



New Study Shows Once-Monthly Boniva[®] is as Clinically Effective as Once-Weekly Fosamax[®] at Increasing Bone Mineral Density in Postmenopausal Women with Osteoporosis

HONOLULU, September 19, 2007 – Women with postmenopausal osteoporosis receiving once-monthly Boniva[®] (ibandronate sodium) achieved clinically comparable increases in bone mineral density (BMD) to those receiving once-weekly Fosamax[®] (alendronate sodium), according to a new study presented at the 29th Annual Meeting of the American Society for Bone and Mineral Research.

The study, called MOTION (Monthly Oral Therapy with Ibandronate for Osteoporosis inIntervention), is the first head-to-head non-inferiority study comparing the efficacy and safety of once-monthly Boniva to once-weekly Fosamax. Efficacy was determined as improvements in BMD of the lumbar spine and total hip over a 12-month period, using a predetermined non-inferiority margin.

In this study, once-monthly Boniva and once-weekly Fosamax were clinically comparable at increasing average BMD at both the lumbar spine and total hip. Overall, adverse events were similar in both treatment groups.

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“For clinicians, the data reinforce the fact that their patients can benefit from once-monthly dosing,” said Sol Epstein, MD, Professor of Medicine and Geriatrics at Mount Sinai Medical School in New York and investigator of the MOTION study.

Boniva and Fosamax are both bisphosphonates, the most frequently prescribed class of medication for the treatment and prevention of postmenopausal osteoporosis.

About MOTION

MOTION was a multicenter, randomized, double-blind, double-dummy, parallel-group, non-inferiority trial that included 1,733 treated women, 55 to 84 years old, with postmenopausal osteoporosis. The women took either once-monthly oral Boniva 150 mg or once-weekly oral Fosamax 70 mg for 12 months. They also received vitamin D and calcium supplements. The primary endpoints were the relative change (%) from baseline in average BMD of the lumbar spine and the total hip after 12 months of treatment. Clinical difference between the two groups was defined as BMD changes of $\geq 1.41\%$ for lumbar spine and $\geq 0.87\%$ for total hip.

The primary efficacy analysis was based on the per protocol population. By 12 months, increase in average lumbar spine BMD was 5.10% among those taking Boniva and 5.78% among those taking Fosamax. Increase in average total hip BMD was 2.94% and 3.03%, respectively. In addition, treatment with Boniva versus Fosamax provided comparable increases in BMD at the trochanter (4.2% for both) and in the femoral neck (2.1% vs. 2.3%, respectively, in a post-hoc analysis). A low BMD is one of the most important underlying causes of fractures in older adults. However, fracture was not an efficacy endpoint in the trial.

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In the safety analysis, the overall incidence of adverse events was similar between the treatment groups. The most frequently reported adverse events (reported by at least 5% of women in either treatment group) included hypertension, dyspepsia, back pain, arthralgia, nasopharyngitis, and influenza. Of the serious adverse events, less than 1% per group were considered treatment related.

About Osteoporosis

Osteoporosis (porous bones) is a disease in which bones become brittle and more likely to break. In the U.S. today, 10 million people -- eight million of them women -- are estimated to already have osteoporosis, and almost 34 million more are estimated to have low bone mass (osteopenia) placing them at increased risk for osteoporosis. Unfortunately, the prevalence of osteoporosis is growing, especially as the number of postmenopausal women in the population continues to rise. Together, osteoporosis and osteopenia are expected to affect an estimated 52 million women and men age 50 and older by 2010, and 61 million by 2020. Direct medical costs of osteoporosis total nearly \$18 billion in the U.S. each year.

About Once-Monthly Oral Boniva

Boniva is indicated for the treatment and prevention of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, Boniva increases bone mineral density and reduces the incidence of vertebral fractures. Boniva also may be considered for postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and reduce the risk of vertebral fracture.

Once-monthly Boniva is a small, film-coated, easy-to-swallow tablet dosed at 150 mg. Patients should take Boniva with plain water on an empty stomach upon rising in the morning. They should remain upright and avoid food, drink and other medications for at least 60 minutes.

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Patients who take Boniva are eligible to sign up for MyBONIVA, a program designed to help enhance compliance (taking therapy as directed) and persistence with this unique once-monthly regimen. For more information on this program call 1-800-4BONIVA or visit www.MyBoniva.com.

Important Safety Information

Boniva is contraindicated in patients unable to stand or sit upright for at least 60 minutes, with uncorrected hypocalcemia, or with known hypersensitivity to any component of Boniva. Boniva, like other bisphosphonates administered orally, may cause upper gastrointestinal disorders such as dysphagia, esophagitis, and esophageal or gastric ulcer. Boniva is not recommended in patients with severe renal impairment. Adequate intake of calcium and Vitamin D is important in all patients.

Rarely, patients have reported severe bone, joint and/or muscle pain after taking bisphosphonate therapy for osteoporosis. Additionally, osteonecrosis of the jaw has been reported in patients treated with bisphosphonates; most cases have been in cancer patients undergoing dental procedures.

The most commonly reported adverse events with once-monthly Boniva regardless of causality were abdominal pain (Boniva 150 mg 7.8% vs. Boniva 2.5 mg 5.3%), hypertension (6.3% vs. 7.3%), dyspepsia (5.6% vs. 7.1%), arthralgia (5.6% vs. 3.5%), nausea (5.1% vs. 4.8%) and diarrhea (5.1% vs. 4.1%). For complete prescribing information for Boniva, see contact information at the end of the news release or go to www.Boniva.com.

Boniva is co-promoted by Roche and GSK.

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About Roche

Hoffmann-La Roche Inc. (Roche), based in Nutley, N.J., is the U.S. pharmaceutical headquarters of the Roche Group, one of the world's leading research-oriented healthcare groups with core businesses in pharmaceuticals and diagnostics. For more than 100 years in the U.S., Roche has been committed to developing innovative products and services that address prevention, diagnosis and treatment of diseases, thus enhancing people's health and quality of life. For additional information about the U.S. pharmaceuticals business, visit our websites: <http://www.rocheusa.com> or www.roche.us.

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