Lilly Reports on Outcome of Phase III Study of Arzoxifene

Based on Preliminary Phase III GJAD Study Results, Lilly Concludes Arzoxifene's Clinical Profile Does Not Support Regulatory Submission

INDIANAPOLIS, Aug 18, 2009 /PRNewswire via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today that initial results from its pivotal, five-year, Phase III GJAD "GENERATIONS" trial for arzoxifene met its primary endpoints of significantly reducing the risk of vertebral fracture and invasive breast cancer in postmenopausal women. However, the study failed to demonstrate a statistically significant difference in key secondary efficacy endpoints, such as non-vertebral fractures, clinical vertebral fractures, cardiovascular events and cognitive function, compared to placebo. In addition, certain adverse events, including venous thromboembolic events, hot flushes and gynecological-related events, were reported more frequently in the arzoxifene group compared with placebo. After reviewing the overall clinical profile of arzoxifene in light of currently available treatments, including Lilly's own osteoporosis products, the company has decided not to submit the compound for regulatory review. The final GJAD "GENERATIONS" study results will be published in 2010.

"At Lilly, our goal is to provide innovative therapies that result in better patient outcomes," said M. Johnston Erwin, global brand development leader for the musculoskeletal platform at Lilly. "While arzoxifene met its primary efficacy objectives in this study, we are disappointed that the GENERATIONS data did not convincingly demonstrate that arzoxifene would represent a meaningful advancement in the treatment of osteoporosis."

"The results of arzoxifene's GENERATIONS study serve as a reminder of the high risks associated with pharmaceutical innovation," commented John Lechleiter, Ph.D., Lilly chairman and chief executive officer. "Despite this setback, our business remains strong, supported by the growth of key marketed products. In addition, we have the largest and most promising clinical stage pipeline in our history with more than 60 molecules in clinical development, including a late-stage pipeline targeting unmet medical needs in areas such as Alzheimer's disease, cancer and diabetes."

The decision not to submit arzoxifene for regulatory review is expected to result in a third-quarter charge to earnings of approximately $.03 to $.04 per share. The company confirmed its previous 2009 earnings per share guidance range of $4.14 to $4.24 on a reported basis, or $4.20 to $4.30 on a pro forma non-GAAP basis.

Lilly is in the process of contacting the clinical investigators conducting ongoing arzoxifene clinical trials. Subject to protocol requirements, the trials will be discontinued, and the patients currently enrolled will be encouraged to speak with a healthcare professional regarding other therapeutic options. Patients involved in arzoxifene clinical studies who have questions should contact their study investigator.

About GJAD "GENERATIONS" Study

The GJAD "GENERATIONS" Study is a Phase III, double-blind, randomized, placebo-controlled, five-year study of 9,354 postmenopausal women, throughout 22 countries, 60-85 years of age, with either documented osteoporosis or low bone mass. Participants were randomly assigned to arzoxifene 20 mg/day or placebo, and also received elemental calcium 500 mg/day and 400-600 IU/day vitamin D.

Primary endpoints were vertebral fractures in the osteoporosis population and invasive breast cancer in the overall study population. Secondary efficacy endpoints included non-vertebral fractures, clinical vertebral fractures, cardiovascular events (coronary events and stroke), and cognitive function. Key safety endpoints included all-cause mortality, gynecological-related events (including endometrial carcinoma and hyperplasia), and venous thromboembolic events (VTEs).

The primary vertebral fracture endpoint was based on three-year data, consistent with FDA guidance on development of osteoporosis products, whereas the primary invasive breast cancer analysis, secondary outcome analyses and safety analyses were based on four-year data.

About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical

needs.

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Forward Looking Statement

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates and global macroeconomic conditions. For additional information about the factors that affect the company's business, please see the company's latest Form 10-Q filed July 2009 and Form 10-K filed February 2009. The company undertakes no duty to update forward-looking statements.

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