Synthes and Lilly Sign Development and Collaboration Agreement

WEST CHESTER, Pa. and INDIANAPOLIS, June 9, 2011 /PRNewswire/ -- Synthes, Inc. (SIX: SYST.VX) and Eli Lilly and Company (NYSE: LLY) today announced the signing of an exclusive worldwide collaboration agreement to address the needs of patients who are cared for by orthopedic surgeons, including those with osteoporosis and those with bone fractures.

The agreement allows for the joint development and licensing of early stage compounds from Lilly to Synthes for use within orthopedic trauma, spine, craniomaxillofacial and reconstructive areas. These compounds have pre-clinical and in some cases clinical data packages and have the potential to aid in the local treatment and regeneration of the skeleton. The two companies will jointly develop site-specific osteoinductive (i.e. bone healing) products based on Synthes' biomaterials combined with Lilly's biologics or pharmaceuticals.

Within a second development program, Synthes and Lilly will jointly conduct and fund the evaluation of additional orthopedic uses for Lilly's osteoporosis drug Forteo® (teriparatide [rDNA origin] injection), marketed as Forsteo® in some countries outside of the United States). Building upon a Phase II study that Lilly has already completed, Lilly and Synthes will collaborate on additional clinical studies to evaluate potential future indications for Forteo, including fracture healing.

In addition to the development component of the agreement, the collaboration also includes the U.S. co-promotion of Forteo to orthopedic surgeons, an important segment of physicians who treat patients with a fracture due to osteoporosis. The companies will also co-promote Forteo in select countries and regions outside of the United States.

"I am very excited about this unique collaboration that will utilize the complementary clinical, development and operational strengths of each partner," said Michel Orsinger, president and CEO of Synthes. "Osteoporosis is one of the most significant unsolved clinical problems in orthopedics. Addressing the osteoporosis disease as well as the resulting fracture and bone defect is a significant strategic priority of both organizations," he continued. "Strategic collaborations between medtech and pharma companies represent a new and promising avenue to develop and market true innovations in a changing, dynamic market environment."

"We believe that patients worldwide will benefit from this collaboration because together we will be able to look for new ways to treat osteoporosis and bone fractures," said Bryce Carmine, executive vice president and president, Lilly Bio-Medicines, Eli Lilly and Company. "At Lilly, we are always exploring new opportunities to bring innovative medicines to people with unmet medical needs and improve outcomes for individual patients."

"Many orthopedic surgeons are in the position to diagnose and treat osteoporosis when their patients present with fractures, and we believe it is imperative to treat the underlying cause of the initial fracture," said Johnston Erwin, Bone/Muscle/Joint global development platform leader, Lilly Bio-Medicines, Eli Lilly and Company. "Our collaboration will also explore ways to treat fractures with Forteo in older patients and/or those who have osteoporosis and, longer term, will look for new ways to deliver medicine locally to the fracture site."

Financial terms of the agreement have not been disclosed.

Forteo, an FDA-approved osteoporosis therapy to help build new bone, is a treatment for postmenopausal women with osteoporosis who are at high risk for fracture(1) and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture.(2) Individuals at high risk for having broken bones include men and women with either a history of broken bones due to osteoporosis, who have several risk factors for fracture, or who cannot use other osteoporosis treatments.(1) Forteo is also approved to treat men and women with osteoporosis associated with sustained, systemic glucocorticoid therapy at high risk for fracture.(3) Forteo is a prescription medicine given as a 20 mcg once daily dose(4) 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.(6) For more information about Forteo, please see the important safety information, including Boxed Warning regarding osteosarcoma, below.

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.

Synthes: A leading medical device company

Synthes is a leading global medical device company, specialized in the development, manufacturing and marketing of instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.

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 degrees F to 46 degrees F (2 degrees C 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 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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This press release contains certain forward-looking statements about the collaboration between Synthes and Lilly and about Forteo for the treatment of osteoporosis in patients who are at high risk for a fracture. It reflects Synthes' and Lilly's current beliefs. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that the product will be commercially successful. There is also no guarantee that the collaboration will be successful. For further discussion of these and other risks and uncertainties, see Lilly's filing with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

The securities of Synthes have been offered and sold outside the United States and have not been and will not be registered under the U.S. Securities Act of 1933, as amended ("Securities Act"). Such securities may not be offered, sold or transferred in the U.S. or to U.S. Persons (as defined in the regulations of the Securities Act), except pursuant to a registration statement filed under the Securities Act or under an applicable exemption under the Securities Act. Hedging transactions involving such securities may not be conducted unless in compliance with the Securities Act. The Synthes securities are deemed "Restricted Securities" as that term is defined in Rule 144 under the Securities Act.

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(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

(Logo: http://photos.prnewswire.com/prnh/20110609/DE15577LOGO)

(1) FORTEO PI. Available at http://pi.lilly.com/us/forteo-pi.pdf. Page 2, Section 1.1. Accessed on April 21, 2011.

(2) FORTEO PI. Available at http://pi.lilly.com/us/forteo-pi.pdf. Page 2, Section 1.2. Accessed on April 21, 2011.

(3) FORTEO PI. Available at http://pi.lilly.com/us/forteo-pi.pdf. Page 2, Section 1.3. Accessed on April 21, 2011.

(4) FORTEO PI. Available at http://pi.lilly.com/us/forteo-pi.pdf. Page 2, Sections 2.1, 2.2, 2.3. Accessed on April 21, 2011.

(5) FORTEO PI. Available at http://pi.lilly.com/us/forteo-pi.pdf. Page 3, Section 3. Accessed on April 21, 2011.

(6) FORTEO PI. Available at http://pi.lilly.com/us/forteo-pi.pdf. Page 3, Section 5.1. Accessed on April 21, 2011.

SOURCE Eli Lilly and Company