Lilly Launches New FORTEO Delivery Device

New design to help patients more easily administer their treatment on a day-to-day basis

INDIANAPOLIS, Oct 15, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced that its new, simpler-to-use FORTEO Delivery Device is available for patient use in the United States. The new delivery device was designed specifically for FORTEO(R) [teriparatide (rDNA origin) injection] patients to help them more easily administer their treatment on a day-to-day basis.

The new delivery device, approved by the U.S. Food and Drug Administration (FDA) in June, is being shipped to pharmacies and is available for patients when they fill their prescriptions in the coming weeks.

Lilly incorporated feedback from patients and healthcare professionals directly into the design of the new FORTEO Delivery Device. Most notably, compared to the current FORTEO Pen, the new design includes a larger and wider body; fewer steps to complete an injection with no priming necessary; and color-coded parts to enhance patient training and communication.

Design matters: patients respond to the new delivery device

To assess the experience of subjects using the new delivery device, Lilly conducted a well-controlled clinical trial over an eight-week period. Of the 106 "non-experienced users" (subjects with limited or no experience using the previous FORTEO Pen) who tested the new delivery device and completed a questionnaire at the end of the trial, responses indicated the following:

-- Ninety-eight percent (98%) agreed that this delivery device was easy to learn how to use.(1)

-- Ninety-eight percent (98%) agreed that it was easy to administer FORTEO with the new delivery device.(1)

-- Ninety-one percent (91%) agreed they would be less reluctant to take injections using the new delivery device.(1)

"Lilly is committed to improving the lives of patients through the development of effective treatment delivery mechanisms," says Vladimir Kopernicky, medical director, U.S. Osteoporosis and Urology, for Eli Lilly and Company. "We hope that this simpler design will help patients adhere to their FORTEO treatment plan so they can receive the full benefits of their medication."

FORTEO is indicated for the treatment of osteoporosis in postmenopausal women who are at high risk for fracture and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. FORTEO, marketed as FORSTEO in the European Union (EU), is the first osteoporosis therapy approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) that actually rebuilds bone.(2,3,4) Since receiving FDA approval in November 2002, more than 2.6 million prescriptions for FORTEO have been filled in the United States.(5)

Information about FORTEO

As part of drug testing, teriparatide, the active ingredient in FORTEO, was given to rats for a significant part of their lifetime. In these studies, teriparatide caused some rats to develop osteosarcoma, a bone cancer. Osteosarcoma in humans is a serious but very rare cancer. Osteosarcoma occurs in about four out of every million older adults each year. It is not known if humans treated with FORTEO also have a higher chance of getting osteosarcoma.

FORTEO should be prescribed only to patients for whom the potential benefits are considered to outweigh the potential risk. The drug should not be prescribed for patients at increased baseline risk for osteosarcoma, including patients with Pagets disease of bone or unexplained elevations of alkaline phosphatase, children or growing adults, or those who have had prior external beam or implant radiation therapy involving the skeleton. Additionally, patients with bone metastases or a history of skeletal malignancies, and those with metabolic bone diseases other than osteoporosis, should not receive FORTEO. Patients with high levels of calcium in their blood should not receive FORTEO due to the possibility of increasing their blood levels of calcium.

Most side effects of FORTEO are mild. Side effects may include nausea, dizziness, leg cramps and joint aches. Injection site reactions include redness, swelling, pain, itching, a few drops of blood and bruising.

FORTEO is supplied in a disposable delivery device that can be used for up to 28 days to give once-daily self-administered injections. FORTEO is available in a 20-mcg dose and is approved to be taken for a period of up to 24 months. A Medication Guide explaining the details of the drug to the patient also accompanies the product. FORTEO also has a "boxed warning" in its package insert about the osteosarcoma findings in rats during preclinical testing. For full prescribing information, please visit http://www.FORTEO.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.

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Forward Looking Statement

This press release contains forward-looking statements about the safety and efficacy of FORTEO 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 FORTEO 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) Data on file, Lilly Research Laboratories (FOR20081009A).

(2) FORTEO Prescribing Information

(3) Osteoporosis Int. 2002;13:267-277.

(4) National Osteoporosis Foundation. Medications to prevent and treat osteoporosis. Available at: http://www.nof.org/patientinfo/medications.htm. Accessed October 10, 2008.

(5) Data on file, Lilly Research Laboratories (FOR20080317A).

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