidney. Empagliflozin was studied in one of the largest clinical trial programs in its class, comprised of more than 10 multinational clinical trials and more than 13,000 adults with type 2 diabetes.

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.

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.

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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