Boehringer Ingelheim and Lilly announce positive top-line Phase III data results for empagliflozin as adjunct to insulin in type 1 diabetes

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RIDGEFIELD, Conn. and INDIANAPOLIS, June 25, 2018 /PRNewswire/ -- Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY) today announced that both randomized controlled trials in the EASE Phase III program, investigating the use of empagliflozin in combination with insulin therapy in adults with type 1 diabetes, met their primary endpoint. The primary efficacy endpoint, defined in both trials as placebo-corrected change from baseline in A1C after 26 weeks of treatment, was met for all investigated doses of empagliflozin (2.5, 10 and 25 mg).

Type 1 diabetes currently affects 1.3 million adults in the U.S. and approximately 30 million adults worldwide. It is an autoimmune disease in which the body does not produce sufficient amounts of insulin, and therefore requires life-long daily insulin administration to regulate blood sugar. For some people with type 1 diabetes, it may be challenging to manage blood sugar levels with insulin alone. People with type 1 diabetes also face risks of complications such as sight loss, heart disease, kidney disease and amputations.

"Despite recent advances in insulin therapy and patient care, less than one third of adults with type 1 diabetes in the U.S. consistently meet target blood sugar levels," noted Thomas Seck, M.D., vice president of Clinical Development and Medical Affairs – Primary Care, Boehringer Ingelheim Pharmaceuticals, Inc. "The EASE trials are part of our comprehensive clinical development program exploring how empagliflozin may improve patient health outcomes and fill treatment gaps for adults with and without type 2 diabetes, and we look forward to sharing the full results from both trials."

The safety profile in both studies was generally consistent with the previously reported safety profile of empagliflozin. The number of adjudicated diabetic ketoacidosis events was comparable between empagliflozin 2.5 mg and placebo and higher than placebo in adults with type 1 diabetes on empagliflozin 10 mg and 25 mg.

The full results from the EASE Phase III program will be presented at the European Association for the Study of Diabetes Annual Meeting on October 4, 2018, in Berlin, Germany.

Empagliflozin is currently not approved for use in people with type 1 diabetes. Boehringer Ingelheim and Lilly are discussing next steps and exploring regulatory options.

About Diabetes
Approximately 30 million Americans and an estimated 425 million adults worldwide have type 1 and type 2 diabetes. Type 2 diabetes is the most common form, accounting for an estimated 90 to 95 percent of all diagnosed adult diabetes cases in the U.S. Diabetes is a chronic condition that occurs when the body does not properly produce, or use, the hormone insulin.

About the EASE Phase III Program
The EASE Phase III program includes two multinational, double-blinded, placebo-controlled Phase III clinical trials to investigate the efficacy, safety and tolerability of once-daily **E**mpagliflozin as **A**djunctive to in**S**ulin th**E**rapy in adults with type 1 diabetes (EASE), an indication for which empagliflozin is currently not approved.

- **EASE-2** [NCT02414958] evaluated 10 mg and 25 mg doses of empagliflozin as adjunct to insulin versus placebo for 52 weeks.
  Primary endpoint: Change from baseline in A1C after 26 weeks of treatment
  Number of patients: 720
- **EASE-3** [NCT02580591] compared 10 mg and 25 mg doses of empagliflozin as adjunct to insulin versus placebo for 26 weeks. Additionally, a lower dose of empagliflozin (2.5 mg) was investigated in this trial
  Number of patients: 960

About Empagliflozin
Empagliflozin is an SGLT2 inhibitor used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. It is the first and only oral diabetes medicine approved to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. The benefit-risk profile of empagliflozin has been well-established in its approved indications. Empagliflozin is currently not approved for use in people with type 1 diabetes.

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. This 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, Conn., is the largest U.S. subsidiary of Boehringer Ingelheim Corporation.

Boehringer Ingelheim is one of the world's top 20 pharmaceutical companies. Headquartered in Ingelheim, Germany, the company operates globally with approximately 50,000 employees. Since its founding in 1885, the company has remained family-owned and today creates value through innovation for three business areas including human pharmaceuticals, animal health and biopharmaceutical contract manufacturing.

Boehringer Ingelheim is committed to improving lives and providing valuable services and support to patients and their families. Our employees create and engage in programs that strengthen our communities. Please visit www.boehringer-ingelheim.us/csr to learn more about how we make more health through our Corporate Social Responsibility initiatives.

In 2017, Boehringer Ingelheim achieved net sales of about $20.4 billion (18.1 billion euros). R&D expenditure corresponds to approximately $3.4 billion (three billion euros), or 17.0 percent of its net sales.

For more information please visit www.boehringer-ingelheim.us, or follow us on Twitter @BoehringerUS.

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 wide range of therapies 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 newsroom.lilly.com/social-channels.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the expansion of clinical trials to evaluate empagliflozin as a treatment for adults with type 1 diabetes and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that empagliflozin will receive additional regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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SOURCE Eli Lilly and Company