



## **FDA Advisory Committee Recommends Approval of EVISTA for the Reduction of Risk for Invasive Breast Cancer in Two Populations of Postmenopausal Women**

**EVISTA is currently indicated for the prevention and treatment of osteoporosis and may provide an important option for postmenopausal women at increased risk for breast cancer**

INDIANAPOLIS, Ind., July 24, 2007 /PRNewswire-FirstCall via COMTEX News Network/ --

Eli Lilly and Company (NYSE: LLY) announced today that the Oncologic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted to recommend approval of its osteoporosis drug EVISTA(R) (raloxifene HCl) for a new use to reduce invasive breast cancer risk in two populations: postmenopausal women with osteoporosis and postmenopausal women at high risk for breast cancer. The Advisory Committees' vote for each population was 8 to 6 and 10 to 4, respectively. Advisory Committee recommendations to the FDA are non-binding.

EVISTA is a selective estrogen receptor modulator, or SERM (recently classified by the FDA as an estrogen agonist/antagonist). EVISTA is currently indicated for the prevention and treatment of osteoporosis in postmenopausal women. Last November, Lilly submitted a new drug application (NDA) to the FDA requesting that it evaluate EVISTA for this new use based on data from approximately 37,000 postmenopausal women that spanned nearly 10 years.

"Today is an especially good day for postmenopausal women," said Gwen Krivi, Ph.D., vice president of Lilly Research Laboratories. "If approved, EVISTA would be the first and only therapy available to address two leading health issues for postmenopausal women -- osteoporosis and breast cancer. Following today's vote, our intention is to continue working with the FDA to make this important option a reality for patients."

The American Cancer Society estimates approximately 180,000 women are diagnosed with invasive breast cancer each year. While the exact causes of breast cancer are unknown, there are certain risk factors linked to the disease, including age, family history, personal history of breast cancer, genetics, race and lifestyle factors. Increased age is a particularly important risk factor, as nearly eight out of 10 breast cancers are found in postmenopausal women age 50 and older.

The Advisory Committee reviewed four studies submitted to the FDA in the NDA package, representing data from three different populations of postmenopausal women:

- \* Postmenopausal women at increased risk for breast cancer in 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)
- \* 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

Lilly will continue to work with the FDA as the agency moves toward action on the NDA submission.

### **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 (recently classified by the FDA as an estrogen agonist/antagonist). 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 liver or kidney 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), hypertension, history of cigarette smoking 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, 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.

For more information about EVISTA, log on to [www.evista.com](http://www.evista.com)

#### 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](http://www.lilly.com). P-LLY

#### 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 research and commercialization. There is no guarantee that EVISTA will be approved for the reduction of invasive breast cancer risk or that it 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.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO> )

#### SOURCE Eli Lilly & Company

Sharon Corbitt, Eli Lilly & Company, office, +1-317-997-1206, cell, +1-317-277-1574, or [corbittsd@lilly.com](mailto:corbittsd@lilly.com)

<http://www.evista.com>

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