Studies Published in the New England Journal of Medicine Highlight Potential New Option in the Treatment of Bone Loss

August 11, 2009

Twice-Yearly Administration of Denosumab Resulted in 68 Percent Reduction in Risk for a Vertebral Fracture and 40 Percent Reduction in Risk for a Hip Fracture in Women with Postmenopausal Osteoporosis

Denosumab Administered Twice-Yearly Reduced the Incidence of New Vertebral Fractures by 62 Percent in Men with Non-Metastatic Prostate Cancer Undergoing Androgen Deprivation Therapy

THOUSAND OAKS, Calif., Aug. 11 /PRNewswire-FirstCall/ -- Amgen Inc. (Nasdaq: AMGN) today announced the publication of results from two pivotal Phase 3 studies investigating the safety and effectiveness of denosumab at reducing fracture risk in more than 7,800 women with postmenopausal osteoporosis and in more than 1,400 men with non-metastatic prostate cancer undergoing androgen deprivation therapy (ADT) leading to bone loss. In both studies, published today in The New England Journal of Medicine (NEJM), patients receiving twice-yearly denosumab experienced significant increases in bone mineral density (BMD) compared to placebo, associated with more than 60 percent reduction in vertebral fracture in both patient populations.(1,2) These data were previously reported by Amgen at medical congresses.

To view the Multimedia News Release, go to: http://www.prnewswire.com/mnr/amgen/39203/

"The discovery of the RANK Ligand pathway represents a significant advance in the understanding of bone biology," said Roland Baron, Ph.D., D.D.S., professor and chair of department of Oral Medicine, Infection, and Immunity at the Harvard School of Dental Medicine. "These results demonstrate that targeting the RANK Ligand pathway with denosumab could represent a promising new approach in two different disease settings characterized by bone loss."

FREEDOM Osteoporosis Study Results: Significant Fracture Reduction Seen Across the Skeleton in Postmenopausal Women with Osteoporosis

Results from the FREEDOM (Fracture REduction Evaluation of Denosumab in Osteoporosis every six Months) study, showed that women receiving a subcutaneous shot of denosumab twice-yearly experienced a 68 percent reduction in the risk of suffering a vertebral (spine) fracture compared to those receiving placebo as well as a 40 percent reduction in the risk of suffering a hip fracture and a 20 percent reduction in the risk of suffering a nonvertebral fracture. Over the three years of this multi-center, randomized, double-blind, placebo-controlled study, women treated with denosumab experienced significant increases in BMD (8.8 percent at the lumbar spine and 6.4 percent at the total hip).(1)

"These results suggest that denosumab offers a new approach to prevention of fractures in women with postmenopausal osteoporosis," said Steven Cummings M.D., lead investigator, study author, and director of the San Francisco Coordinating Center of the California Pacific Medical Center Research Institute. "It reduces the risk of all major types of fractures and, because it is given as an injection twice a year, it also has the potential to help compliance to treatment."

Fracture is one of the most common health events suffered by postmenopausal women with osteoporosis.(3) Globally, one woman in three over 50 years of age will experience a fracture in her lifetime.(3) A woman who has broken a bone as a result of osteoporosis has more than an eight-out-of-ten chance of breaking another bone.(4) Half of women who break a hip, a life changing event, will permanently need assistance to walk.(5)

The overall incidence and type of side effects with denosumab were similar to placebo in the FREEDOM study. Rates of adverse events (AEs) were similar in both groups (93 percent). Rates of serious AEs were 25.8 percent for denosumab and 25.1 percent for placebo. The most common AEs across both treatment arms were arthralgia, back pain, hypertension and nasopharyngitis. There were no reported cases of osteonecrosis of the jaw among patients taking denosumab. Serious adverse events of skin infections, predominantly cellulitis, were reported more commonly in the denosumab group (0.4 percent vs.