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Boehringer Ingelheim and Eli Lilly and Company announce positive top-line pivotal Phase III data results for empagliflozin

INGELHEIM, Germany, Jan. 7, 2013 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) today announced top-line results for four completed Phase III clinical trials for empagliflozin, an investigational sodium glucose co-transporter-2 (SGLT-2) inhibitor being studied for treatment of patients with type 2 diabetes (T2D). In all four studies, the primary efficacy endpoint, defined as significant change in HbA1c from baseline compared to placebo, was met with empagliflozin (10 and 25 mg) taken once daily.

These four pivotal studies from the empagliflozin trial program are:

- **Study 1245.20** (n=986) evaluated 10 mg and 25 mg doses of empagliflozin as monotherapy versus placebo for 24 weeks.[1]
- **Study 1245.23** (n=1,504) compared 10 mg and 25 mg doses of empagliflozin as an add-on to metformin and metformin plus sulfonylurea versus placebo for 24 weeks.[1]
- **Study 1245.19** (n=499) assessed 10 mg and 25 mg doses of empagliflozin as an add-on to pioglitazone and pioglitazone plus metformin versus placebo for 24 weeks.[1]
- **Study 1245.36** (n=741) evaluated 25 mg dose of empagliflozin in patients with type 2 diabetes with mild, moderate or severe renal impairment, and 10 mg dose in those with mild renal impairment versus placebo for 52 weeks.[1]

Incidence of adverse events was similar for placebo, empagliflozin 10mg and 25mg. Genital infections occurred more often with empagliflozin (both dosages) compared with placebo. This safety information is consistent with findings reported in the Phase II study results for empagliflozin.[2]

Empagliflozin is part of a class of drugs being investigated for the reduction of blood glucose levels in adults with T2D. In clinical trials to date, SGLT-2 inhibitors have been shown to reduce blood glucose.

"Boehringer Ingelheim and Lilly are encouraged by the efficacy and safety results for empagliflozin," said Prof. Klaus Dugi, Corporate Senior Vice President Medicine, Boehringer Ingelheim. "Many patients with type 2 diabetes are not meeting their blood sugar level goals, and alternative treatment options are needed for them. We believe we are now one step closer to bringing a new treatment option to these patients."

"We are pleased with the results for these Phase III clinical trials for empagliflozin," said Enrique Conterno, President, Lilly Diabetes. "Diabetes is growing at a tremendous rate across the world. Patients and their physicians need more treatment options in order to help improve their blood sugar levels and reach their treatment goals."

Empagliflozin is being investigated in adults with T2D in a Phase III clinical trial program that will enroll over 14,500 patients.[1] In total, this program comprises eight multinational clinical trials, including a large cardiovascular outcome trial.

The pivotal studies for empagliflozin completed in 2012, and Boehringer Ingelheim and Lilly anticipate filing for regulatory review in the U.S., Europe and Japan in 2013. Boehringer Ingelheim and Lilly plan to present detailed data disclosures for many of these studies at scientific medical meetings and publications in 2013 and 2014.

About Diabetes

Approximately 25.8 million Americans[3] and an estimated 371 million people worldwide[4] have type diabetes. T2D is the most common type, accounting for an estimated 90 percent of all diabetes cases.[3] Diabetes is a chronic disease that occurs when the body either does not properly produce, or use, the hormone insulin.[5]

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 four 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
The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 145 affiliates and more than 44,000 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 pledges to act socially responsible. 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 2011, Boehringer Ingelheim achieved net sales of about $17.1 billion (13.2 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 23.5% of its net sales.

For more information, please visit http://us.boehringer-ingelheim.com and follow us on Twitter at http://twitter.com/boehringerus.

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 organizations. 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.

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.

This press release contains forward-looking statements about empagliflozin, a compound under investigation. 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 will 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. Data on file, Boehringer Ingelheim Pharma GmbH &Co KG.
2. Woerle HJ, Ferrannini E, Berk A, et al. Safety and Efficacy of Empagliflozin as Monotherapy or Add-On to Metformin in a 78-Week Open-Label Extension Study in Patients with Type 2 Diabetes. Abstract #49-LB. Presented at the American Diabetes Association's (ADA's) 72nd Scientific Sessions®. June 8-12, Philadelphia, PA.
3. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for

Disease Control and Prevention, 2011.
4. International Diabetes Federation. IDF Diabetes Atlas Poster. 2012 Update. 2012 (5th Edition).
5. International Diabetes Federation. IDF Diabetes Atlas, 5th Edition: What is Diabetes? http://www.idf.org/diabetesatlas/5e/what-is-diabetes. Accessed on: December 18, 2012.

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