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**FOR IMMEDIATE RELEASE, OCTOBER 5, 1999:**

## **LOCAL PHYSICIAN INVOLVED IN THE CLINICAL STUDY OF RALOXIFENE**

### **FDA Approves Evista<sup>®</sup> (Raloxifene) for the Treatment of Osteoporosis**

Craig R. Sweet, M.D., board certified in Reproductive Endocrinology & Infertility and Obstetrics & Gynecology, was involved in the Phase III clinical study investigating Evista (Raloxifene) in the post-menopausal patient. The U.S. Food and Drug Administration (FDA) recently approved the use of Evista for the *treatment of post-menopausal osteoporosis*.

Raloxifene, marketed by the Eli Lilly and Company as Evista, is a Selective Estrogen Receptor Modulator (SERM). This medication is often described as a “designer estrogen” because it both prevents and treats osteoporosis in a similar manner as estrogen while not exhibiting some of the common undesirable side effects. Specifically, Evista does not increase the risk of breast or uterine cancers, breast discomfort and uterine bleeding. In fact, Evista seems to have an “anti-estrogen” effect at these specific sites.

What also makes Evista unique is its ability to improve lipid profiles as well as to seemingly reduce the incidence of breast cancer by 76%.<sup>1,2</sup> It should be noted that Evista is not indicated for these specific uses and research is ongoing.

As an FDA approved drug, Evista was approved two years ago for the prevention of post-menopausal osteoporosis. Studies had shown Evista to increase bone mineral density at the lumbar

spine and hip by about 2% over a 24-month period.<sup>3</sup> This increase was compared to using calcium alone, which lost 1% of the bone mass over the two-year study period. The FDA approved data was based on 50 studies conducted in 28 countries with 12,000 women evaluated in the various studies.

More recently, the FDA approved Evista for the treatment of post-menopausal osteoporosis.<sup>4</sup> Findings from the ongoing Multiple Outcomes of Raloxifene Evaluation (MORE) trial, a multicenter study involving 7,705 women with osteoporosis, were the basis for the FDA decision. Administered once daily, Evista decreased the incidence of spinal fracture by about half. This work conclusively showed the medication to not only increase bone mineral density (BMD) but to also reduce clinical fractures. Evista also significantly increased spinal and hip BMD compared with the placebo groups.

Post-menopausal osteoporosis threatens approximately 23 million American women.<sup>5</sup> Approximately every 30 seconds in the U.S., one osteoporotic fracture occurs among women. One in two women over age 50 will suffer an osteoporotic fracture during her lifetime.<sup>6,7</sup> Evista is the only SERM on the market to both prevent *and* treat post-menopausal osteoporosis, a debilitating disease.

Women who may want to consider taking Evista are:

1. Women who have documented post-menopausal thinning of the bones (osteopenia).
2. Women who have documented post-menopausal osteoporosis of the bones.
3. Women who do not wish or should not take estrogens.
4. Women who do not want to have vaginal bleed with their hormone therapy.
5. Women who are concerned about the theoretical risks of estrogen and breast cancer.

Women who are of reproductive age, nursing, have severe liver problems or have a history of blood clots should be cautious while taking Evista. Hot flashes may occur in 6% more of the women on Evista compared to placebo. Leg cramps also occur in 4% more of the women on Evista compared to placebo. Full prescribing information is available via fax by calling 1-800-753-0352, extension 708.

Dr. Sweet commented, "This medicine has a wonderful potential for the prevention and now the treatment of many diseases that are found in women." Dr. Sweet is available to discuss the advantages and the disadvantages of the use of Evista in the post-menopausal patient. Additional information on Evista can be found on his web site at <http://www.dreamababy.com/evista-approved.htm>.

## **References:**

1. Walsh BW, et al. Effects of Raloxifene on serum lipids and coagulation factors in healthy postmenopausal women. JAMA 1999;279:1445-51.
2. Cummings SR. et al. the effect of Raloxifene on risk of breast cancer in postmenopausal women: Results from the MORE Randomized Trial. JAMA 1999;281:2189-97.
3. Delmas PD, et al. Effects of Raloxifene on bone mineral density, serum cholesterol concentrations and uterine endometrium in postmenopausal women. NEJM 1997;337:1641-7.
4. Cummings SR, et al. Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with Raloxifene: Results from a 3-year randomized clinical trial. JAMA 1999;282:637-45.
5. 1996 and 2015 Osteoporosis Prevalence figures. State-by-State Report. Washington, DC, National Osteoporosis Foundation, 1997.1. (<http://www.nof.org/>)
6. Arch Intern Med. 1991;151:2026-32.
7. J Bone Res. 1995;10:175-7.

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