PSORIASIS

CONSISTENCY OF RESPONSE MAINTAINED ACROSS DEMOGRAPHIC SUBGROUPS OF PSORIASIS PATIENTS TREATED WITH GUSELKUMAB FOR UP TO 3 YEARS IN THE VOYAGE 1 AND 2 TRIALS

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Introduction/Objective: VOYAGE 1 and 2 are ongoing Phase 3, randomized, double-blind, placebo/active comparator-controlled trials for guselkumab, a fully human monoclonal antibody targeting interleukin-23, in moderate-to-severe plaque psoriasis. Long-term consistency of response to guselkumab across demographic subgroups for up to 3 years' treatment is presented.

Materials/Methods: In VOYAGE 1 (N=837) and VOYAGE 2 (N=992), patients were randomized to GUS 100mg at Wks 0, 4, 12, then every 8 weeks (q8wk); placebo at Wks 0, 4, 12, followed by guselkumab at Wks 16, 20, then q8wk; or adalimumab 80mg at Wk0, 40mg at Wk1, then 40mg q2wk until Wk47 (VOYAGE 1) or Wk23 (VOYAGE 2). In VOYAGE 1, all patients received open-label GUS 100mg q8wk, Wks 52-156. VOYAGE 2 incorporated a randomized withdrawal study design, followed by open-label guselkumab,, Wks 76-156. Data for patients randomized to guselkumab and those randomized to placebo and switched to guselkumab at Wk16 were combined. Efficacy assessment used prespecified treatment-failure rules (nonresponder status after discontinuing for lack of efficacy, psoriasis worsening, or prohibited treatment).

Results: In VOYAGE 1 and 2, proportions of patients receiving guselkumab with an

Investigator Global Assessment (IGA) 0/1 response were 83.1% at Wk100 and 82.6% at Wk156. Similar IGA 0/1 response rates were observed at Wks 100 and 156, respectively, in subgroups of men (82.8%, 81.1%) and women (83.9%, 86.6%); patients <45 years (83.5%, 82.3%), 45-65 years (83.3%, 84.9%), and ≥65 years (77.4%, 66.0%) of age; patients of body weight ≤90 kg (86.9%, 88.0%) and >90 kg (78.0%, 75.4%); and patients of Asian race (76.4%, 78.1%) and White race (84.0%, 83.4%). No new safety signals were identified.

Conclusions: Regardless of gender, age, body weight, and race, durable, and consistent clinical responses were maintained for up to 3 years of treatment with guselkumab in the overall VOYAGE 1 and 2 moderate-to-severe psoriasis study populations.