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Head-to-Head Osteoporosis Fracture Study to Compare Evista® and Fosamax®

With an ever-increasing number of therapy options, managing postmenopausal women's health has never been more promising-or confusing. Today, however, Eli Lilly and Company has announced a new, large-scale, head-to-head clinical trial designed to provide clarity among two leading therapy options used to prevent and treat osteoporosis in women past menopause.

The EVista Alendronate Comparison (EVA) trial is a head-to-head fracture study comparing Evista (raloxifene HCl), a selective estrogen receptor modulator (SERM), and Fosamax (alendronate sodium), a bisphosphonate. Both drugs are available in the United States for the prevention and treatment of osteoporosis in postmenopausal women.

The EVA trial is the first large-scale, head-to-head study comparing a SERM and a bisphosphonate. It's also the first head-to-head fracture trial comparing approved osteoporosis therapies.

"This clinical trial represents a considerable investment that underscores Lilly's continuing confidence in the efficacy and growth potential of Evista," said Deirdre Connelly, women's health business unit leader, Eli Lilly and Company. "We believe EVA will show that Evista is at least equivalent to Fosamax in reducing the risk of fractures, plus may offer additional significant health benefits."

"We're eager to compare Evista against the leading bisphosphonate," said Leo Plouffe, Jr., M.D., Lilly U.S. medical director for women's health. "Previous clinical trials have shown that Evista significantly reduced the risk of osteoporosis-related fractures in postmenopausal women and provided encouraging data regarding the drug's potential effects in the breast and heart. It's exciting to add EVA to our growing list of ongoing clinical trials that will help further establish the efficacy and safety profile of Evista."

"We know from previous clinical trials that raloxifene and alendronate are both effective therapies for preventing and treating osteoporosis in postmenopausal women," said Jane Cauley, Ph.D., a University of Pittsburgh researcher who has studied both drugs in the clinical setting. "But it's inappropriate to compare the data from these previous clinical trials because the studies were designed differently. You need a head-to-head study such as EVA to make meaningful comparisons."

EVA Study Design

The EVA clinical trial is a rigorously designed multi-center, double-blind, randomized study. It will enroll about 3,000 postmenopausal women, 50-80 years of age, with osteoporosis who live in the United States, Puerto Rico and Canada. Approximately half the patients will receive raloxifene 60mg/day and the other half alendronate 10mg/day. All patients will be followed for five years, with early results expected in 2006.

The primary objective of EVA is to compare the effect of Evista and Fosamax on reducing the risk of osteoporosis-related fractures of any type, including those of the spine, hip and wrist. In addition, EVA will compare a number of other important endpoints, including the incidence of osteoporotic fractures at specific sites, the incidence of newly diagnosed breast cancer and other safety-related endpoints.

Approximately 150 investigation sites will participate in the EVA trial. Patient recruitment is expected to begin in October 2001. EVA will be the first large-scale osteoporosis clinical trial to place special emphasis on recruiting African-American, Hispanic and other postmenopausal minority women in North America. This is important as minority women have largely been underrepresented in previous osteoporosis studies.

"Many factors beyond fracture reduction efficacy may be involved in the choice of a therapy for osteoporosis, including additional health benefits and side effects," said Wulf Utian, M.D., Ph.D., executive director, North American Menopause Society. "Given the problems associated with comparing results across separate clinical trials, a head-to-head, evidence-based trial evaluating a SERM to a bisphosphonate will assist physicians and patients in making informed therapeutic decisions."

Postmenopausal women and healthcare professionals who are interested in learning more about the EVA study can call toll free at 1-877-CTLILLY (1-877-285-4559).