



September 26, 2005

New Study to Give Insight into Teriparatide use in the Real World Setting

Data presented mark the first information from large observational study

NASHVILLE - Data presented at the 27th Annual Meeting of the American Society for Bone and Mineral Research (ASBMR) will provide a glimpse into the patient population who are prescribed FORTEO® (teriparatide [rDNA origin] injection) by way of baseline characteristics from a new observational study.

The efficacy of teriparatide has been demonstrated in clinical trials, but subjects enrolled in these studies met stringent inclusion/exclusion criteria to ensure consistency in safety and efficacy data.

Given the pristine nature of the clinical trial participants, questions remain as to the experience of patients in a real world clinical setting, including response of those who may have taken other osteoporosis therapies, response of patients who have co-morbidities, and varying degrees of osteoporosis severity.

The Direct Assessment of Non-Vertebral Fractures in Community Experience (DANCE) study is a prospective, non-interventional observational study designed to examine the long-term effectiveness, safety and tolerability of teriparatide given daily in a large, diverse patient population. The data will provide physicians with data that may more closely mirror patients in their own practices rather than those from clinical trials.

Data from these studies will be presented as posters during ASBMR at the following times:

Saturday, September 24, 2005

11:30 a.m. 2:30 p.m.

- Factors Associated with Patient Compliance to Teriparatide: Study Addendum to the DANCE Observational Study

Monday, September 26, 2005

11:30 a.m. 2:30 p.m.

- Rationale and Evidence for Initiating Teriparatide Therapy: Interim Results from DANCE
- Baseline Characteristics of Subjects Enrolled during the First 18 Months of DANCE

FORTEO (teriparatide [rDNA origin] injection), the first and only bone formation agent approved for the treatment of osteoporosis, was granted FDA approval in November 2002. It stimulates new bone formation by increasing the number and activity of bone forming cells called osteoblasts. FORTEO is approved 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. These include men (and postmenopausal women) with a history of osteoporosis-related fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy, based upon physician assessment.

Until FORTEO's approval, the only approved osteoporosis treatments were antiresorptives, which work mainly to slow or stop bone loss by reducing the number and action of bone-removing cells called osteoclasts.

Important Safety Information about FORTEO

In two-year studies in rats, FORTEO® caused an increase in the incidence of osteosarcoma, a malignant bone tumor, which was dependent on dose and duration of treatment. Although no case of osteosarcoma has been reported in the patients who received FORTEO in clinical trials, it is not known if humans treated with FORTEO are at increased risk for this cancer.

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 Paget's 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. In clinical trials, the most frequent treatment-related adverse events reported at the 20-microgram (mcg) dose

approved for marketing were mild, similar to placebo and generally did not require discontinuation of therapy. Reported adverse events that appeared to be increased by FORTEO treatment were leg cramps and dizziness (2.6 and 8 percent, respectively), compared with placebo (1.3 percent and 5.4 percent, respectively).

FORTEO is supplied in a disposable pen 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 should be taken for a period of up to 24 months. Lilly has implemented a risk management program that includes comprehensive measures regarding the appropriate use of FORTEO in the target patient population. A Medication Guide explaining the details of the drug to the patient also accompanies the product. FORTEO also has a black box 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 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.