Patient-reported outcomes for GSK1070806, an anti-IL-18 monoclonal antibody: a phase 1b, randomised, double-blind, parallel-group placebo-controlled study of patients with atopic dermatitis

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Introduction/Background: Administration of GSK1070806, an anti-IL-18 monoclonal antibody, in patients with atopic dermatitis (AD) resulted in significant clinical improvements versus placebo after 12 weeks.

Objectives: Assessment of patient-reported outcomes (PROs) for patients with AD receiving GSK1070806.

Methods: In this multicentre, randomised, double-blind, parallel-group study (NCT04975438), adults (≥18 years) with confirmed AD diagnosis for ≥6 months and moderate-to-severe disease (Eczema Area and Severity Index ≥16; Investigator’s Global Assessment score ≥3) received 2 mg/kg GSK1070806 or placebo (single one-hour intravenous infusion). PRO measures included Peak Pruritis Numerical Rating Scale (PP-NRS), Dermatology Life Quality Index (DLQI), Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b (PROMIS-SD 8b), Brief Fatigue Inventory Item 3 (BFI-Item 3), and Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F). PROs were assessed at baseline and either daily (PP-NRS and BFI-Item 3) or a combination of weekly (up to Week 4) and biweekly (after Week 4) (PROMIS-SD, DLQI and FACIT-F) for up to 24 weeks. Changes from baseline
(CFB) in PP-NRS and DLQI scores at Week 12 were analysed using a Bayesian repeated measures model with all other PROs analysed descriptively.

**Results:** Of 34 enrolled patients (53% female, mean [standard deviation] age 44.8 [16.9] years), 23 received GSK1070806 and 11 received placebo. Posterior median of difference (95% credible interval) CFB at Week 12 in PP-NRS were -4.6 (-5.5, -3.7; GSK1070806) and -0.5 (-1.7, 0.7; placebo), and for DLQI were -6.1 (-8.8, -3.4; GSK1070806) and -0.01 (-4.3, 4.1; placebo). Observed mean PROMIS-SD 8b, BFI-Item 3 and FACIT-F scores also indicated improvements among patients who received GSK1070806 versus placebo.

**Conclusions:** Patients with moderate-to-severe AD who received GSK1070806 experienced positive improvements across all PROs versus placebo. These results provide further evidence of GSK1070806 benefit in patients with moderate-to-severe AD.

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