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FDA Advisory Committee Recommends Approval of Lilly's Fortéo™ for the Treatment of Osteoporosis in Postmenopausal Women

Eli Lilly and Company has announced that the U.S. Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee unanimously recommended that the FDA approve Fortéo™ (teriparatide injection, rDNA origin), its investigational bone formation drug, as a treatment for osteoporosis in postmenopausal women and issued a 5-5 split vote on its recommendation as a treatment to increase bone mass in men with the disease. The FDA generally follows the recommendations of the advisory committee, though they are not binding.

"Today's review of Fortéo by the FDA advisory committee is an important step in delivering on our promise to remain at the forefront of osteoporosis research and in providing innovative solutions for the millions of Americans who suffer from this disease," said Dr. John Lechleiter, executive vice president, pharmaceutical products and corporate development, Lilly. "We will continue to work closely with the FDA in an effort to make this new compound available to physicians and patients with osteoporosis."

For individuals who have suffered prior osteoporotic fractures or have very low bone mass, a critical need remains for a therapy that can go beyond slowing or stopping bone loss. Fortéo is a bone formation agent - the first in a new class of investigational drugs that work primarily to stimulate new bone formation by increasing the number and/or activity of bone-forming cells called osteoblasts. Currently approved osteoporosis treatments work primarily to slow or stop bone loss, by reducing the number and/or activity of bone-removing cells called osteoclasts.

"Individuals with severe osteoporosis - who have suffered fractures or lost substantial amounts of bone - need a therapy that not only increases bone mass but also restores bone architecture, both of which could result in a dramatic reduction in osteoporosis-related fractures," said Dr. Felicia Cosman, osteoporosis specialist and medical director of the Clinical Research Center at Helen Hayes Hospital and clinical director of the National Osteoporosis Foundation. "Today's recommendation for the approval of the bone formation agent Fortéo represents an important step forward in treating these patients."

The development program for Fortéo included 25 clinical trials enrolling more than 2,800 men and postmenopausal women with osteoporosis. Pivotal Phase III clinical trial data - published May 10 in *The New England Journal of Medicine* - showed that the investigational drug stimulated new bone formation, significantly lowered fracture risk and significantly increased bone mineral density compared with placebo in postmenopausal women with osteoporosis during an average of 18 months' treatment. Other pivotal clinical trial data for men with osteoporosis showed significant increases in bone mineral density over 12 months' average treatment compared with placebo. In the two pivotal clinical trials, the most frequent treatment-related adverse events reported at the dose requested for marketing (20 micrograms) were generally mild; leg cramps were reported significantly more (2 percent) in postmenopausal women compared with placebo.

As is customary during the review process and as part of the recommendation, the Advisory Committee provided guidance related to duration of treatment, potential patient population, labeling and postmarketing surveillance.

Approximately 10 million American women and men over the age of 50 have osteoporosis, and another 18 million are at risk for developing the disease due to low bone mass.¹ Studies suggest that osteoporosis may be a quickly progressing disease once a fracture occurs.² Direct annual costs associated with treating osteoporotic fractures in the U.S. are estimated between \$10 and \$15 billion and are expected to more than quadruple - exceeding \$60 billion annually - by 2030.³

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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.

This press release contains forward-looking statements about the investigational compound Fortéo that reflect management's current beliefs. However, as with any pharmaceutical under development, there are risks and uncertainties in the process of development and regulatory review. There are no guarantees that the product will receive regulatory approvals or prove to be commercially successful. In particular, while the FDA typically follows the recommendations of its advisory committees, there is no assurance that it will do so. There is also no assurance of the timing of final FDA action on the compound. In addition, new pharmaceutical products can face risks of intellectual property claims and product litigation. For further discussion of these and

other risks and uncertainties affecting the company's business, please see Exhibit 99 to the company's latest Form 10-Q filed May 2001.

References:

¹*Boning Up on Osteoporosis: A Guide to Prevention and Treatment.* National Osteoporosis Foundation.2000;2, 6, 31, 44.

²Consensus Conference: Osteoporosis Prevention, Diagnosis and Therapy. *Journal of the American Medical Association.* 2001;285:787.

³Lindsay R, et al. Risk of New Spinal Fracture in the Year Following Fracture. *Journal of the American Medical Association.* 2001;285:320-324.