ProliaÃ,® (Denosumab) Phase 2 Extension Study Showed Continued Increase in Bone Mineral Density Over Eight Years of Treatment

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THOUSAND OAKS, Calif., Sept. 17, 2011 /PRNewswire/ -- Amgen (NASDAQ: AMGN [1]) today announced new long-term data showing that Prolia® (denosumab) treatment for up to eight years in postmenopausal women with low bone mass or osteoporosis was associated with a continued increase in bone mineral density (BMD), an important determinant of bone strength, and a persistent reduction in markers of bone turnover. The data were presented at the annual meeting of the American Society for Bone and Mineral Research (ASBMR) in San Diego.

Results of the Phase 2 study extension showed that for postmenopausal women with low bone mass or osteoporosis who received up to eight years of continued treatment with Prolia, BMD at the lumbar spine and total hip increased on average by 16.8 percent and 6.9 percent as compared to baseline, respectively. The overall adverse event profile is consistent with events previously reported.

"We don't yet have a cure for osteoporosis, and many postmenopausal women with this condition who are at high risk for fractures require long-term therapy for this serious disease," said lead author Michael McClung, M.D., founding director, Oregon Osteoporosis Center. "This study provides additional data that Prolia continues to increase bone mineral density progressively over a treatment period of eight years. This study supports the long-term clinical experience of Prolia for women with this chronic condition."

This Phase 2 study extension sought to determine the effects of up to eight years of continued treatment with Prolia on BMD and bone turnover markers in postmenopausal women with low bone mass or osteoporosis.

In the original Phase 2 dose-ranging trial for Prolia, 412 postmenopausal women with a BMD T-score (amount of matter per cubic centimeter of bones) between -1.8 and -4.0 (lumbar spine) and/or -1.8 and -3.5 (total hip or femoral ne
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SOURCE [2]

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Links:
[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=AMGN
[2] http://www.bio-medicine.org/medicine-technology-1/Prolia-AE--28Denosumab-29-Phase-2-Extension-Study-Showed-Continued-Increase-in-Bone-Mineral-Density-Over-Eight-Years-of-Treatment-20341-1/