Proportions of Patients Achieving a Minimal Disease Activity State upon Treatment with Tildrakizumab in a Psoriatic Arthritis Phase 2B Study

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Background: Tildrakizumab (TIL) is a high-affinity anti-interleukin-23p19 monoclonal antibody approved in the US, EU, and Australia to treat moderate to severe plaque psoriasis. A randomised, double-blind, placebo-controlled, multiple-dose, phase 2b study evaluating the efficacy and safety of TIL was recently completed (NCT02980692).

Objectives: To characterise and evaluate the rate of minimal disease activity (MDA) up to week (W)52 from the phase 2b study.

Methods: Patients (pts) ≥18 years old with active psoriatic arthritis (PsA) and ≥3 tender and ≥3 swollen joints were randomised 1:1:1:1:1 to receive TIL 200 mg every 4 weeks (QW) to W52, TIL 200 mg Q12W to W52, TIL 100 mg Q12W to W52, TIL 20 mg Q12W to W24—TIL 200 mg Q12W to W52, or placebo (PBO) Q4W to W24—TIL 200 mg Q12W to W52. MDA was assessed throughout the study; an MDA response was achieved when at least 5 of 7 criteria were met. Safety was assessed throughout the study and included treatment-emergent adverse event (TEAE) monitoring.

Results: Of 500 pts screened, 391 were randomised and received ≥1 dose of study drug. At baseline (BL), mean age was 48.8 years, 55% were female, 97% were White, mean body mass index was 29.7 kg/m², and pts had PsA for a median (range) of 4.4 (0–42.8) years since diagnosis. Baseline disease characteristics related to MDA varied little between study arms (Table).

By W24, MDA state was achieved in significantly more pts receiving TIL vs PBO (45%–64%), including pts who switched from PBO to TIL (47%); (Figure).

Among the overall pt population from BL—W24/W25—W52, 50.4%/39.9% and 2.3%/10% experienced a TEAE and serious TEAE, respectively. From BL—W24, 1 serious infection (chronic tonsillitis) was reported for TIL 20 mg W24, W52, 50.4%/39.9% and W24/W25 47% to TIL vs PBO (47%) (Table).

By W24, MDA state was achieved in significantly more pts receiving TIL vs PBO (47%).

Conclusion: TIL produced clinically meaningful improvement in pts with PsA, resulting in a large proportion of pts achieving MDA by W52, and was well tolerated through W52.

References:

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Data are reported as mean.

Table. Baseline disease characteristics related to minimal disease activity

Table 2B 200 mg n = 78 TIL 200 mg n = 79 TIL 100 mg n = 77 TIL 20 mg n = 78 Q4W Q12W Q12W Q12W Q12W Q12W

Swellen joint count 10.4 10.0 11.0 9.4 11.8 11.6
Tender joint count 16.6 19.5 21.3 19.0 19.7
Patient GADA score 57.8 61.1 60.3 61.9 65.2
Patient pain 55.4 59.6 59.2 60.9 64.2
assessment Enthesitis (LEI) score* 1.9 1.5 2.2 2.2 1.5
PASI** 7.6 6.2 8.8 6.6 5.0
HAQ-DI score 1.0 1.0 1.0 1.1 1.2

Data are reported as mean.

*Total patients analysed (n) = 76, 79, 76, 78, 78, respectively.
**Total patients analysed (n) = 77, 79, 76, 75, 75, respectively.

PASI, Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 hours; Q12W, every 12 hours; TIL, tildrakizumab.

Effect of Sex on Disease Characteristics and Disease Impact in Patients with Psoriatic Arthritis (PsA): Insights from the Real-world, Observational Multinational PsA Biobank Cohort

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Conclusion: TIL produced clinically meaningful improvement in pts with PsA, resulting in a large proportion of pts achieving MDA by W52, and was well tolerated through W52.