

Patients randomised in the main period (N = 473, full analysis set)

RGB-14-P (n = 242, full analysis set)

Denosumab (n = 231, full analysis set)

Participants dosed (n = 242, safety analysis set)

Participants dosed (n = 231, safety analysis set)

Pharmacodynamic analysis set (n = 241)

Immunogenicity analysis set (n = 239)

Per-protocol analysis set (n = 240)

Pharmacodynamic analysis set (n = 229)

Immunogenicity analysis set (n = 228)

Per-protocol analysis set (n = 227)

Primary efficacy analyses

Percentage CfB in LS BMD at Week 52 (n = 242)
AUEC of the CfB in sCTX concentration until Week 26 (n = 241)

Primary efficacy analyses

Percentage change in LS BMD at Week 52 (n = 231)
AUEC of the CfB in sCTX concentration until Week 26 (n = 229)

Completed main period n = 225

Withdrawn in main period n = 17

Reason for end of treatment^a

Withdrawal by participant n = 8

Adverse event n = 2

Lost to follow-up n = 3

Death n = 0

Protocol deviation n = 1

Other n = 2

Completed main period n = 211

Withdrawn in main period n = 20

Reason for end of treatment^a

Withdrawal by participant n = 13

Adverse event n = 2

Lost to follow-up n = 0

Death n = 1

Protocol deviation n = 0

Other n = 2