

Amgen Announces Positive Top-Line Results for Denosumab in Trial for Delay of Skeletal Related Events in Bone Metastases Patients Compared to Zometa(R)

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Second of Three Pivotal Phase Three Bone Metastases Trials Meets Primary Endpoint Denosumab Delayed Time to Skeletal Related Events

THOUSAND OAKS, Calif., Aug. 3 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) today announced positive top-line results from a pivotal Phase 3 head-to-head trial evaluating denosumab administered subcutaneously versus Zometa (zoledronic acid) administered as an intravenous (IV) infusion in the treatment of bone metastases in 1,776 advanced cancer patients with solid tumors (not including breast and prostate cancer) or multiple myeloma.

For the primary endpoint, patients treated with denosumab experienced a similar time to first skeletal-related event (SRE) (fracture, radiation to bone, surgery to bone, or spinal cord compression) compared with those receiving Zometa (hazard ratio 0.84, 95 percent CI: 0.71-0.98), which is statistically significant for non-inferiority (p