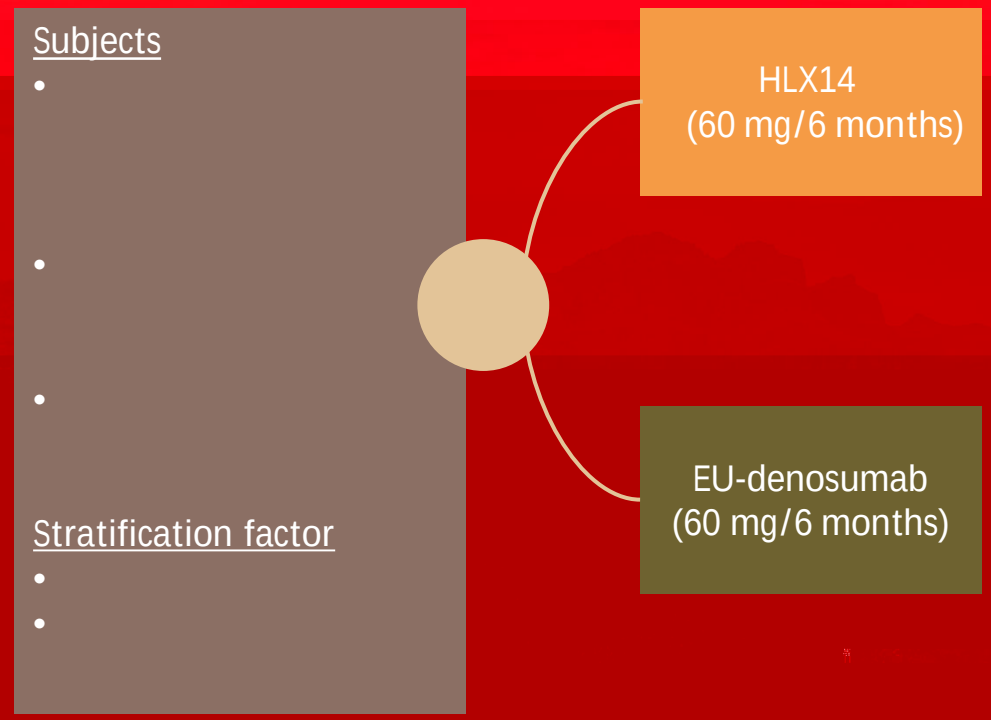

2025 ANNUAL MEETING

Here we report the efficacy, PD, and safety in a phase 3 study of HLX14 vs. European Union-sourced reference denosumab (EU-denosumab) in postmenopausal women with osteoporosis at high risk of fracture.

2019 2009 2017

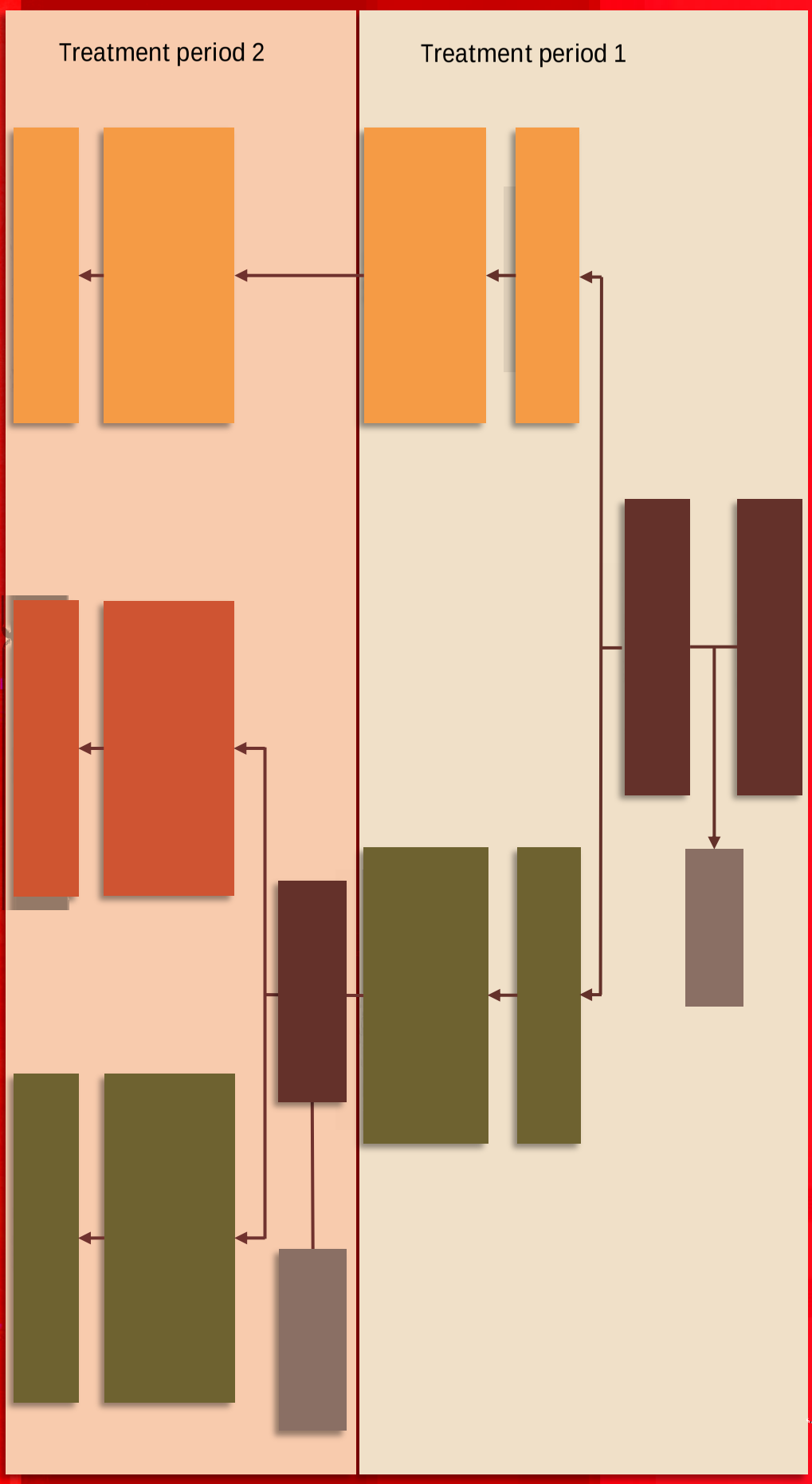
A randomized, double-blind, multicenter, phase 3 trial (NCT05352516)



Primary endpoints

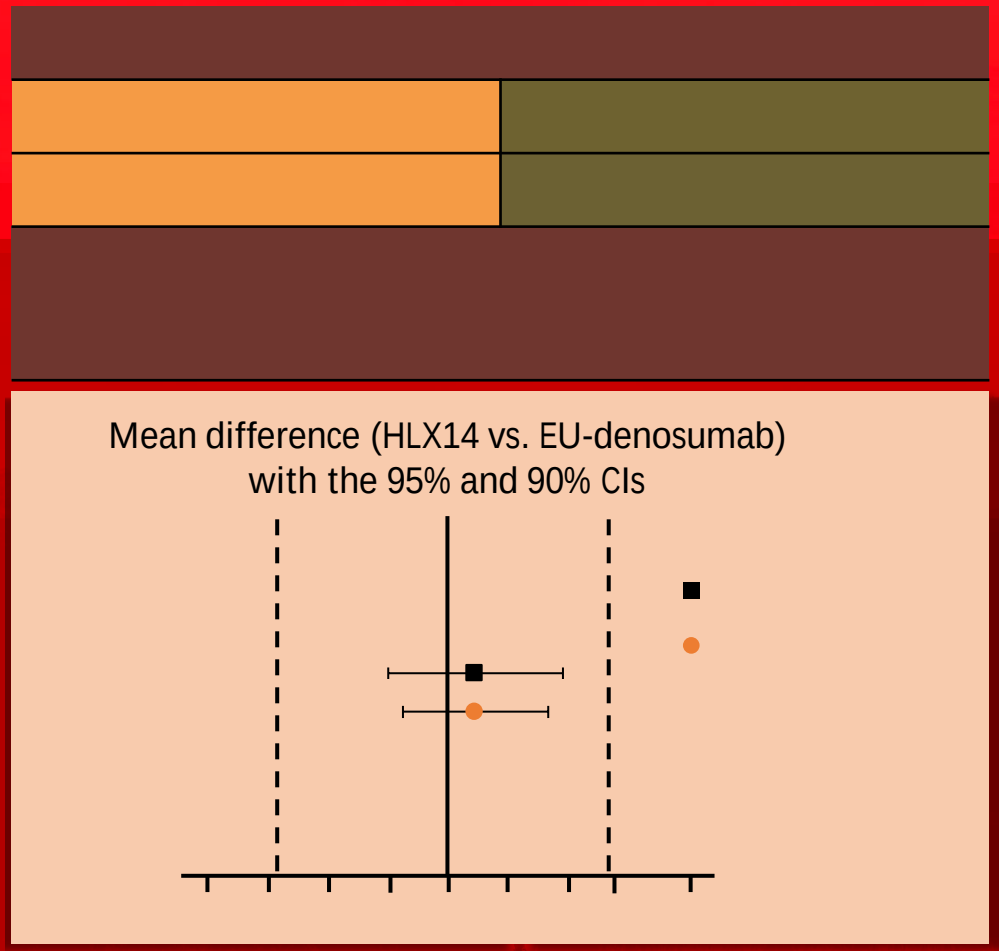
- Efficacy: % change in BMD at lumbar spine from baseline to Week 52
- PD: AUEC of percent change of s-CTX from baseline to Week 26 ($AUEC_{0\text{-}26W}$)

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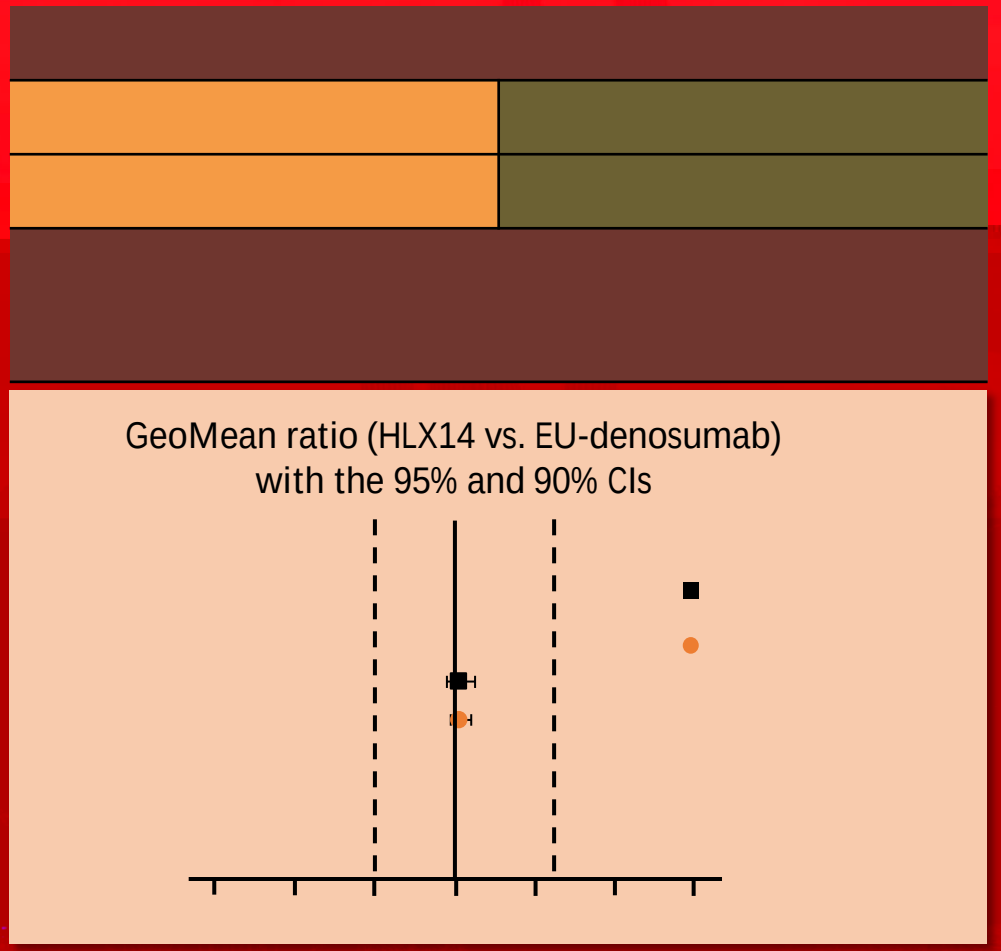

Treatment period 2
Treatment period 1

Characteristics	HLX14 (N = 256)	EU-denosumab (N = 258)

Efficacy[a], Mean (SD) for % change in LS-BMD at Week 52



PD[b], $AUEC_{0-26W}$



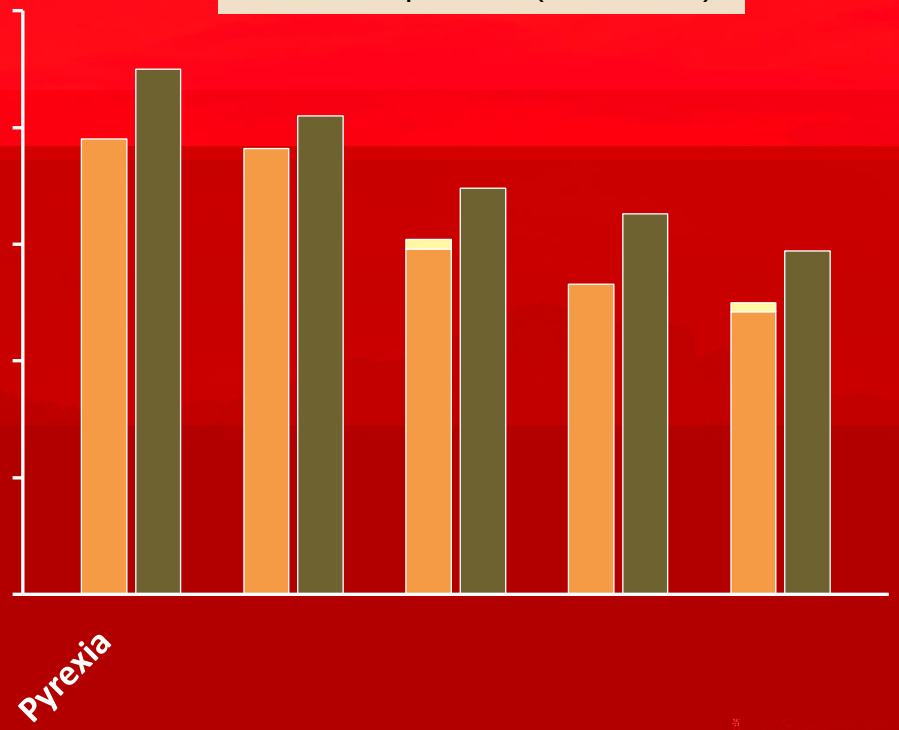
Mean (± SD) for % change from baseline to Week 78 in s-CTX concentration



Incidence of TEAEs by PT occurring in 10% subjects in the two treatment periods[a]

Treatment period 1 (D1 to D364)

Treatment period 2 (D365 to D546)



efficacy and PD equivalence to EU-denosumab

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Orthopaedic Research

