



New FORTEO(R) and EVISTA(R) Data to be Presented at Premiere Scientific Meeting for Bone and Mineral Research

10 New Studies of Teriparatide and Four Studies of Raloxifene Showcased at the 2010 ASBMR Annual Meeting

INDIANAPOLIS, Oct 14, 2010 /PRNewswire via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today announced that a total of 14 U.S. and global studies involving its osteoporosis medications, FORTEO(R) [teriparatide (rDNA origin) injection] and EVISTA(R) (raloxifene HCl tablets), will be presented at the American Society for Bone and Mineral Research (ASBMR) 2010 Annual Meeting from October 15-19 in Toronto, ON, Canada.

In partnership with TransPharma Medical Ltd., Lilly conducted a Phase II study and will present an oral poster session comparing efficacy, safety and teriparatide pharmacokinetics of teriparatide delivered transdermally and via SQ injection in a three-month, randomized, multicenter study in postmenopausal women with osteoporosis.

Of the nine additional studies involving teriparatide, eight investigated the effects of the treatment, with three also testing safety. Additional notes about teriparatide or raloxifene studies to be presented include:

- One study used data from the teriparatide Fracture Prevention Trial to study the effect of body composition on bone.
- Another study compared baseline characteristics, persistence to therapy and reasons for discontinuation between the Puerto Rican population and mainland United States population enrolled in a large observational study of teriparatide.
- Two studies will be presented that investigated the Osteoporosis Patient Assessment Questionnaire (OPAQ) and were conducted using the Multiple Outcomes of Raloxifene Evaluation (MORE) trial database.
- One study used data to develop a modified version of OPAQ, while another study examined the relationship between a comprehensive measure of risk of fracture, based on FRAX(R), and health-related quality of life as measured by OPAQ.

The presentations are scheduled:

- Comparison of Transdermal and subcutaneous teriparatide pharmacokinetics and pharmacodynamics of bone markers in postmenopausal women (*Lead Author: Yael Kenan*)
 - Oct. 15, 5:45 p.m. to 7:00 p.m., [Poster No. FR0376]
 - Oct. 16, 11:30 a.m. to 1:30 p.m., [Poster No. SA0376]
- Effects of teriparatide and strontium ranelate on periosteal bone formation in the ilium of postmenopausal women with osteoporosis (*Lead Author: R.R. Recker*)
 - Oct. 15, 5:45 to 7:00 p.m., [Poster No. FR0378]
 - Oct. 16, 11:30 a.m. to 1:30 p.m., [Poster No. SA0378]
- Teriparatide treatment in Japanese subjects with osteoporosis at high risk of fracture: effect of bone mineral density and bone turnover markers during 12-month, randomized, placebo-controlled, double-blind and 12-month open-label study periods (*Lead Author: Toshio Matsumoto*)
 - Oct. 15, 5:45 p.m. 7:00 p.m., [Poster No. FR0376]
 - Oct. 16, 11:30 a.m. to 1:30 p.m., [Poster No. SA0376]
- Association of fracture risk and quality of life as measured by the Osteoporosis Patient Assessment Questionnaire (*Lead Author: Steven Watts*)
 - Oct. 16, 11:30 a.m. to 1:30 p.m., [Poster No. SA0358]
- Fracture incidence, quality of life and back pain in elderly women (age >75 years) with osteoporosis treated with teriparatide: 36-month results from the European Forsteo Observational Study (EFOS) (*Lead Author: J.B. Walsh*)
 - Oct. 17, 11:00 a.m. to 1:00 p.m., [Poster No. SU0374]
- The anabolic effect of teriparatide in postmenopausal women with osteoporosis measured using nuclear scintigraphy during and after therapy (*Lead Author: Amelia EB Moore*)
 - Oct. 17, 11:00 a.m. to 1:00 p.m., [Poster No. SU0379]

- Teriparatide and risk of nonvertebral fractures in women with postmenopausal osteoporosis (*Lead Author: John H. Kregg*)
 - Oct. 17, 11:00 a.m. to 1:00 p.m., [Poster No. SU0300]
- Relationship between body composition and the skeleton (*Lead Author: Xiaohai Wan*)
 - Oct. 17, 11:00 a.m. to 1:00 p.m., [Poster No. SU0299]
- Modification of the Osteoporosis Patient Assessment Questionnaire using item response theory methods (*Lead Author: April N. Naegeli*)
 - Oct. 17, 11:00 a.m. to 1:00 p.m., [Poster No. SU0410]
- Characteristics of a Puerto Rican population initiating teriparatide therapy in the DANCE study (*Lead Author: Valerie Ruff*)
 - Oct. 18, 11:30 a.m. to 1:30 p.m., [Poster No. MO0370]
- Attitudes toward compliance of patients participating in a randomized controlled trial (*Lead Author: Deborah Gold*)
 - Oct. 18, 11:30 a.m. to 1:30 p.m., [Poster No. MO0394]
- Fractures in Commercial and Medicare Patients Treated with Raloxifene or Alendronate: A Retrospective Database Analysis (*Lead Author: Shonda A. Foster*)
 - Oct. 18, 11:30 a.m. to 1:30 p.m., [Poster No. MO0402]
- Safety and Effectiveness Profile of Raloxifene in Long-term, Prospective, Observational Study (Final Report) (*Lead Author: Etsuro Hamaya*)
 - Oct. 18, 11:30 a.m. to 1:30 p.m., [Poster No. MO0409]
- The effect of teriparatide on bone material properties is not different in postmenopausal women who were previously treatment-naïve or treated with alendronate (*Lead Author: Birgit Buchinger*)
 - Oct. 18, 5:30 p.m. to 5:45 p.m., [Poster No. 1251]

Important Safety Information 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.

Talk to your 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 such as redness, swelling, pain, itching, a few drops of blood, and bruising. These are not all the possible side effects of FORTEO.

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.rti.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.

Keep your FORTEO Delivery Device in the refrigerator between 36 degrees to 46 degrees F (2 degrees to 8 degrees 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 information about FORTEO, please see the full prescribing information, including boxed warning (<http://pi.lilly.com/us/forte-pi.pdf>). You may also learn more about FORTEO at www.Forteo.com.

Important Safety Information about EVISTA(R) (raloxifene HCl tablets)

You should not take EVISTA if you have had or are at risk for getting blood clots in the legs, lungs or eyes, as it may increase the risk of blood clots. Stop taking EVISTA and call your doctor if you have leg pain or warmth, swelling of the legs, hands or feet, chest pain, shortness of breath or a sudden vision change, as these may be signs of a blood clot. Being unable to move around for long periods may increase this risk. If you will need to be still for a long time, talk to your doctor about ways to reduce the risk of blood clots.

EVISTA does not increase the risk of a heart attack or stroke in women who have had or are at risk for a heart attack; however, EVISTA increases the likelihood of dying from stroke in these women, should one occur. Before taking EVISTA tell your doctor if you have had a stroke, a mini-stroke, irregular heartbeat, high blood pressure, heart attack, history of smoking, or believe you have other risk factors for stroke or a heart attack.

Before Taking EVISTA

EVISTA is not right for everyone. You should only take prescription EVISTA if you are past menopause.

Before taking EVISTA, talk to your doctor about all your medical conditions. If you are pregnant, nursing or may become pregnant, do not take EVISTA, as it may cause fetal harm. Women with liver or kidney disease should use EVISTA with caution.

EVISTA should not be taken with estrogens in the form of pills, patches or injections.

Side Effects

Side effects may include hot flashes, leg cramps, swelling, flu-like symptoms, joint pain, and sweating. 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.

For more information about EVISTA, please see the Full Prescribing Information, including Boxed Warning (<http://pi.lilly.com/us/evista-pi.pdf>), and Medication Guide (<http://pi.lilly.com/us/evista-ppi.pdf>). You may also learn more about EVISTA at www.EVISTA.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, 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. Additional information about Lilly is available at www.lilly.com.

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