



FORSTEO(R) Receives Positive Opinion from the European Committee for Medicinal Products for Human Use for the Treatment of Glucocorticoid-Induced Osteoporosis

INDIANAPOLIS, Feb 22, 2008 (PR Newswire Europe via COMTEX News Network) -- If approved, bone formation agent for osteoporosis would be available for new patient population

Eli Lilly and Company (NYSE: LLY) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Evaluation Agency (EMA) has issued a positive opinion recommending approval of FORSTEO(R) (teriparatide [rDNA origin] injection) for the treatment of osteoporosis associated with sustained, systemic glucocorticoid therapy in women and men at increased risk for fracture. The opinion issued by the CHMP will need to be ratified by the European Commission before the new indication is considered approved.

Teriparatide works to stimulate new bone formation by increasing the number and action of bone-building cells called osteoblasts. Teriparatide, originally authorized for marketing in 2003 for the treatment of osteoporosis in postmenopausal women at high risk for fracture, received an expanded indication for the treatment of men at increased risk for fracture in 2007.

"Research has shown that patients taking chronic glucocorticoid therapy may begin to experience bone loss after three to six months of such treatment, resulting in a high incidence of fractures in this patient population," said Gwen Krivi, Ph.D., vice president of Lilly Research Laboratories. "Today's decision by the CHMP brings us one step closer to providing teriparatide as a treatment option for patients suffering from glucocorticoid-induced osteoporosis."

Glucocorticoid-induced osteoporosis, or GIOP, is bone loss associated with chronic use of glucocorticoid medications. These medications are often prescribed for inflammatory conditions, such as rheumatoid arthritis and obstructive pulmonary disease. Globally, an estimated one to three percent of adults over the age of 50 use glucocorticoids. Studies in Europe show that 0.5 to 0.9 percent of the general population and two percent of medical outpatients received prolonged glucocorticoid therapy at any one time.(i) Chronic glucocorticoid therapy is the most common cause of secondary osteoporosis(ii), leading to bone loss and an increased risk for fracture. Up to 50 percent of individuals on chronic glucocorticoid therapy will eventually have an osteoporotic fracture.(iii)

"Currently, physicians and patients only have access to one class of therapies for the treatment of glucocorticoid-induced osteoporosis," said Dr. Steven Boonen, professor of medicine at the Leuven University Centre for Metabolic Bone Diseases in Belgium. "Pending final approval of this new indication, teriparatide would provide physicians and patients with a new treatment option that builds bone."

The submission package to support the safety and efficacy profile of teriparatide included new data from the "Teriparatide or Alendronate in Glucocorticoid-Induced Osteoporosis" study published in the November 15, 2007 issue of the New England Journal of Medicine. This head-to-head comparator study showed that in patients with glucocorticoid-induced osteoporosis teriparatide significantly increased lumbar spine bone mineral density (BMD) from baseline (7.2 percent) compared to alendronate (3.4 percent) at 18 months of therapy.(iv)

Information about Teriparatide

Teriparatide, marketed in the U.S. since 2002, was first approved in the E.U. in 2003 for the treatment of established osteoporosis in postmenopausal women who have an increased risk of fracture.

As part of drug testing, teriparatide 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 teriparatide also have a higher chance of getting osteosarcoma.

Teriparatide 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 teriparatide.

Patients with high levels of calcium in their blood should not receive teriparatide 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 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 teriparatide treatment were muscle cramps and dizziness (3.6 and 8 percent, respectively), compared with placebo (2.9 percent and 5.2 percent, respectively).

Teriparatide is supplied in a disposable pen device that can be used for up to 28 days to give once-daily self-administered injections. Teriparatide is available in a 20-microgram dose and should be taken for a period of up to 18 months. For full prescribing information, please visit <http://www.lilly.co.uk>

About Parathyroid Hormone (PTH1-34)

Parathyroid hormone (PTH1-84) is the natural hormone that regulates calcium and phosphate in bone and kidney. Teriparatide is the active fragment (1-34) of the human parathyroid hormone and acts to stimulate bone formation by directly affecting bone forming cells (osteoblasts), indirectly increasing the intestinal absorption of calcium and increasing the re-absorption of calcium and excretion of phosphate by the kidney.

About Osteoporosis

Osteoporosis is a debilitating disease that affects an estimated 75 million people in Europe, U.S. and Japan(v). Osteoporosis, which means "porous bone," is a disease in which the density and quality of bone are reduced. As the bones become more porous and fragile, the risk of fracture is greatly increased. The loss of bone occurs "silently" and progressively and no symptoms are apparent until the first fracture occurs.(vi)

The most common fractures associated with osteoporosis occur at the hip, spine and wrist. The incidence of these fractures, particularly at the hip and spine, increases with age in both women and men.(vii)

Vertebral fractures can result in serious consequences, including loss of height, intense back pain and deformity.

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.co.uk.

Forward Looking Statement

This press release contains forward-looking statements about the safety and efficacy of teriparatide 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 teriparatide for the treatment of osteoporosis 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.

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- (i) Clin Rheumatol. 2007; 26: 144-153.
- (ii) Trends in Endo. And Meta. 2006;17(4); 144-149.
- (iii) Endocrinol Metab Clin N Am. 2003; 32; 135-157.
- (iv) N Engl J Med. 2007; 357:2028-39.
- (v) International Osteoporosis Foundation. "Facts and statistics about osteoporosis and its impact."

Available at <http://www.iofbonehealth.org/facts-and-statistics.html#factsheet-category-22>. Accessed on February 8, 2008.

(vi) International Osteoporosis Foundation. "What is osteoporosis?" Available at <http://www.iofbonehealth.org/patients-public/about-osteoporosis/what-is-osteoporosis.html>. Accessed on February 8, 2008 .

(vii) International Osteoporosis Foundation. "What is osteoporosis?" Available at <http://www.iofbonehealth.org/patients-public/about-osteoporosis/what-is-osteoporosis.html>. Accessed on February 8, 2008.

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