Treatment with Prolia® for up to 10 years was effective, generally well tolerated and had a favourable risk-benefit profile

Results from the Phase III randomized FREEDOM trial and open-label extension

Primary endpoints

Safety monitoring, including assessments of adverse event and serious adverse event incidences, changes in safety parameters (e.g. serology and haematology), and participant incidence of antibodies against denosumab.

Secondary endpoints

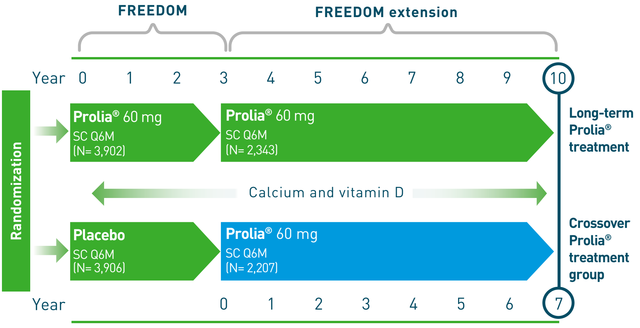
Incidence of new vertebral, non-vertebral and hip fractures.

Actual values, changes, and percent changes in bone mineral density of the lumbar spine, total hip, femoral neck, and one-third radius from FREEDOM baseline and extension baseline at all time points when bone mineral density was collected.

Other secondary outcomes included: actual values, changes, and percent changes in bone turnover markers (e.g. CTx-1, P1NP, and bone-specific alkaline phosphatase), intact parathyroid hormone and osteoprotegerin from FREEDOM baseline and extension baseline at pre-specified time points in a subset of participants.

Trial design

International, multicentre, open-label, single-arm trial



Inclusion criteria

Patients who completed the FREEDOM trial (i.e. completed 3-year visit), did not discontinue treatment, and did not miss more than one dose of Prolia® or placebo.

Results

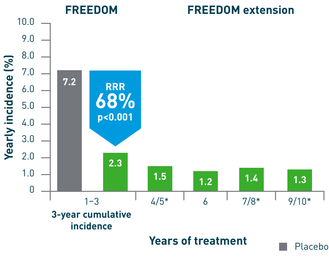
Safety

The yearly exposure-adjusted incidence for all adverse events was stable throughout the trial for both the long-term and crossover group separately and combined.

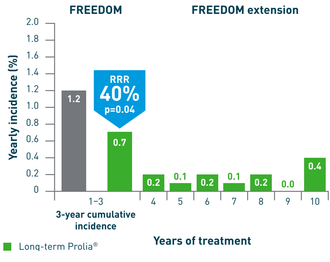
Fracture Incidence

The incidence of new vertebral, non-vertebral and hip fractures during the extension remained similar to the incidence observed during the FREEDOM trial. The cumulative incidence of new vertebral fractures and non-vertebral fractures was lower than the estimated incidence.

Vertebral fracture



Hip fracture

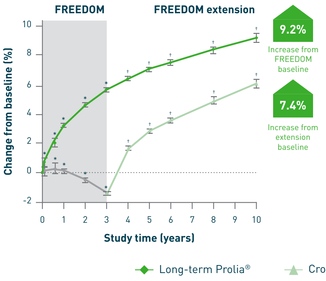


*Annualized incidence (2-year incidence/2).

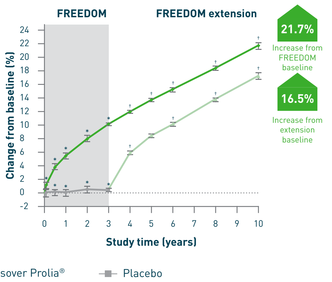
Bone mineral density

The mean percentage change in bone mineral density from the FREEDOM baseline (long-term group) and extension baseline (crossover group) until Year 7 of the extension was significant (p<0.05).

Lumbar spine



Total hip



Long-term Prolia® Crossover Prolia® Placebo

*p<0.05 compared with FREEDOM baseline
†p<0.05 compared with FREEDOM and extension baselines

Conclusion

In the FREEDOM trial and its extension, treatment with **Prolia®** for up to 10 years was **effective, generally well tolerated** and had a **favourable risk-benefit profile**.

Prolia® safety profile information can be found in the Summary of Product Characteristics. Please click here.

CTx-1: C-terminal telopeptide of type 1 collagen; P1NP: N-terminal propeptide of type 1 procollagen; Q6M: every 6 months; SC: subcutaneous.

References: Bone HG et al. *Lancet Diabetes Endocrinol* 2017; 5(7):513–523.

prolia® denosumab
ACT BEFORE IMPACT

AMGEN

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Date of preparation: January 2018
EUHQ-P-162-1117-058694