

## Lilly Provides Update on Evacetrapib Phase 3 Trial

INDIANAPOLIS, Feb. 19, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) has accepted the recommendation of the ACCELERATE study academic executive committee, based on emerging science in the cardiovascular field, to extend the Phase 3 trial of the investigational medicine evacetrapib by approximately six months. The decision is not based on any data from ACCELERATE, as both the academic committee and the company remain blinded to efficacy results.

Last patient visit in ACCELERATE - which is evaluating evacetrapib in approximately 12,000 people with high-risk atherosclerotic cardiovascular disease (ASCVD) -- is now expected in July 2016.

The academic executive committee based its recommendation on analysis of recent results from other drugs being studied to reduce major adverse cardiovascular events (MACE). Both the committee and Lilly believe longer treatment will allow appropriate testing of the ACCELERATE hypothesis: that evacetrapib added to statins can reduce MACE events compared to statins alone in patients with ASCVD.

As part of the study extension, a futility analysis previously anticipated in Q1 2015 is now expected to occur in Q3 2015.

## About evacetrapib

Evacetrapib (LY2484595) is a potent and selective inhibitor of cholesteryl ester transfer protein (CETP), and in clinical studies has demonstrated effects on high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol, and cholesterol efflux. Evacetrapib is in Phase 3 clinical studies and is not approved as a treatment for prevention or reduction of cardiovascular risk or any other indication anywhere in the world.

## **About ACCELERATE**

The ACCELERATE study is evaluating 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 - is 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 is 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 <a href="http://clinicaltrials.gov/">http://clinicaltrials.gov/</a>

## **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 <a href="https://www.lilly.com">www.lilly.com</a> and <a href="https://www.lilly.com">newsroom.lilly.com</a>/social-channels.

This press release contains forward-looking statements about evacetrapib as a potential treatment for patients with ASCVD. It reflects Lilly's current beliefs; however, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug development, regulatory review, and commercialization. There is no guarantee that future study results will be consistent with study findings to date, or that evacetrapib will receive regulatory approvals or, if approved, will 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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