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Lilly to Discontinue Development of Evacetrapib for High-Risk Atherosclerotic Cardiovascular Disease

INDIANAPOLIS, Oct. 12, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and the ACCELERATE study's academic leadership have accepted the recommendation of the independent data monitoring committee to terminate the Phase 3 trial of the investigational medicine evacetrapib, due to insufficient efficacy. Lilly will discontinue development of evacetrapib for the treatment of high-risk atherosclerotic cardiovascular disease and will now conclude other studies in the program.

The independent data monitoring committee based its recommendation on data from periodic data reviews, which suggested there was a low probability the study would achieve its primary endpoint based on results to date. The study is not being stopped for safety findings. After further analysis, results of the study will be presented in scientific forums in the future.

"We're obviously disappointed in this outcome, as we hoped that evacetrapib would offer an advance in treatment for people with high-risk cardiovascular disease. We'll be working with investigators to appropriately conclude these trials," said David Ricks, Lilly senior vice president and president of Lilly Bio-Medicines. "We remain confident in our pipeline as we prepare for launches in other therapeutic areas with significant unmet needs."

"This unfortunate outcome for evacetrapib does not change our ability to generate long-term growth," said Derica Rice, Lilly executive vice president and chief financial officer. "Our recent string of positive data-readouts and our strong pipeline position us to grow revenue and expand margins through the remainder of this decade."

The decision to discontinue development of evacetrapib is expected to result in a fourth-quarter charge to research and development expense of up to $90 million (pre-tax), or approximately $0.05 per share (after-tax). The company will incorporate this estimated charge into its updated 2015 guidance that will be provided as part of its third quarter 2015 earnings press release on Thursday, Oct. 22, 2015.

About ACCELERATE
The ACCELERATE study was designed to evaluate the efficacy and safety of evacetrapib in participants with high-risk atherosclerotic cardiovascular disease (ASCVD). The pivotal Phase 3 trial - Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition With Evacetrapib in Patients at a High Risk for Vascular Outcomes - was designed as a multi-center, randomized, double-blind, placebo-controlled trial being conducted at 540 sites in 37 countries, with 12,095 patients enrolled. The primary outcome measure was designed to be time to first occurrence of any component of the composite cardiovascular events of cardiovascular death, myocardial infarction, stroke, coronary revascularization, or hospitalization for unstable angina. More information on the ACCELERATE trial is available at https://clinicaltrials.gov.

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 (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Lilly's product pipeline and about charges relating to the decision to discontinue development of evacetrapib and reflects Lilly's current beliefs. However, there are substantial risks and uncertainties in the process of pharmaceutical research, development, and commercialization. For further discussion of these and other risks and uncertainties, see Lilly's most recent 10-K and 10-Q filings with the United States Securities and Exchange Commission. Except as may be required by law, Lilly undertakes no duty to update forward-looking statements for events occurring after the date of this release.

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