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Retrospective study analyzes expenses of osteoporosis-related fracture over 3 years

Data emphasizes the excess long-term cost of fracture to Medicare patients

Montreal, September 15, 2008 – In a retrospective analysis of more than 30,000 female Medicare patients 65 years and older, osteoporosis fractures resulted in fracture-related medical expenses of \$15,522 per person over three years. The study, presented at the American Society for Bone and Mineral Research (ASBMR) 30th Annual Meeting, is the first to analyze the actual long-term fracture-related medical expenses incurred over a three-year period using a U.S. medical claims database.

Medicare costs were evaluated for successive six-month periods following a fracture. Each period was compared to the six months prior to the initial fracture to determine the excess fracture-related expenses. Nearly a quarter of the total additional medical costs were incurred beyond the first six months of acute care. Patients with wrist, hip, humerus, and clavicle fractures incurred excess medical costs continuously over each six month period of the three-year follow-up.

"The medical needs resulting from an osteoporotic fracture extend well beyond simply caring for the broken bone," said Diana Brixner, RPh, PhD, Executive Director of the Pharmacotherapy Outcomes Research Center, University of Utah Health Sciences Center. "Beyond the acute care needs, long-term care as a result of the fracture is the next largest expense, but other health problems such as pain, disability, and depression related to the fracture can occur and also contribute to the expanded medical expenses."

The majority of patients (64 percent) were not treated for osteoporosis during the three years following their fracture, despite being at high risk for suffering another fracture. Fourteen percent of patients experienced another fracture during the three-year follow-up period, contributing an additional \$16,872 per patient in Medicare medical expenses. The average time before occurrence of the subsequent fracture was approximately 13 months. Nonvertebral

fractures accounted for 85 percent of all the fragility fractures and 87 percent of the total additional medical expenses observed in the study.

"Significant patient morbidity and medical expense could be spared if osteoporosis was not under diagnosed and undertreated," said Dr. Brixner. "Therapies that help prevent both vertebral and nonvertebral fractures can help mitigate fracture-related downstream costs. As our population ages, more than ever, patients who are at risk need to be identified and considered for treatment."

Study Details

In this analysis, women aged 65 years and older were identified from a medical and pharmaceutical claims database (Medstat MarketScan®) and had a new Medicare claim for a closed non-traumatic (index) fracture at any of seven skeletal sites (hip, wrist, humerus, clavicle, leg, pelvis or spine) between July 1, 2000 and June 30, 2005. Out of 1,665,837 women 65 years and older, 31,758 (3 percent) were identified with a Medicare claim for one of the specified fragility fractures. Women with a claim for malignant neoplasm, radiation oncology or chemotherapy were excluded. The cohort was followed in 6-month increments over a 3-year follow-up period. To estimate the fracture-related excess medical cost, each post-fracture time increment was compared to the 6-month period preceding the fracture. Only Medicare payments were included in the analysis. The excess medical cost was examined by place of service, fracture site, and subsequent fractures and reported in 2007 US dollars. A women was considered to be on osteoporosis therapy if she had at least 2 prescriptions with a therapy indicated for the treatment of osteoporosis, without a gap greater than 45 days between refills

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

About Osteoporosis

Osteoporosis is often a silent disease that affects millions of men and women, in which the bones become weaker and more likely to fracture over time. In fact, in the U.S. today, 10 million people are estimated to already have osteoporosis and almost 34 million more are estimated to have low bone mass, placing them at increased risk for fracture. Of the 10 million Americans estimated to have osteoporosis, eight million are women and two million are men. Osteoporosis in men remains largely underrecognized and underdiagnosed. Each year the incidence of osteoporosis-related fractures in women is greater than the incidence of heart

attacks, strokes, and breast cancer combined. The good news is that there are prescription medications available that are approved to reduce both vertebral and nonvertebral fracture risk.

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.

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About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).

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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; (13) the ability to stay on the leading edge of innovation and maintain a positive reputation on our brand; and (14) the ability to successfully separate the company's coffee business. 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.
