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Medical Center

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EMBARGOED UNTIL WEDNESDAY, AUGUST 13, 2008 AT 5.00 P.M. ET

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Tibolone Reduces Risk of Fractures and Breast Cancer but Increases Stroke Risk in Older Women
International trial finds mixed results for drug used by postmenopausal women

(San Francisco, August 13, 2008) Tibolone, a synthetic drug used in many countries mainly to treat menopausal symptoms, reduces the risk of fractures and breast cancer, but also increases the risk of stroke in older women. Those are the findings of a study published in the August 14 issue of the *New England Journal of Medicine*.

Researchers recruited 4,538 women from 22 countries, between the ages of 60 and 85, for this randomized, double-blind study. Half were given 1.25 mg of tibolone daily, half were given an identical placebo. Those given tibolone had a decreased risk of vertebral fractures by 45% and the risk of other types of fractures by 26%.

In addition tibolone reduced the risk of breast cancer. The effect of tibolone was comparable to that seen in women given the drugs tamoxifen or raloxifene.

“The reduction in breast cancer risk was a surprise to us,” says Steven R. Cummings, M.D., of the California Pacific Medical Center Research Institute and the lead author of the study. “We don’t know how tibolone reduces breast cancer risk. Understanding its mechanism might point us toward new ways to prevent the disease.” In addition, the rate of colon cancer was lower in women who received tibolone. The mechanism for this effect is also unknown.

However, the drug came with a significant side effect: the rate of stroke was 2.3 per 1,000 woman – years higher in women taking tibolone than those taking the placebo, representing a doubling of the risk of stroke. The study did not include women under age 60, and thus cannot determine whether tibolone significantly increases risk in that age group.

Even so, Dr. Cummings says tibolone may still have some value for younger women. “Stroke is very rare among women under age 60, so although taking tibolone does slightly increase the risk for women in their 50s, the benefits of treatment for bothersome menopausal symptoms would outweigh those risks.”

Dr. Cummings says the drug should not be given to women who have risk factors for stroke, such as hypertension or diabetes, nor should it be continued after age 65.

Tibolone is currently approved in 90 countries worldwide for the treatment of menopausal symptoms, and in 45 countries to prevent osteoporosis. It is not available in the United States.

California Pacific Medical Center. Beyond Medicine.

At San Francisco's California Pacific Medical Center, we believe in the power of medicine. We research the most up-to-date treatments, hire the most qualified individuals, and practice the most modern, innovative medicine available. We deliver the highest quality expert care, with kindness and compassion, in acute, post-acute and outpatient services, as well as preventive and complementary medicine. But we also believe that medicine alone is only part of the solution. That's why we look intently at each individual case and treat the whole person, not just the illness. It's why we go beyond medical care and provide our patients with things like disease counseling, family support and wellness treatments. As one of California's largest private, community-based, not-for-profit, teaching medical centers, and a Sutter Health affiliate, we are able to reach deep into our community to provide education, screening and financial support in some of the city's most underserved neighborhoods. Because medicine can transform a body. But going beyond medicine can transform a life.

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