Electronic supplemental material 1

Bone Mineral Density Gains With a Second 12-Month Course of Romosozumab Therapy Following Placebo or Denosumab

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Short title Second course of romosozumab

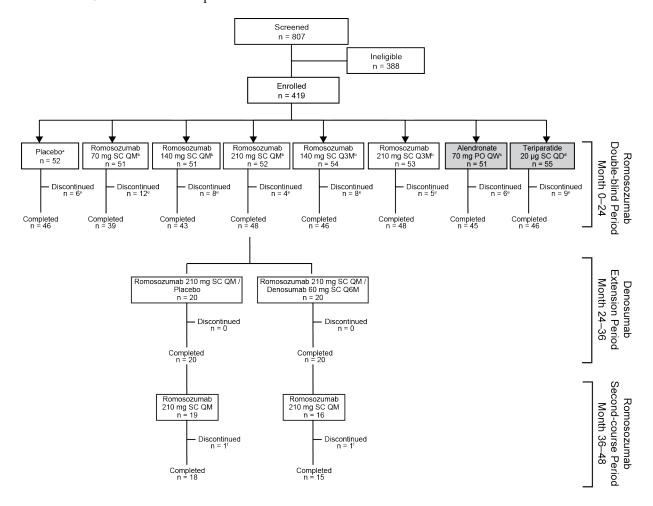
ClinicalTrials.gov NCT00896532

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Online Resource Fig 1. Disposition of study subjects who were initially randomized to romosozumab 210 mg QM in the month 0 to 24 double-blind period



Participants were randomized 1:1:1:1:1:1:1 for the first 24 months of treatment. Administration of placebo and the various romosozumab doses was blinded; alendronate and teriparatide were administered open-label. At month 24, participants were rerandomized (1:1) within treatment groups to receive blinded placebo or denosumab 60 mg SC Q6M for 12 months, followed by a 12-month second-course period with romosozumab 210 mg QM. Of the participants initially randomized to romosozumab 210 mg QM, 19 placebo-treated and 16 denosumab-treated participants entered the second-course period. All participants were instructed to take calcium (\geq 1 g) and vitamin D (\geq 800 IU) daily.

^aAt month 12, subjects initially randomized to receive placebo continued to receive placebo up to month 24.

^bAt month 12, subjects initially randomized to receive a specific dose and schedule of romosozumab continued to receive their assigned treatment up to month 24.

^cAt month 12, subjects initially randomized to receive alendronate (*gray box*) were transitioned to receive romosozumab 140 mg QM for 12 months up to month 24, were randomized to the denosumab extension period, and completed the study at month 36 and are not included in the present analysis.

^dSubjects initially randomized to receive teriparatide (*gray box*) completed the study at month 12 and are not included in the present analysis.

^eCumulative number of subjects who discontinued the study during the first 24 months.

^fNumber of subjects who discontinued the study between month 36 and month 48.

IV intravenous, PO orally, QD every day, QM every month, Q3M every 3 months, Q6M every 6 months, QW every week, SC subcutaneous.