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Lilly Announces Preliminary Coronary and Breast Cancer Results from Raloxifene Use for The Heart (RUTH) Study

Company Also Reinforces Prescribing Information

INDIANAPOLIS, April 12, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) is announcing preliminary results from the Raloxifene Use for The Heart trial (RUTH), a large-scale placebo-controlled study that investigated whether 60 mg daily dose of raloxifene HCl would reduce the risk of coronary events (e.g., heart attack) and the risk of invasive breast cancer in postmenopausal women with known heart disease or at high risk for heart attack.

Raloxifene HCl is currently marketed in the U.S. as EVISTA(R) for the prevention and treatment of osteoporosis in postmenopausal women. EVISTA is not approved by the Food and Drug Administration (FDA) in the U.S. for preventing or reducing the risk of cardiovascular disease or breast cancer.

The study included more than 10,000 women from 26 countries who were followed for up to seven years. All women enrolled in RUTH had known heart disease or were at high risk for heart attack.

Primary Endpoint Findings

Preliminary analyses of the study's two primary endpoints indicate:

- EVISTA did not increase or decrease the combined endpoint of non-fatal heart attack, fatal heart attack, and hospitalized acute coronary syndrome compared to placebo.
- EVISTA treatment decreased the endpoint of invasive breast cancer compared to placebo.

"Because EVISTA did not prevent coronary events, we want to reinforce for physicians that EVISTA should not be prescribed for cardioprotection," said Alan Breier M.D., vice president and chief medical officer, Lilly. "Physicians should be aware that the modest reduction of LDL, or 'bad' cholesterol, previously seen in EVISTA's clinical trials and currently reflected in the label, did not translate into cardioprotection in the RUTH study," he said.

"Additionally, Lilly is pleased to have important new data on EVISTA's potential for reducing the risk of invasive breast cancer in postmenopausal women and looks forward to submitting it to the FDA for its review," Breier concluded.

Secondary Endpoint Findings

Preliminary analyses of the following secondary endpoints indicate:

- There was no difference in overall mortality or cardiovascular mortality among women who took EVISTA compared to placebo.
- Among women taking EVISTA, there was no difference in the overall number of strokes compared to placebo; however, there was an increase in stroke mortality, but the overall incidence was low.
- There was an increase in venous thromboembolic events (VTEs) for patients taking EVISTA. This is consistent with what has been observed in previous trials and is reflected in EVISTA's current label.

The RUTH Executive Committee, an external oversight committee for all main scientific issues related to the conduct of the trial, is currently working to complete the data analyses for expedited publication.

Lilly is working with the FDA and other regulatory agencies to finalize data analyses from this study and update the product label accordingly. In the interim, healthcare providers should consider the following when prescribing EVISTA for the prevention and treatment of osteoporosis in postmenopausal women:

-- EVISTA is not indicated and should not be prescribed for cardioprotection.

-- Until data analyses are complete, it is recommended the benefit/risk profile of EVISTA in postmenopausal women with a history of stroke or other significant stroke risk factors such as transient ischemic attack (TIA) or atrial fibrillation, be considered when prescribing EVISTA.

-- To reduce overall stroke risk, all postmenopausal women, regardless of EVISTA use, should control high blood pressure, take medication as directed, and adopt a healthy lifestyle (improving eating habits, weight control, exercise and smoking cessation) as recommended by the American Heart Association.

Physicians and consumers can contact the Lilly Answers Center at 1-800-LillyRX if they have questions regarding EVISTA.

Other Important Safety Information about EVISTA

EVISTA(R) is not for everyone. If you are or still can become pregnant, are nursing, have severe liver problems, or have had blood clots that required a doctor's treatment, you should not take EVISTA(R). An infrequent but serious side effect of EVISTA (R) is blood clots in the veins -- being immobile for a long time may add to the risk.

The most commonly reported side effects were hot flashes and leg cramps. Side effects with EVISTA(R) have usually been mild, and most women didn't find them serious enough to stop taking it.

You may be at increased risk for osteoporosis if you are Caucasian (white) or Asian, have a slender build, don't exercise, or have a family history of the disease. If you don't get enough calcium and/or vitamin D in your diet, you should also take these supplements. For detailed information about EVISTA(R), visit Lilly's website at www.EVISTA.com.

About Osteoporosis

More than 50 percent of all women over the age of 75 are estimated to have osteoporosis, and due to their advanced age, have a high risk of fracture. In fact, most American women over the age of 50 will experience one or more osteoporosis-related fractures during their lifetimes, and women with osteoporosis who have two or more previous fractures have up to a nine times greater risk of future fracture compared with women who have not suffered a previous fracture.

About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class 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. Additional information about Lilly is available at www.lilly.com.

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This press release contains forward-looking statements about the safety and efficacy of Evista and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of research and commercialization. There is no guarantee that the product will continue to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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