



Research Suggests FORTEO® Significantly Increases Bone Strength

SAN DIEGO, Sept. 19, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today presented a study that assessed the effects of 18 months of treatment with FORTEO® (teriparatide [rDNA origin] injection) on vertebral and proximal femoral strength, and the relationship of these effects to changes in the underlying volumetric BMD (vBMD) of postmenopausal women with osteoporosis. Researchers concluded that FORTEO increased vertebral and femoral strength in the spine and hip bones compared to baseline.¹ These findings were presented in an oral presentation at the 2011 Annual Meeting of the American Society for Bone and Mineral Research (ASBMR) in San Diego, Calif.

"Low bone strength is an important factor in the risk of fracture for patients with osteoporosis," said Tony Keaveny, MD, director, Orthopaedic Biomechanics Laboratory, Department of Mechanical Engineering, University of California, Berkeley. "These data provide supportive evidence that treatment with FORTEO has the potential to increase bone strength in two areas prone to fracture, the hip and spine."

The study used finite element analysis (FEA) of quantitative CT scans to measure changes in vertebral and proximal femoral strength. Although FEA is one of the most widely accepted means of non-invasive bone strength assessments, data are scarce on changes in vertebral and femoral bone strength for patients treated with FORTEO; therefore, the biomechanical effects of FORTEO treatment in postmenopausal women are not well understood.²

Researchers performed FEA of quantitative CT scans from study participants to measure bone strength and found statistically significant increases in both vertebral and femoral strength in women treated with FORTEO, compared to baseline (median: 16.6 percent and 2.3 percent, respectively, $p \leq 0.05$).³ The results indicated significant increases in both trabecular and peripheral densities in the spine (median: 12.8 percent and 5.8 percent, respectively, $p \leq 0.05$) and an increase in trabecular density in the hip (median: 3.9 percent, $p \leq 0.05$).⁴ There was no observed change in peripheral density in the hip.⁴

"These study results are encouraging, as they provide additional evidence that FORTEO treatment may result in increased bone strength in appropriate patients," said Kelly Krohn, MD, Eli Lilly and Company. "Studies that reinforce the already established efficacy of medications can help healthcare professionals determine the right medicine to treat their patients with osteoporosis."

FORTEO is used in both men and postmenopausal women with osteoporosis who are at high risk for having broken bones (fractures). FORTEO is used in both men and women with osteoporosis due to use of glucocorticoid medicines, such as prednisone, for several months, who are at high risk for having broken bones (fractures). FORTEO can be used by people who have had a fracture related to osteoporosis, or who have several risk factors for fracture, or who cannot use other osteoporosis treatments.⁵

FORTEO is a prescription medicine given as a 20 mcg once daily dose available in a 2.4 mL prefilled delivery device for subcutaneous injection over 28 days.⁵

During the drug testing process, the medicine in FORTEO caused some rats to develop osteosarcoma, which, in humans, is a serious but rare bone cancer. Osteosarcoma has been reported rarely in people who took FORTEO, and it is unknown if people who take FORTEO have a higher chance of getting the disease. Before patients take FORTEO, patients should tell their healthcare provider if they have Paget's disease of bone, are a child or young adult whose bones are still growing or have had radiation therapy.⁵ For more information about FORTEO, please see the important safety information, including Boxed Warning regarding osteosarcoma, below.

About the Study⁶

"Increases in both vertebral and femoral strength in postmenopausal osteoporotic women after 18 months of treatment with teriparatide" was an 18-month, open-label study using finite element analysis of quantitative CT scans to analyze the effects of treatment with FORTEO on vertebral and proximal femoral strength.

Quantitative CT scans were taken of the lumbar spine and hip at baseline and at 18 months (or at an early termination visit). All

patients who had two evaluable CT scans at both time points were included in the analysis (n=30 spine; n=26 hip).

Volumetric density was measured for the trabecular, peripheral (outer 2-3 mm of bone that contains both cortical and some adjacent trabecular bone) and both ("integral") compartments. Non-linear finite element analysis was performed for uniform compression for the spine and a sideways fall for the hip to provide measures of vertebral and femoral strength.

Important Safety Information about FORTEO

What is the most important information I should know about FORTEO?

WARNING: POTENTIAL RISK OF OSTEOSARCOMA

During the drug testing process, the medicine in FORTEO caused some rats to develop a bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer. Osteosarcoma has been reported rarely in people who took FORTEO. It is not known if people who take FORTEO have a higher chance of getting osteosarcoma. Before you take FORTEO, you should tell your healthcare provider if you have Paget's disease of bone, are a child or young adult whose bones are still growing, or have had radiation therapy.

Who should not take FORTEO?

- You should not take FORTEO for more than 2 years over your lifetime.
- Do not use FORTEO if you are allergic to any of the ingredients in FORTEO. Serious allergic reactions have been reported.

What should I tell my healthcare provider before taking FORTEO?

- Before you take FORTEO, you should tell your healthcare provider if you have a bone disease other than osteoporosis, have cancer in your bones, have trouble injecting yourself and do not have someone who can help you, have or have had kidney stones, have or have had too much calcium in your blood, take medications that contain digoxin (Digoxin, Lanoxicaps, Lanoxin), or have any other medical conditions.
- You should also tell your healthcare provider, before you take FORTEO, if you are pregnant or thinking about becoming pregnant. It is not known if FORTEO will harm your unborn baby. If you are breastfeeding or plan to breastfeed, it is not known if FORTEO passes into your breast milk. You and your healthcare provider should decide if you will take FORTEO or breastfeed. You should not do both.

What are the possible side effects of FORTEO?

- FORTEO can cause serious side effects including a decrease in blood pressure when you change positions. Some people feel dizzy, get a fast heartbeat, or feel faint right after the first few doses. This usually happens within 4 hours of taking FORTEO and goes away within a few hours. For the first few doses, take your injections of FORTEO in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, stop taking FORTEO and call your healthcare provider. FORTEO may also cause increased calcium in your blood. Tell your healthcare provider if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- Common side effects of FORTEO include nausea, joint aches, pain, leg cramps, and injection site reactions including injection site pain, swelling and bruising. These are not all the possible side effects of FORTEO. You are encouraged to report negative side effects of Prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Additional safety information about FORTEO

- There is a voluntary patient registry for people who take FORTEO. The purpose of the registry is to collect information about the possible risk of osteosarcoma in people who take FORTEO. For information about how to sign up for this patient registry, call 1-866-382-6813 or go to www.forteoregistry.org.

- The FORTEO Delivery Device has enough medicine for 28 days. It is set to give a 20-microgram dose of medicine each day. Before you try to inject FORTEO yourself, a healthcare provider should teach you how to use the FORTEO Delivery Device to give your injection the right way. Inject FORTEO one time each day in your thigh or abdomen (lower stomach area). Do not inject all the medicine in the FORTEO Delivery Device at any one time. Do not transfer the medicine from the FORTEO Delivery Device to a syringe. This can result in taking the wrong dose of FORTEO. If you take more FORTEO than prescribed, call your healthcare provider. If you take too much FORTEO, you may have nausea, vomiting, weakness, or dizziness.

How should I store FORTEO?

- Keep your FORTEO Delivery Device in the refrigerator between 36°F to 46°F (2°C to 8°C). Do not freeze the FORTEO Delivery Device. Do not use FORTEO if it has been frozen. Do not use FORTEO after the expiration date printed on the delivery device and packaging. Throw away the FORTEO Delivery Device after 28 days even if it has medicine in it (see the User Manual).

For more safety information, please see Medication Guide (<http://pi.lilly.com/us/forteo-medguide.pdf>) and Prescribing Information, including Boxed Warning (<http://pi.lilly.com/us/forteo-pi.pdf>). Please see full user manual that accompanies the delivery device.

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About Eli Lilly and Company

Eli Lilly and Company, a leading innovation-driven company, is developing a growing portfolio of 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. Information about Lilly is available at www.lilly.com. P-LLY

FORTEO® is a registered trademark of Eli Lilly and Company.

This press release contains forward-looking statements about FORTEO for the treatment of osteoporosis. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that FORTEO will continue to be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

¹ Keaveny, T., et al. "Increases in both vertebral and femoral strength in postmenopausal osteoporotic women after 18 months of treatment with teriparatide." Abstract presented at the ASBMR 2011 Annual Meeting, Sept. 19, 2011, 4:00 PM.

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⁵ FORTEO PI. Available at <http://pi.lilly.com/us/forteo-pi.pdf>.

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