PSORIASIS

MAINTENANCE OF RESPONSE THROUGH UP TO 3-YEARS OF CONTINUOUS GUSELKUMAB TREATMENT OF PSORIASIS IN THE VOYAGE 2 PHASE 3 TRIAL

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Introduction/Objective: Guselkumab (GUS) is a fully human monoclonal antibody that binds and blocks IL-23. Study results of the VOYAGE 2 phase 3, randomized, double-blind, placebo/active comparator-controlled clinical trial of patients with moderate-to-severe psoriasis, through up to 3 years of continuous GUS treatment, are presented.

Materials/Methods: Patients (N=992) were randomized to GUS 100 mg at Wks 0, 4, and 12, then every 8 weeks (q8wk); PBO at Wks 0, 4, and 12 followed by GUS 100 mg at Wks 16, 20, then q8wk; or ADA 80 mg at Wk 0, 40 mg at Wk 1, then 40 mg q2wk until Wk 23. Wks 28-72 incorporated a randomized withdrawal study design. During Wks 76-156, patients received open-label treatment with GUS 100 mg q8wk. Physician and patient reported outcomes were assessed. Efficacy was analyzed using prespecified treatment failure rules starting at Wk 76 (patients were considered nonresponders after discontinuing due to lack of efficacy, worsening of PsO, or use of a prohibited treatment). Data for patients randomized to GUS and for those originally randomized to PBO who then switched to GUS at week 16 were combined (GUS group).

Results: The proportions of patients in the GUS group who achieved designated clinical responses at Wks 100 and 156, respectively, were: Psoriasis Area and Severity Index (PASI) 90 — 79.1%, 77.2%; PASI 100 — 48.4% , 48.8%; Investigator Global Assessment (IGA) 0/1 — 83.1%, 83.0%; IGA 0 — 52.7%, 52.9%; Dermatology Life Quality Index (DLAI) 0/1 — 70.2, 68.4%; Psoriasis Symptoms and Signs diary (PSSD) symptom score 0 — 35.7%, 37.5%; and PSSD sign score 0 — 22.0%, 25.9%. No new or additional safety

signals were identified.

Conclusions: Durable and robust levels of efficacy were maintained through up to 3 years of continuous GUS treatment for multiple endpoints in the VOYAGE 2 trial; treatment with GUS was well-tolerated.