# US FDA issues complete response letter for empagliflozin 2.5 mg as adjunct to insulin for adults with type 1 diabetes

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RIDGEFIELD, Conn. and INDIANAPOLIS, March 20, 2020 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has issued a complete response letter for the supplemental New Drug Application (sNDA) of the investigational medicine empagliflozin 2.5 mg as an adjunct to insulin for adults with type 1 diabetes. Empagliflozin 2.5 mg is being developed by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY).

The letter indicates that the FDA is unable to approve the application in its current form, consistent with the outcome of the Endocrinologic and Metabolic Drugs Advisory Committee in November.

"The challenges of managing blood sugar levels for those with type 1 diabetes, and the desire for new treatment options, reveal important unmet needs in the diabetes community," 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 remain committed to the continued study of therapies that may improve outcomes for adults with cardiorenal metabolic conditions, including diabetes."

**About Diabetes**
Approximately 34.2 million Americans and an estimated 463 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.

**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. Clinical trials have been initiated to evaluate the impact of empagliflozin on people living with 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 percent 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