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Eli Lilly and Company Submits New Drug Application for EVISTA for Reduction of Invasive Breast Cancer Risk in Postmenopausal Women

Submission is Largest in Lilly History, Including Data From Approximately 37,000 Women

INDIANAPOLIS, Dec 07, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today that it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration's Division of Drug Oncology Products (DDOP) for EVISTA(R) (raloxifene HCl) for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for breast cancer. EVISTA is currently indicated for the treatment and prevention of osteoporosis in postmenopausal women.

"If approved, EVISTA would be the only therapy to address two leading health issues for postmenopausal women -- osteoporosis and breast cancer," said Gwen Krivi, Ph.D., vice president of Lilly Research Laboratories. "We believe this potential new indication for EVISTA would provide a tremendous opportunity for postmenopausal women with these health issues."

The filing, submitted in November 2006, includes data from four clinical trials -- two pivotal trials and two supportive trials, representing data from three different patient populations:

* Postmenopausal women at increased risk for invasive breast cancer in the Study of Tamoxifen and Raloxifene (STAR) trial

* Postmenopausal women with known or at increased risk for coronary disease in the Raloxifene Use for The Heart (RUTH) trial

* Postmenopausal women with osteoporosis in the Multiple Outcomes of Raloxifene Evaluation (MORE) and Continuing Outcomes Relevant to EVISTA (CORE) trials.

Results from the STAR trial, which was funded by the National Cancer Institute (NCI) and conducted by researchers with the National Surgical Adjuvant Breast and Bowel Project (NSABP), were published in the Journal of the American Medical Association on June 28, 2006. Results from the RUTH trial were published in the New England Journal of Medicine on June 13, 2006. The NDA includes data from more patients than any other submission in Lilly's history -- approximately 37,000 postmenopausal women from four studies that have spanned nearly 10 years.

The American Cancer Society estimates approximately 200,000 women are diagnosed with invasive breast cancer each year.(i) While the exact causes of breast cancer are unknown, there are many risk factors associated with its development, including age, family or personal history of breast cancer, genetics, race and lifestyle factors. Increased age is a particularly important risk factor, as the majority of breast cancer cases occur in women over age 50.(ii) It is important for postmenopausal women to speak with their doctor or healthcare professional about their personal risk for breast cancer.

Information About EVISTA(R)

EVISTA(R) (raloxifene HCl) is a prescription medication that prevents and treats osteoporosis in women past menopause. EVISTA is neither an estrogen nor a hormone. EVISTA is a Selective Estrogen Receptor Modulator, or SERM. It helps build bone without negatively affecting the breast or uterus. EVISTA prevents and treats osteoporosis by actually helping make bones stronger and less likely to break. More than 52 million prescriptions for EVISTA have been filled since the FDA approved it in 1997.

EVISTA 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 cannot take EVISTA. An infrequent but serious side effect of EVISTA is blood clots in the veins -- being immobile for a long time may add to the risk.

EVISTA does not increase or decrease the incidence of heart attack, stroke, cardiovascular death or overall death. In a study of postmenopausal women at high risk for cardiovascular disease taking EVISTA, there was no increase in the incidence of stroke; however, there was an increase in the incidence of death due to stroke. If you have had a stroke or have a history of other significant risk factors for stroke, such as a mini-stroke (TIA/transient ischemic attack), or a type of irregular heartbeat

(atrial fibrillation), you should discuss with your doctor or healthcare professional the risks versus benefits of taking EVISTA.

The most commonly reported side effects are hot flashes and leg cramps. Side effects with EVISTA are usually mild, and most women don't find them serious enough to stop taking it.

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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(i) How many women get breast cancer? American Cancer Society. Accessed at http://www.cancer.org/docroot/CRI/content/CRI_2_2_1X_How_many_people_get_breas t_cancer_5.asp?rnav=cri. On November 1, 2006.

(ii) What causes breast cancer? American Cancer Society. Accessed at http://www.cancer.org/docroot/CRI/content/CRI_2_2_2X_What_causes_breast_cancer _5.asp?sitearea=. on November 14, 2006.

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