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IBANDRONATE REDUCES

STUDY DEMONSTRATES IBANDRONATE REDUCES
NEW VERTEBRAL FRACTURES WITH BETWEEN-DOSE INTERVALS
OF GREATER THAN TWO MONTHS

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Ibandronate, a potent bisphosphonate currently under clinical investigation for the treatment and prevention of osteoporosis in post-menopausal women, was shown to reduce new vertebral fractures, according to data presented here at the 24th annual meeting of the American Society for Bone Mineral Research (ASBMR). Based on findings from the large, multinational study¹, ibandronate is the first bisphosphonate shown to reduce new vertebral fractures with a between dose interval of greater than two months, holding promise for development of new convenient, less frequent dosing regimens. Ibandronate is under joint development by Roche and GlaxoSmithKline.

Results presented from BONE, a three-year, pivotal phase III trial in more than 2,900 women with postmenopausal osteoporosis showed oral 2.5 mg daily ibandronate reduced the risk of new vertebral fractures by 62 percent compared with placebo. In addition, study results showed an intermittent (20 mg) dose of oral ibandronate taken every other day for 24 days followed by a between-dose interval of greater than two months (i.e. 9-10 weeks), reduced the risk of new vertebral fractures by 50 percent compared with placebo.¹

"These findings are encouraging because they show that ibandronate reduced the risk of new vertebral fractures in women with post-menopausal osteoporosis", said Robert Recker, M.D., chief of endocrinology and director of the Osteoporosis Research Center at the Creighton University School of Medicine, Omaha, Nebraska and an investigator in the study. "Importantly, data from the intermittent regimen provide a scientific basis for evaluation of new dosing regimens that require less frequent dosing. Such regimens may offer added convenience for patients", he said.

Study and Findings

The presentation reported findings from a three-year, randomized, double-blind, placebo-controlled, multinational phase III pivotal study and expanded on information first reported at the World Congress on Osteoporosis earlier this year. In the study, 2,946 post-menopausal women between age 55 and 80 years with osteoporosis were treated with either placebo or one of two oral ibandronate schedules: daily (2.5 mg) or intermittent (20 mg) taken every other day for 24 days followed by a between-dose interval of greater than two months. All participants received daily oral calcium (500 mg) and vitamin D (400 IU) supplementation.

Over the three years of the study, the daily and intermittent ibandronate regimens significantly reduced new vertebral fractures by 62 percent and 50 percent, respectively, compared to placebo. The cumulative incidence of vertebral fractures in the placebo group was 9.6% over three years, 4.7% in the 2.5mg daily group and 4.9% in the 20mg intermittent group.

In the study, ibandronate demonstrated a favorable tolerability profile, with the most commonly reported adverse events being (percent of patients taking placebo, ibandronate 2.5 mg daily, and ibandronate 20 mg intermittent, respectively): upper respiratory tract infection (31, 32, 31), back pain (13, 14, 16), arthralgia (14, 14, 15), dyspepsia (9, 11, 9) and bronchitis (7, 11, 9). The percentage of patients who withdrew from the study due to adverse events was approximately 18 percent in each of the three groups.

About Ibandronate

Ibandronate has been studied to date in clinical trials involving more than 9,000 patients. The ongoing clinical development program is evaluating monthly oral and intermittent intravenous dosage regimens in women with post-menopausal osteoporosis.

About Osteoporosis

Osteoporosis is a disease characterized by low bone mass, increased fragility and a consequent increase in fracture risk and disability. It is estimated that one out of three post-menopausal women aged 50 years and older is affected by osteoporosis. One in two women over the age of 50 will have an osteoporosis-related fracture in their lifetime. Approximately 80 percent of people with osteoporosis are women, and 20 percent are men.

About the Roche/GlaxoSmithKline Alliance

In December 2001, Roche and GlaxoSmithKline announced that they will co-develop and plan to co-promote ibandronate for the treatment of postmenopausal osteoporosis. Roche and GlaxoSmithKline plan to co-promote ibandronate in all countries, except Japan. The Roche/GSK alliance provides expertise and commitment to bring new osteoporosis therapies to market as quickly as possible.

About Roche

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Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well being and quality of life.

About GlaxoSmithKline

GlaxoSmithKline, one of the world's leading research-based pharmaceutical and healthcare companies, is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information, visit GlaxoSmithKline on the World Wide Web at www.gsk.com

Recker R, Stakkestad JA, Weber T, Cohen S, Delmas P, Schimmer R, Mahoney P, Kilbride J. Non-vertebral fracture benefit from oral ibandronate administered daily or with a unique drug-free interval: results from a pivotal phase III study in postmenopausal osteoporosis (PMO). Oral presentation 1038 at: annual meeting of the American Society for Bone Mineral Research, September 21, 2002, San Antonio Texas.

Delmas P et al. Oral ibandronate significantly reduces fracture risk in postmenopausal osteoporosis when administered daily or with a unique drug-free interval: results from a pivotal phase III study. Oral presentation at: the World Congress on Osteoporosis, May 2002, Lisbon, Portugal, abstract 037.

National Institutes of Health Osteoporosis and Related Bone Diseases - National Resource Center; Fast Facts on Osteoporosis