Results: 7180 subjects were included in the study (Romo, n=3589; Pbo, n=3591). At month 12, the mean change from baseline in LS BMD T-score was 0.88 for Romo and 0.03 for Pbo. At month 24 (after both treatment groups received DMAb in the second year) mean increases in LS BMD T-score were 1.11 for Romo/DMAb and 0.38 for Pbo/DMAb. At month 12, the mean changes in TH BMD T-score were 0.32 for Romo and 0.01 for Pbo. At month 24, mean changes in TH BMD T-score were 0.45 for Romo/DMAb and 0.17 for Pbo/DMAb. In the Romo group, 99% of subjects showed an increase in LS BMD at month 12, with 89% achieving $\geq 6\%$ gains (figure 1). Administration of Romo during the first year led to reductions versus Pbo in the relative risk of fractures during the second year, despite both groups receiving DMAb in the second year (reductions of 81% for vertebral fractures [$p<0.001$]; 32% for clinical fractures [$p=0.052$]; 39% for major osteoporotic fractures [$p=0.034$]).

Conclusions: Romo versus Pbo resulted in substantially higher BMD T-score increases after one year. After transition to DMAb, BMD gains in both treatment groups were similar in the second year. One year of Romo treatment, followed by transition to DMAb, resulted in unprecedented gains in BMD and substantially reduced fracture rates during the second year even though subjects in both groups received DMAb. These data support the clinical benefit of rebuilding the skeletal foundation with Romo treatment before transition to DMAb.

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OP0345 DENOSUMAB COMPARED WITH RISEDRONATE IN GLUCOCORTICOID-TREATED SUBJECTS: RESULTS FROM THE FINAL 24-MONTH ANALYSIS OF A RANDOMISED, DOUBLE-BLIND, DOUBLE-DUMMY STUDY

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Background: Denosumab 60 mg subcutaneously Q6M increased spine and hip BMD significantly more than risedronate 5 mg orally QD at 12 months in glucocorticoid-treated subjects (as previously reported¹).

Objectives: This analysis compared the BMD effects of denosumab vs risedronate and further characterised denosumab safety in this population at 24 months.

Methods: This phase 3, randomised, double-blind, double-dummy study enrolled adults ≥ 18 years receiving ≥ 7.5 mg daily prednisone (or equivalent) for <3 months (glucocorticoid-initiating subpopulation) or ≥ 3 months (glucocorticoid-continuing subpopulation). All subjects <50 years had history of osteoporotic fracture. Glucocorticoid-continuing subjects ≥ 50 years had lumbar spine (LS), total hip (TH), or femoral neck BMD T-scores ≤ -2.0 , or ≤ -1.0 and history of fracture. Subjects were randomised 1:1 to denosumab 60 mg subcutaneously Q6M or risedronate 5 mg orally QD for 24 months. This analysis assessed denosumab superiority over risedronate for percentage change from baseline in LS and TH BMD at 24 months.

Results: Of 795 randomised subjects, 590 (74.2%) completed the 24 month study (glucocorticoid-initiating: 109/145 denosumab, 117/145 risedronate; glucocorticoid-continuing: 186/253 denosumab, 178/252 risedronate). Denosumab

was superior to risedronate for increases from baseline in LS and TH BMD at all timepoints assessed through 24 months in each subpopulation (figure 1). Adverse events, serious adverse events (including infection), and fractures were similar between groups.

Abstract OP0345 – Figure 1 Bone mineral density percentage change (95% CI) from baseline through month 24

Conclusions: In conclusion, denosumab was superior to risedronate for increases in spine and hip BMD through 24 months. The overall safety profile was similar between groups. Denosumab may offer a valuable osteoporosis treatment option for patients receiving glucocorticoids.

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What's new: latest advances in treatment in JIA and osteoarthritis

OP0346-PARE A PARTNERSHIP IN IMPLEMENTATION: ADAPTING AN OSTEOARTHRITIS GUIDEBOOK ACROSS EUROPEAN CULTURES – WITH PATIENTS, FOR PATIENTS

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Background: A guidebook for patients with osteoarthritis (OA) was co-developed with UK patients during an OA research study.¹⁻³ The JIGSAW-E project is now disseminating and implementing the OA management guidelines and Guidebook in clinical practice in UK, Netherlands, Norway, Denmark and Portugal.⁴