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CONSISTENT EFFICACY IN PATIENT SUBGROUPS ACROSS BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS: RESULTS FROM A PHASE 2 STUDY OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: Guselkumab (GUS) is a monoclonal antibody targeting interleukin-23 that has demonstrated efficacy in a phase 2 trial of psoriatic arthritis (PsA) (1).

Objectives: Here subgroup analyses were conducted to evaluate the consistency of efficacy on the primary endpoint, ACR20 response.

Methods: In this randomized, double-blind, placebo-controlled, Phase-2 trial, pts with active PsA (≥3 tender, ≥3 swollen joints, C-reactive protein ≥3 mg/L, ≥3% body surface area [BSA] of plaque psoriasis) despite current or previous treatment with standard-of-care therapies were randomised 2:1 to subcutaneous GUS 100 mg (n=100) or placebo (PBO, n=49) at Wk0, Wk4, and every 8 wks (q8w) through Wk44. At Wk16, pts with ≥5% improvement in both swollen and tender joints could escape early to open-label ustekinumab. Pts continuing PBO crossed-over to receive GUS 100mg at Wk 24, 28 then q8w through Wk44. The primary analysis was performed in a modified Intent-to-Treat (mITT) population which included all randomized subjects who received at least 1 administration of study agent based on their assigned treatment regardless actual treatment received. Pts who met treatment failure criteria, escaped early, or had missing data at Wk24 were considered non-responders for ACR20 at Wk24. Pre-planned subgroup analyses by demographic and disease characteristics at baseline and PsA medication use were performed, using the same data handling rules as in the primary analysis.

Results: At Wk24, 58/100 (58.0%) of pts in the GUS vs 9/49 (18.4%) in the PBO group achieved an ACR20 response (p<0.001). Efficacy was consistently observed in subgroups defined by demographics (gender, age, weight, region), disease characteristics at baseline (disease duration, PsA subtypes, tender/swollen joint counts), HAQ-DI, CRP, presence of dactylitis or enthesitis, PASI, and BSA) or PsA medication use (prior use of DMARDs or anti-TNFs, concomitant use of MTX, oral corticosteroids, or NSAIDs) (Table). The treatment effect was statistically significant in the majority of subgroups with the lower bound of the 95% confidence interval of the difference between GUS and PBO exceeding 0 in favor of GUS. There are a few exceptions where small sample sizes of the corresponding subgroups defined otherwise, although the sample size is small and the data should be interpreted with caution.

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