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CHMP Recommends Empagliflozin for Approval to Reduce Blood Sugar Levels in Adults with Type 2 Diabetes in Europe

Positive opinion is based on data from one of the largest clinical registration programs in its class, involving more than 13,000 adults with type 2 diabetes

RIDGEFIELD, Conn. and INDIANAPOLIS, March 21, 2014 /PRNewswire/ -- Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company (NYSE: LLY) today announced a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency, recommending approval of empagliflozin, an investigational sodium glucose co-transporter 2 (SGLT2) inhibitor, as an adjunct to diet and exercise to improve glycemic control, or blood glucose levels, in adults with type 2 diabetes (T2D).

The positive opinion is 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 adults with T2D. Following a CHMP positive opinion, the European Commission generally follows the recommendation and usually issues its final decision on marketing authorization within two months.¹

"The CHMP positive opinion brings us a step closer to having a potential new treatment option for adults in Europe with type 2 diabetes," said Prof. Klaus Dugi, corporate senior vice president medicine, Boehringer Ingelheim. "If approved, empagliflozin would be the third product approved in Europe as part of the Boehringer Ingelheim and Eli Lilly and Company Diabetes alliance."

Empagliflozin is a member of the 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.

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.²

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

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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¹ European Medicines Agency. Frequently Asked Questions. (http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/q_and_a/q_and_a_detail_000114.jsp). Accessed March 18, 2014.

² International Diabetes Federation. Diabetes Atlas, 6th Edition. 2013. (<http://www.idf.org/diabetesatlas>). Accessed March 18, 2014.

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