Boehringer Ingelheim and Lilly announce outcome of FDA Advisory Committee meeting for empagliflozin 2.5 mg as adjunct to insulin for adults with type 1 diabetes

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RIDGEFIELD, Conn. and INDIANAPOLIS, Nov. 13, 2019 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) voted 14 to 2 that the benefits of empagliflozin 2.5 mg do not outweigh the risks to support approval as an adjunct to insulin for adults with type 1 diabetes. Empagliflozin 2.5 mg is an SGLT2 inhibitor being developed by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY). A separate brand name has been proposed for empagliflozin 2.5 mg in type 1 diabetes.

"With about 40,000 Americans diagnosed with type 1 diabetes every year, we see today's meeting as an important means of elevating the discussion around the challenges of managing blood sugar levels for those with type 1 diabetes and the need for new treatment options," said Mohamed Eid, M.D., M.P.H., M.H.A., vice president, Clinical Development & Medical Affairs, Cardio-Metabolism & Respiratory Medicine, Boehringer Ingelheim Pharmaceuticals, Inc. "We continue to believe the totality of data from the EASE program indicates a favorable benefit-risk profile for empagliflozin 2.5 mg in adults with type 1 diabetes and look forward to continuing to work with the FDA in this review process."

The supplemental New Drug Application (sNDA) included data from the EASE (Empagliflozin as Adjunctive to inSulin thErapy) phase III program, which found that empagliflozin 2.5 mg in combination with insulin provided a statistically significant reduction in A1C (0.28%) versus insulin given with a matched placebo in adults with type 1 diabetes. Secondary endpoints of the trial demonstrated reductions in weight (1.8 kg) and systolic blood pressure (2.1 mmHg), compared to insulin plus placebo. Adverse events occurred with similar frequency among patients treated with empagliflozin 2.5 mg in combination with insulin, compared to those treated with insulin plus placebo. The number of diabetic ketoacidosis events was comparable between empagliflozin 2.5 mg in combination with insulin and insulin plus placebo.

"The EASE clinical trial data provides important information supporting the potential role of empagliflozin 2.5 mg for adults with type 1 diabetes," said Jeff Emmick, M.D., Ph.D., vice president, Product Development, Lilly. "Today, less than one third of people with type 1 diabetes in the U.S. consistently meet target blood sugar levels with insulin, putting them at increased risk for long-term complications. We are committed to participating in the ongoing dialogue around improving patient health and treatment options for this community."

Advisory committees provide the FDA with independent opinions and recommendations from outside medical experts during the drug review process. The FDA is not obligated to follow their recommendation, but it often does.

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 Empagliflozin as Adjunctive to inSulin thErapy in adults with type 1 diabetes (EASE), an indication for which empagliflozin is currently not approved.

- **EASE-2 [NCT02414958]** evaluated 10 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 2.5, 10 and 25 mg doses of empagliflozin as adjunct to insulin versus placebo for 26 weeks

  Primary endpoint: Change from baseline in A1C after 26 weeks of treatment

  Number of patients: 960

Boehringer Ingelheim and Eli Lilly and Company
In January 2011, Boehringer Ingelheim and Eli Lilly and Company announced an alliance that centers on compounds representing several of the largest diabetes treatment classes. Depending on geographies, the companies either co-promote or separately promote the respective molecules each contributing to the alliance. The alliance leverages the strengths of two of the world's leading pharmaceutical companies to focus on patient needs. By joining forces, the companies demonstrate their commitment, not only to the care of people with diabetes, but also to investigating the potential to address areas of unmet medical need to help those living with heart failure or chronic kidney disease.

Currently, no Boehringer Ingelheim and Lilly products are approved for the treatment of heart failure or chronic kidney disease.

About Boehringer Ingelheim Pharmaceuticals, Inc.
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 our goal is to improve the lives of humans and animals through its three business areas: human pharmaceuticals, animal health and biopharmaceutical contract manufacturing.

Boehringer Ingelheim concentrates on developing innovative therapies that can improve and extend patients' lives. As a research-driven pharmaceutical company, it plans in generations for long-term success. Its research efforts are focused on diseases with high, unmet medical need. In animal health, the company stands for advanced prevention.

In 2018, Boehringer Ingelheim achieved net sales of around $20.7 billion (17.5 billion euros). R&D expenditure of almost $3.7 billion (3.2 billion euros) corresponded to 18.1 per cent of net sales.

Boehringer Ingelheim is committed to improving lives and strengthening our communities. Please visit www.boehringer-ingelheim.us/csr to learn more about Corporate Social Responsibility initiatives.

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 empagliflozin as a potential treatment for type 1 diabetes and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug 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 a further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see Lilly's most recent Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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SOURCE Eli Lilly and Company