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Lilly Announces Update on Regulatory Submission Timing for Basal Insulin Peglispro

INDIANAPOLIS, Feb. 23, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced a delay in the submission of basal insulin peglispro (BIL) to regulatory agencies beyond the first quarter of 2015. The delay includes filings with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency.

Lilly will delay submission in order to generate additional clinical data to further understand and characterize the potential effects, if any, of changes in liver fat observed with BIL treatment in the Phase III trials. Lilly intends that ongoing clinical trials will continue as planned. In the clinical development program to date, in which more than 6,000 patients with type 1 and type 2 diabetes were treated for up to 18 months (approximately 3,900 patients treated with BIL), no drug-induced liver impairment or Hy's Law cases have been observed.

"Lilly believes in the potential of BIL and its novel mechanism of action. The development of BIL remains important to us and we are committed to further evaluating the safety and efficacy of this investigational treatment for people with diabetes," said Enrique Conterno, President, Lilly Diabetes. "While we are disappointed with the delay, we feel it is important to gain a better understanding of the potential effects of BIL on the liver before asking regulators to review the drug for approval. Our priority is delivering safe and innovative medicines to meet the needs of people living with diabetes, and that's what we aim to accomplish with this additional work."

The length of the delay cannot be determined until clinical trial plans have been developed. However, the company anticipates the submission is likely to occur after 2016. Lilly is working to determine next steps, including potential consultations with regulators. Information regarding future submission timing will be provided following these activities.

About Basal Insulin Peglispro

Basal insulin peglispro (BIL), which was discovered and developed in Lilly Research Laboratories, is currently in Phase III clinical trials and is being studied as a once-daily treatment for type 1 and type 2 diabetes. In the clinical trial program to date, consisting of more than 6,000 patients, approximately 3,900 patients have been treated with BIL. In the core Phase III clinical trial program - consisting of seven IMAGINE trials in patients with type 1 and type 2 diabetes - superiority in HbA1c for BIL was seen in all six trials that were conducted against active comparators.

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.

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. (P-LLY)

This press release contains forward-looking statements about an investigational compound basal insulin peglispro, which is currently in development for the treatment of 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 basal insulin peglispro will receive required 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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