New Phase III Data Presented for Once Monthly Dosing Regimen of Risedronate to Treat Postmenopausal Osteoporosis

Release Date:
Wednesday, September 19, 2007 8:08 am EDT

Terms:
P&G Corporate Announcements

Dateline City:
HONOLULU

Results from a Phase III clinical trial evaluating the efficacy and safety of risedronate 150 mg once monthly for the treatment of postmenopausal osteoporosis were presented at the American Society for Bone and Mineral Research (ASBMR) 29th Annual Meeting. In the non-inferiority study comparing risedronate 150 mg once monthly to risedronate 5 mg daily [Actonel(R) (risedronate sodium tablets)] increases in bone mineral density (BMD) were similar for patients taking either the monthly or daily dosing regimens.

In the study, BMD was measured at the lumbar spine, total hip, femoral neck, and femoral trochanter. There were no statistically significant differences in BMD increases between the risedronate 150 mg once monthly and the 5 mg daily dose groups at 12 months. In the study, the tolerability and safety profiles were also similar for the monthly and daily dosing regimens of risedronate.

"Risedronate is already approved to reduce the risk of both spinal and nonspinal fractures," said Michael McClung, M.D., Founding Director of the Oregon Osteoporosis Center in Portland, Oregon. "For patients who prefer less frequent dosing, risedronate 150 mg, if approved, would provide the convenience of a once monthly dosing option."

About the Study

The MERIT-OP (Monthly Evaluation of Risedronate Trial in Osteoporosis) study is a 2-year, randomized, double-blind, active-control (5 mg daily risedronate) clinical trial which evaluated 1,292 postmenopausal women (94% Caucasian) between 50 and 88 years old, mean age 64.9, from 47 clinical centers in 13 countries. The participants had osteoporosis, defined as a lumbar spine (LS) BMD T-score less than -2.5 or a LS BMD T-score less than -2.0 and at least one prevalent vertebral fracture. Patients were randomized to dosing regimens of either risedronate 150 mg monthly or risedronate 5 mg daily and received daily supplements of calcium (1,000 mg) and vitamin D (400-1000 IU). The primary efficacy endpoint of the study was to demonstrate non-inferiority of the risedronate 150 mg monthly regimen to the risedronate 5 mg daily regimen as assessed by percent change from baseline in LS BMD at 12 months. The 24 month results will be reported at a later time. At 12 months, the mean LS BMD increases were 3.54% and 3.43% for the monthly and daily regimens, respectively. The most common adverse events for risedronate 5 mg and risedronate 150 mg, respectively, were upper abdominal pain (6.1% vs. 8.2%), influenza (4.2% vs. 8.9%) and constipation (7.3% vs. 5.8%).

The trial was sponsored by The Alliance for Better Bone Health.

About Actonel(R) (risedronate sodium tablets)

Actonel is approved for the prevention and treatment of osteoporosis in postmenopausal women. Actonel has been proven to reduce the incidence of vertebral fractures, and nonvertebral fractures at a composite endpoint of leg, hip, pelvis, clavicle, humerus and wrist. The following doses are approved: Actonel 5 mg daily, Actonel 35 mg once-a-week, and Actonel 75 mg two consecutive days per month.

In clinical trials, Actonel was generally well tolerated. Actonel is contraindicated in patients with hypocalcemia, known hypersensitivity to any component of this product, or inability to stand or sit upright for at least 30 minutes. Hypocalcemia and other disturbances of bone and mineral metabolism should be effectively treated before starting Actonel therapy. Actonel is not recommended for use in patients with severe renal impairment (creatinine clearance < 30 mL/min).

Bisphosphonates may cause upper gastrointestinal disorders such as dysphagia, esophagitis and esophageal or gastric ulcer. Patients should pay particular attention to the dosing instructions, as failure to take the drug according to instructions may compromise clinical benefits and may increase the risk of adverse events.

Among patients treated with bisphosphonates, there have been infrequent reports of severe and occasionally incapacitating bone, joint and/or muscle pain. Rare occurrences of osteonecrosis, primarily of the jaw (ONJ), have been reported in patients receiving bisphosphonates. Most ONJ cases have occurred in cancer patients undergoing dental procedures. In the majority of cases reported, patients had received intravenous bisphosphonate therapy.

In clinical trials of up to 3-years duration, the overall incidence of adverse events with Actonel 5 mg daily was comparable to placebo. The most commonly reported adverse events regardless of causality were infection (primarily upper respiratory, placebo 29.7% vs Actonel 5 mg 29.9%), back pain (23.6% vs 26.1%), and arthralgia (21.1% vs 23.7%).
In a clinical trial comparing Actonel 35 mg Once-a-Week and Actonel 5 mg daily for 1 year, the overall safety and tolerability profiles of the two dosing regimens were similar. The most commonly reported adverse events regardless of causality were infection (Actonel 35 mg 20.6% vs Actonel 5 mg 19.0%), arthralgia (14.2% vs 11.5%) and constipation (12.2% vs 12.5%).

In a clinical trial comparing Actonel 75 mg two consecutive days/month and Actonel 5 mg daily for 1 year, the overall safety and tolerability profiles of the two dosing regimens were similar. The most commonly reported adverse events regardless of causality were arthralgia (Actonel 75 mg 10.4% vs Actonel 5 mg 9.5%), dyspepsia (9.1% vs 7.3%), and back pain (8.8% vs 10.8%).

Please see full prescribing information for Actonel(R) (risedronate sodium tablets) for additional safety information. For a copy of the full prescribing information for Actonel visit the Actonel Web site at http://www.actonel.com.

About The Alliance for Better Bone Health

The Alliance for Better Bone Health was formed in May 1997 to promote bone health and disease awareness through numerous activities to support physicians and patients around the globe. It is a collaboration between Procter & Gamble Pharmaceuticals and sanofi-aventis U.S.

About Procter & Gamble (NYSE: PG)

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About sanofi-aventis

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (Euronext: SAN) and in New York (NYSE: SNY).

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Language:
English

Ticker Slug:
Ticker: PG
Exchange: NYSE