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Lilly Ends Basal Insulin Peglispro Development Program

INDIANAPOLIS, Dec. 4, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that it will cease development of basal insulin peglispro (BIL), a potential treatment for type 1 and type 2 diabetes, in order to focus research and development efforts on other assets in its portfolio and pipeline.

In February, Lilly announced it was delaying regulatory submission in order to better understand and characterize the potential effects, if any, of changes in liver fat observed with BIL treatment compared with insulin glargine treatment in the Phase 3 IMAGINE trials. No drug-induced liver impairment or Hy's Law cases were observed in the IMAGINE clinical development program of more than 6,000 patients with type 1 and type 2 diabetes treated for up to 18 months (approximately 3,900 patients treated with BIL).

Over the past several months, Lilly engaged with regulatory authorities and other external experts to assess potential development plans for BIL that could provide additional clarity on the liver fat data observed in the IMAGINE trials. The decision to stop the program was informed by these conversations - and not by any new safety signals - and was ultimately driven by the decision to focus research and development efforts on other potential treatments.

"While we are encouraged by the efficacy data we observed for BIL, we know that moving forward would have required a significant amount of time and investment with no assurance that we would find conclusive answers," said Enrique Conterno, president, Lilly Diabetes. "We are disappointed in the outcome for BIL, but we have an unprecedented opportunity to build upon the industry's broadest diabetes portfolio, which includes six new treatments approved since the middle of 2014. Lilly remains fully committed to innovative research in the diabetes space, including insulins, as we strive to make life better for people around the world."

The decision to discontinue development of BIL is expected to result in a fourth-quarter charge to Lilly's GAAP and non-GAAP research and development expense of an estimated $55 million (pre-tax), or approximately $0.03 per share (after-tax). Lilly's previously issued GAAP and non-GAAP EPS guidance of $2.40-$2.45 and $3.40-$3.45, respectively, remain unchanged. Lilly will report its 2015 results on Jan. 28, 2016.

BIL, discovered and developed in Lilly Research Laboratories, was being studied as a once-daily treatment for type 1 and type 2 diabetes. BIL is a hepato-preferential basal insulin. Its activity profile is derived from its reduced effect in peripheral tissue, making it more similar to endogenous insulin compared to other exogenous insulins with a conventional activity profile.

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.

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This press release contains forward-looking statements about an investigational compound, basal insulin peglispro and about Lilly's diabetes portfolio. 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. 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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