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Lilly Commends Surgeon General's Report on Bone Health

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Medical Director likens bones to architecture, emphasizes prevention

Today the Surgeon General of the United States of America released the office's first opinion on bone health, emphasizing the importance of lifestyle choices in maintaining strong bones. As a manufacturer of innovative osteoporosis treatments, Eli Lilly and Company commends the Surgeon General's foresight and dedication to addressing the importance of maintaining healthy bones.

"Our bones are the fundamental architecture of our bodies. Like bricks in a building's foundation, if they crumble or fracture, the entire structure is weakened and compromised," said K. Shaw Lamberson, M.D., Medical Director of Lilly's Women's Health Reproductive Medicine Division.

But unlike actual architecture, bones constantly rebuild themselves, which is why taking care of them is so important - bones are living tissue, constantly going through a cycle of regeneration. By doing regular, weight-bearing exercise and getting enough calcium and vitamin D, you increase the likelihood that your bones will remain strong for a lifetime.

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 for fracture. In fact, most American women over the age of 50 will experience one or more osteoporosis related fractures during their lifetime.

"Awareness is one of the key artillery we have to battle osteoporosis. This is an exciting day for those who have fought to raise awareness and find solutions to this often silent disease," said Lamberson. "The Surgeon General has given the public this great resource, and now it's up to the public to take the steps necessary to protect their body's structural integrity by focusing on prevention."

Lilly's osteoporosis unit provides a continuum of care for the disease, the only pharmaceutical company to manufacture medicines that uniquely treat the disease in each of its stages. Lilly manufactures two osteoporosis medications:

EVISTA® (raloxifene HCl), the first SERM (Selective Estrogen Receptor Modulator) approved for use in preventing and treating osteoporosis in postmenopausal women, and

FORTEO® (teriparatide [rDNA origin] injection) the first and only bone formation agent 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 on physician assessment.

Important Safety Information about EVISTA
EVISTA is not for everyone. If you are or still can become pregnant, are nursing, have severe liver problems, or have had blood clots that required a doctor's treatment, you should not 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. The most commonly reported side effects were hot flashes and leg cramps. Side effects with EVISTA have usually been mild, and most women didn't find them serious enough to stop taking it.

You may be at increased risk for osteoporosis if you are Caucasian (white) or Asian, have a slender build, don't exercise, or have a family history of the disease. If you don't get enough calcium and/or vitamin D in your diet, you should also take these supplements. For full prescribing information, please visit http://www.evista.com

Important Safety Information about FORTEO
In two-year studies in rats, teriparatide 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 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, 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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Forteo® (teriparatide [rDNA origin] injection, Lilly)