PSORIASIS

EFFICACY AND SAFETY OF GUSELKUMAB ADMINISTERED WITH A NOVEL SELF-INJECTION DEVICE FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS: RESULTS FROM THE PHASE III ORION SELF-DOSE STUDY THROUGH WEEK 16

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Introduction/Objective: To evaluate the efficacy and safety of guselkumab (GUS) administered using a novel, self-injection device in adult patients with moderate-to-severe plaque psoriasis.

Materials/Methods: ORION is a Phase 3, multicenter, randomized, double-blind, placebo (PBO)-controlled study evaluating GUS administered using a self-SC, prefilled injection device. Patients (age≥18 years, moderate-to-severe psoriasis for ≥6 months, IGA score ≥3, PASI score ≥12, BSA ≥10%, and candidates for/may have received systemic therapy/phototherapy) were enrolled.
Patients were randomized to PBO (N=16) at wks0, 4, 12, then GUS 100mg at wks16, 20, 28 or GUS (N=62) at wks0, 4, 12, 20, 28. Co-primary endpoints were proportions of patients achieving an IGA score of cleared (0) or minimal (1) and a PASI 90 response at wk16. Major secondary endpoints were proportions of patients achieving an IGA score of 0 and a PASI 100 response at wk16.

Results: Baseline demographics and psoriasis disease characteristics were generally similar between the PBO- and GUS-treatment groups. At wk16, significantly higher proportions of GUS vs PBO patients achieved an IGA score of 0/1 (80.6% vs. 0.0%, p<0.001) and a PASI 90 response (75.8% vs. 0.0%, p<0.001). In addition, significantly higher proportions of GUS vs PBO patients achieved an IGA score of 0 (56.5% vs 0.0, p<0.001) and a PASI 100 response (50.0% vs 0.0, p<0.001) at wk16.
Through wk16, proportions of patients with ≥1 AE were comparable between groups (GUS: 62.9%, PBO: 68.8%). Discontinuations due to AEs were GUS: 1.6%, PBO: 6.3%. Two GUS patients had SAEs (1 chest discomfort and 1 atypical chest pain). There were no serious

infections, malignancies, or deaths.

Conclusions: GUS administered using a novel self-injection device was efficacious and well-tolerated in patients with moderate-severe psoriasis. These findings were consistent with those previously reported from the pivotal phase 3 studies where GUS was administered using a different self-injection device.