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)

Three billion times a day, P&G brands touch the lives of people around the world. The company has one of the strongest portfolios of trusted, quality, leadership brands, including Pampers(R), Tide(R), Ariel(R), Always(R), Whisper(R), Pantene(R), Mach3(R), Bounty(R), Dawn(R), Gain(R), Pringles(R), Folgers(R), Charmin(R), Downy(R), Lenor(R), Iams(R), Crest(R), Oral-B(R), Actonel(R), Duracell(R), Olay(R), Head & Shoulders(R), Wella(R), Gillette(R), and Braun(R). The P&G community consists of 138,000 employees working in over 80 countries worldwide. Please visit http://www.pg.com for the latest news and in-depth information about P&G and its brands.

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).

For P&G: All statements, other than statements of historical fact included in this release, are forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995. Such statements are based on financial data, market assumptions and business plans available only as of the time the statements are made, which may become out of date or incomplete. We assume no obligation to update any forward-looking statement as a result of new information, future events or other factors. Forward-looking statements are inherently uncertain, and investors must recognize that events could differ significantly from our expectations. In addition to the risks and uncertainties noted in this release, there are certain factors that could cause actual results to differ materially from those anticipated by some of the statements made. These include: (1) the ability to achieve business plans, including with respect to lower income consumers and growing existing sales and volume profitably despite high levels of competitive activity, especially with respect to the product categories and geographical markets (including developing markets) in which the Company has chosen to focus; (2) the ability to successfully execute, manage and integrate key acquisitions and mergers, including (i) the Domination and Profit Transfer Agreement with Wella, and (ii) the Company's merger with The Gillette Company, and to achieve the cost and growth synergies in accordance with the stated goals of these transactions; (3) the ability to manage and maintain key customer relationships; (4) the ability to maintain key manufacturing and supply sources (including sole supplier and plant manufacturing sources); (5) the ability to successfully manage regulatory, tax and legal matters (including product liability, patent, and intellectual property matters as well as those related to the integration of Gillette and its subsidiaries), and to resolve pending matters within current estimates; (6) the ability to successfully implement, achieve and sustain cost improvement plans in manufacturing and overhead areas, including the Company's outsourcing projects; (7) the ability to successfully manage currency (including currency issues in volatile countries), debt, interest rate and commodity cost exposures; (8) the ability to manage continued global political and/or economic uncertainty and disruptions, especially in the Company's significant geographical markets, as well as any political and/or economic uncertainty and disruptions due to terrorist activities; (9) the ability to successfully manage competitive factors, including prices, promotional incentives and trade terms for products; (10) the ability to obtain patents and respond to technological advances attained by competitors and patents granted to competitors; (11) the ability to successfully manage increases in the prices of raw materials used to make the Company's products; (12) the ability to stay close to consumers in an era of increased media fragmentation; and (13) the ability to stay on the leading edge of innovation and maintain a positive reputation on our brands. For additional information concerning factors that could cause actual results to materially differ from those projected herein, please refer to our most recent 10-K, 10-Q and 8-K reports.

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