PSORIASIS

LONG-TERM EFFICACY AND SAFETY OF GUSELKUMAB IN PSORIASIS PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS: A POOLED ANALYSIS FROM VOYAGE 1 AND VOYAGE 2

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Introduction/Objective: Long term efficacy and safety of guselkumab (GUS) in patients with and without psoriatic arthritis (PsA) from the VOYAGE 1 and VOYAGE 2 studies were evaluated.

Methods: In VOYAGE 1 (N=837) and VOYAGE 2 (N=992), patients were randomized to GUS 100mg at Wks 0, 4, and 12, then q8wk; PBO at Wks 0, 4, and 12, GUS 100mg at Wks 16 and 20 then q8wk; or ADA 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 during Wks 52-156. VOYAGE 2 incorporated a randomized withdrawal phase, followed by open-label GUS treatment during Wks 76-156. Pooled analyses were conducted based on self-reported PsA status at baseline. Data for patients randomized to GUS or PBO with crossover to GUS were combined. Efficacy was assessed using prespecified treatment failure rules (nonresponder status for all time points after discontinuing due to lack of efficacy, worsening of PsO, or use of a prohibited treatment).

Results: In VOYAGE 1 and 2, high proportions of patients receiving GUS had an IGA 0/1 response at Wk100 (83.1%, n=1103) and Wk156 (82.6%, n=1042). Similar IGA 0/1 response rates were observed in the subgroups of patients with PsA at baseline (Wk100- 85.4%, n=198; Wk156- 82.3%, n=192) and without PsA at baseline (Wk100- 82.7%,

n=905; Wk156- 82.7%, n=850). Rates of adverse events (AEs) through Wk156 were also comparable for patients with PsA vs those without PsA at baseline, respectively: ≥1 AE, 77.8% vs 83.7%; ≥1 serious AE, 12.0% vs 11.9%; ≥1 infection, 53.8% vs 65.4%; and ≥1 serious infection, 1.3% vs 2.6%.

Conclusions: Consistent, durable, and high levels of clinical responses were observed among PsO patients with and without PsA at baseline; GUS was well-tolerated through up to 3 years of treatment.