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Topline results from TREK-AD: a randomized, double-blind, placebo-controlled, Phase 2b study of eblasakimab in adult patients with moderate-to-severe atopic dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) is a common, chronic, multifactorial skin disease with a predominant immune signature of T-helper 2 cells. Cytokines interleukin (IL)-4 and IL-13 have been postulated as key drivers of AD. Both signal through a shared type-2 receptor, a heterodimer comprised of IL-4Rα and IL-13Rα1. Eblasakimab is a potential first-in-class, monoclonal antibody that binds IL-13Rα1 with high affinity and blocks the signaling of IL-4 and IL-13 through the type-2 receptor, while sparing the type-1 receptor. TREK-AD (TRials with EblasaKimab in Atopic Dermatitis), a randomized, double-blind, placebo-controlled, Phase 2b dose-ranging dose study [NCT05158023] evaluated the efficacy and safety of eblasakimab as monotherapy in adult patients with moderate-to-severe AD who are candidates for systemic therapy.

Materials & Methods: 289 patients were randomized (1:1:1:1:1) to receive one of four doses of subcutaneous injections of eblasakimab once-monthly [Q4W] at 400mg [n=59] or 600mg [n=59], or once every two weeks [Q2W] at 300mg [n=58] or 400mg [n=56]), or placebo Q2W [n=57] for 16 weeks, following 2–3 loading doses of 600mg or placebo for Q2W or Q4W groups, respectively. Patients had chronic AD present for ≥1 year and at screening and baseline had eczema area and severity index (EASI) ≥16; validated Investigator's Global Assessment of AD (vIGA-AD) score ≥3 (scale of 0 to 4); ≥10% body surface area of AD involvement. Primary and key secondary endpoints at week 16 included EASI percent change from baseline (%CFBL), the proportions of patients with at least a 75% or 95% improvement in EASI (EASI75, EASI90) and vIGA-AD score of 0/1.

Results: The primary endpoint, EASI %CFBL to week 16, was met for eblasakimab doses 600mg Q4W, 300mg Q2W, and 400mg Q2W vs placebo (73.0% [*P*=0.001], 69.8% [*P*=0.005], and 65.8% [*P*=0.029] vs 51.1%), respectively. %CFBL was significant from Week 4. Eblasakimab at 600mg Q4W also achieved significantly greater EASI75 vs placebo at week 16 (52.0% vs 24.4% *P*=0.004). Other efficacy outcomes for this treatment arm vs placebo at week 16 included: EASI90 (27.6% vs 7.9%, *P*=0.008); vIGA-AD (31.2% vs 15.1%, *P*=0.050). The Q2W regimens were also significantly better vs placebo for EASI75, EASI90, and vIGA 0/1 with eblasakimab 400mg Q2W (43.6%, *P*=0.036; 25.3%, *P*=0.018; and 32.6%, *P*=0.038) and eblasakimab 300mg Q2W (51.2%, *P*=0.005; 30.8%, *P*=0.003; and 33.1%, *P*=0.033). Discontinuation rates were comparable between active arms and higher for placebo. Eblasakimab was safe and well-tolerated. 5.2% of patients experienced conjunctivitis (placebo: 1.8%); 4.7% experienced injection site reactions (placebo: 1.8%); otherwise the frequency of adverse events was comparable between active and placebo arms.

Conclusion: In moderate-to-severe AD, eblasakimab demonstrated a competitive efficacy and safety profile, with monthly dosing from initiation comparable to dosing every two weeks, supporting advancement to a Phase 3 clinical program.