Women's Health UPDATE

Study of Osteoporosis Drugs May Aid Physicians and Patients

(NAPSA)—Osteoporosis, America's "silent disease," is a chronic condition that can lead to bone loss and susceptibility to fractures, especially of the hip, spine and wrists. One in two women over age 50 will have an osteoporosis-related fracture in her lifetime. More than 10 million people in the U.S. are estimated to have osteoporosis and another 34 million are estimated to have low bone mass. Although osteoporosis can affect men and women alike, more than 80 percent of those with the disease are women. The loss of bone mass that can occur after menopause increases the risk of a woman developing osteoporosis and other related fractures.

Bone mineral density (BMD) measures the density of bone and is the standard measurement to diagnose osteoporosis. BMD is a major determinant of bone strength. The lower the BMD score, the greater the risk of fracture. It has been established that women with postmenopausal osteoporosis have accelerated bone turnover, with the result that the amount of new bone produced is insufficient to replace the amount of bone that is "resorbed" or broken down. An increase in bone turnover is common after menopause.

In the first U.S. head-to-head study comparing two leading osteoporosis treatments in postmenopausal women with osteoporosis, Fosamax® Once Weekly (alendronate sodium) increased BMD more than Actonel® Once-a-Week (risedronate) with similar tolerability. The results of the 12-month Fosamax Actonel Comparison Trial (FACT) were presented recently at the American Society for Bone Mineral Research (ASBMR) meeting in Seattle.

The study findings showed Fosamax provided greater increases in BMD at all sites measured as early as six months. In comparison with Actonel, Fosamax lowered levels of biochemical markers of bone turnover further within the normal premenopausal range within three months. Reducing and stabilizing bone turnover, which leads to increased bone density, are important factors in improving bone strength in patients with osteoporosis. A 12-month extension of this study, and a second similarly designed study, are currently underway.

Osteoporosis is called the "silent disease" because bone loss occurs without symptoms.

"In this 12-month study, Fosamax demonstrated greater increases in BMD and greater reductions in bone turnover and similar tolerability compared to Actonel," said Dr. Marc Hochberg, Professor of Medicine and Epidemiology and Preventive Medicine at the University of Maryland School of Medicine in Baltimore. "Studies like FACT, that make direct 'head-to-head' comparisons between treatments, are important because they provide important information to clinicians for use in making treatment decisions for postmenopausal women with osteoporosis."

Side effects were similar between the two groups, including upper gastrointestinal side-effects occurring in 22.5 percent and 20.1 percent of the patients in the Fosamax and Actonel groups, respectively (p=0.364). Drug related side effects greater than or equal to one percent in either treatment group in this study, included abdominal pain, diarrhea, constipation, heartburn/dyspepsia, flatulence, nausea, vomiting, joint pain, muscle pain, and headache.

The year-long clinical trial examined more than 1,000 postmenopausal osteoporotic women with low BMD (T-score less than or equal to -2.0 at either hip trochanter, total hip, femoral neck or spine). The study compared the effects of Fosamax 70 mg Once-Weekly to Actonel 35mg Once-A-Week on BMD, bone turnover and tolerability. Study participants had a mean age of 65 years and were given 1,000 mg of calcium daily and 400 international units (IU) of vitamin D either from food or a supplement.

Important information about Fosamax

Fosamax, like other bisphosphonates, should be used with caution in people with certain stomach or digestive problems. Fosamax should not be used if the patient has certain disorders of the esophagus that delay emptying or if the patient is unable to stand or sit upright for at least 30 minutes. In addition, Fosamax should not be used in patients with severe kidney disease or low levels of calcium in their blood, in patients who are allergic to Fosamax or in patients who are pregnant or nursing. Patients who have difficulty swallowing liquids should not take Fosamax oral solution.

Some patients may develop severe digestive reactions including irritation, inflammation or ulceration of the esophagus. The risk of severe esophageal experiences appears to be greater in patients who fail to follow dosing instructions (see prescribing information for more details). Patients who experience new or worsening heartburn, difficulty or pain when swallowing or chest pain should stop taking the drug and consult their doctor. The most commonly reported side effects with Fosamax in other clinical studies have been abdominal pain, musculoskeletal pain, indigestion, regurgitation and nausea.

Fosamax is the only medicine approved by the U.S. Food and Drug Administration for the treatment of osteoporosis to reduce the risk of both spine and hip fractures in postmenopausal women.

For more information about Fosamax, please visit www.fosamax.com.

Fosamax is prescribed for:

- The treatment or prevention of osteoporosis (thinning of bone) in women after menopause. It reduces the chance of having a hip or spinal fracture.
- Treatment to increase bone mass in men with osteoporosis.
- The treatment of osteoporosis in both men and women receiving corticosteroid medications (for example, prednisone).