# FDA Approves Lilly's Osteoporosis Drug EVISTA(R) (raloxifene HCl) to Reduce The Risk of Invasive Breast Cancer in Two Populations of Postmenopausal Women

## First treatment approved to reduce invasive breast cancer risk in postmenopausal women with osteoporosis

INDIANAPOLIS, Sept 14, 2007 /PRNewswire-FirstCall via COMTEX News Network/ --

Today, Eli Lilly and Company (NYSE: LLY) announced that the U.S. Food and Drug Administration (FDA) has approved its osteoporosis drug EVISTA(R) (raloxifene HCl) for a new use to reduce the risk of invasive breast cancer in two populations: postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer.

"The FDA's decision marks a major milestone. For the first time, postmenopausal women with osteoporosis will have one treatment option that can help address two leading health concerns -- osteoporosis and invasive breast cancer," said Gwen Krivi, Ph.D., vice president of Lilly Research Laboratories. "Further, postmenopausal women at high risk for invasive breast cancer will have an alternative therapy for invasive breast cancer risk reduction."

EVISTA, a selective estrogen receptor modulator or SERM (recently classified by the FDA as an estrogen agonist/antagonist), is already approved for the prevention and treatment of osteoporosis in postmenopausal women. In July, the Oncologic Drugs Advisory Committee (ODAC) to the FDA voted to recommend approval for the new uses. Today's decision and the positive recommendation from ODAC were based on data submitted in November 2006 in a new drug application (NDA), evaluating clinical results from approximately 37,000 postmenopausal women that spanned nearly 10 years.

Earlier this year, the osteoporosis label for EVISTA was updated to include safety information from the Raloxifene Use for The Heart (RUTH) trial, which evaluated postmenopausal women with known or at increased risk for coronary disease taking EVISTA. This trial found no increase in the incidence of stroke, but an increase in the incidence of death due to stroke.

Since the new label for EVISTA(R) (raloxifene HCl) includes new uses and an expanded patient population, Lilly worked with the FDA to revise the package insert, which will now include a boxed warning. The warning highlights information already included in the Contraindications and Warnings & Precautions sections of the prior label. It emphasizes that women with an active or past history of venous thromboembolism should not take EVISTA and that women at risk for stroke should receive EVISTA only after evaluating the risk-benefit balance with their healthcare providers.

"Thousands of women each year are diagnosed with invasive breast cancer," said Dr. Lawrence Wickerham, M.D., associate chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP), and associate professor of human oncology at Drexel University School of Medicine. "Today's approval of EVISTA for these new uses gives postmenopausal women at risk for this disease an important new treatment option that allows them to take a proactive approach to reducing their risk."

While the exact causes of breast cancer are unknown, certain risk factors are linked to the disease, including age, family history, personal history of breast cancer, genetics and lifestyle factors(1). The increased incidence of breast cancer as women age is notable, as nearly eight out of 10 breast cancers are found in women age 50 and older(2). The American Cancer Society estimates that approximately 180,000 women are diagnosed with invasive breast cancer each year(3).

In addition, age is an important risk factor associated with osteoporosis. According to the National Osteoporosis Foundation, approximately 55 percent of people affected by osteoporosis are age 50 and over(4).

"As women age and enter the postmenopausal phase of their lives, the incidence of certain diseases, such as invasive breast cancer and osteoporosis, increases dramatically," said Steven Cummings, M.D., emeritus professor of medicine and epidemiology and biostatistics at the University of California San Francisco. "Therefore, it's important for postmenopausal women to be aware of these serious risks and have treatment choices to address them."

The FDA evaluated a data package that included multiple trials assessing three different populations of postmenopausal women:

-- The Study of Tamoxifen and Raloxifene (STAR) trial, sponsored by the National Cancer Institute (NCI) and coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP), involved postmenopausal women at increased risk for invasive breast cancer. The observed incidence rates of invasive breast cancer were EVISTA 4.4 and tamoxifen 4.3, per 1000 women per year.

-- The Raloxifene Use for The Heart (RUTH) trial looked at postmenopausal women with known or at increased risk for coronary disease. The study demonstrated that EVISTA significantly reduced the risk of invasive breast cancer in postmenopausal women by 44 percent with an absolute risk reduction of 0.6 percent.

-- The Multiple Outcomes of Raloxifene Evaluation (MORE) and Continuing Outcomes Relevant to Evista (CORE) trials evaluated postmenopausal women with osteoporosis. Both four-year trials showed that EVISTA reduced the risk of invasive breast cancer in women by 71 percent with an absolute risk reduction of 1.1 percent, and 56 percent with an absolute risk reduction of 1.0 percent, respectively.

Important Safety Information About EVISTA(R)

EVISTA is not for everyone. If you are or still can become pregnant, are nursing, 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), hypertension, history of cigarette smoking or a type of irregular heartbeat (atrial fibrillation), you should discuss with your healthcare professional the risks versus benefits of taking EVISTA.

If you have kidney or liver problems, you should discuss these conditions with your healthcare professional before taking EVISTA.

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

Important Limitations of Use for Breast Cancer Risk Reduction

EVISTA is indicated to reduce the risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer. The American Cancer Society estimates that approximately 180,000 women are diagnosed with invasive breast cancer each year(3).

EVISTA does not treat existing breast cancer, reduce the risk of getting breast cancer again or reduce the risk of all forms of breast cancer. For more information about EVISTA including prescribing information and boxed warning, log on to www.evista.com

About Lilly

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Forward Looking Statement

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 development and commercialization. There is no guarantee that EVISTA 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.

1. American Cancer Society. What causes breast cancer? Accessed at http://www.cancer.org/docroot/CRI/content/CRI_2_2_2X_What_causes_breast_cancer _5.asp?sitearea= on September 11, 2007.

2. American Cancer Society. Breast Cancer Facts & Figures 2005-2006. Accessed at www.cancer.org/downloads/STT/CAFF2005Br).pdf on September 11, 2007.

3. American Cancer Society. How many women get breast cancer? 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 September 11, 2007.

4. National Osteoporosis Foundation. Fast Fasts of Osteoporosis. Accessed at http://www.nof.org/osteoporosis/diseasefacts.htm on September 11, 2007.

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