Rocatinlimab significantly improves clinical responses in patients with moderate-to-severe atopic dermatitis by week 2 in a randomized double-blind placebo-controlled phase 2b study

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Introduction/Background: Moderate-to-severe atopic dermatitis (msAD) can cause chronic cycles of pruritus and scratching, impacting quality of life.

Objectives:

1. To evaluate rocatinlimab for the treatment of msAD
2. To investigate the onset of action of rocatinlimab on pruritus Numerical Rating scale (pNRS) and Eczema Area and Severity Index (EASI) in adults with msAD

Methods: A multicenter, randomized, double-blind, placebo-controlled Phase 2b trial (NCT03703102) evaluated rocatinlimab (anti-OX40 monoclonal antibody) for msAD. Primary endpoint achievement (Percent change from baseline to week 16 in EASI) has been presented. Randomized patients (1:1:1:1:1) received subcutaneous rocatinlimab 150mg/600mg every 4 weeks (Q4W) or 300mg/600mg every 2 weeks (Q2W) for 36 weeks, or placebo (Weeks 0–18) followed by rocatinlimab (600mg Q2W Weeks 18–36). All cohorts had 20-week off-treatment follow-up.

Results: Clinical response onset with rocatinlimab was evaluated post-hoc (N=267; rocatinlimab: n=210; placebo: n=57) by investigating pNRS and EASI between baseline and Week 16. Difference in least squares mean of percent change from baseline between rocatinlimab cohorts and placebo were assessed. Pruritus was significantly improved with rocatinlimab by Week 2 in all cohorts (~18.40% to
−21.96%; p≤0.018) except 600mg Q4W (−9.66%; p=0.208), and in all cohorts by Week 4 (−15.70% to −27.19%; p≤0.045); EASI improvements were significant in all rocatinlimab cohorts by Week 6 (−20.50% to −32.13%; p≤0.001) compared with placebo, and the 300mg and 600mg Q2W cohorts by Week 2 (−13.27% and −13.66%; p≤0.028). Further improvements with rocatinlimab continued to Week 16 compared with placebo; improvements from baseline continued in all active cohorts to Week 36 and were maintained for 20 weeks off-treatment, suggesting rocatinlimab may have potential for disease modification in adults with msAD.

**Conclusion:** Rocatinlimab improved pNRS and EASI by Week 2; improvements continued and were maintained off-treatment until the end of study.

**Keywords (5/5):** atopic dermatitis, moderate-to-severe, rocatinlimab, pruritis, OX40

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