

Rademikibart monotherapy in adult and adolescent patients with moderate-to-severe atopic dermatitis (AD): A 1-year, phase III, randomized, double-blinded, placebo-controlled trial (RADIANT-AD)

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Backgrounds

Rademikibart is a next-generation monoclonal antibody that binds to a unique IL-4R α epitope with higher affinity than dupilumab, inhibiting the biological activities of IL-4 and IL-13.^{1,2}

Clinical trials in atopic dermatitis (AD) were positive.³⁻⁸ Rademikibart induced rapid reductions in AD signs and symptoms that persisted without plateauing across 16 weeks of treatment, with sustained 52-week long-term efficacy.

Objectives

To report the primary and secondary endpoints at Week 16 and long-term efficacy/safety outcomes over 52 weeks from the phase III trial (NCT05017480) of rademikibart in adult and adolescent patients with moderate-to-severe atopic dermatitis.

Methods

This Phase III trial (NCT05017480) enrolled 259 patients (204 adults, 55 adolescents) with moderate-to-severe atopic dermatitis (AD) inadequately controlled by or ineligible for topical therapy. Patients were randomized 1:1 to rademikibart (600mg

loading, then 300mg Q2W) or placebo for 16 weeks, followed by a 36-week open-label phase with rademikibart 300mg Q2W for all.

Results

At Week 16, greater proportions of patients treated with rademikibart vs. placebo (all $p < 0.0001$) achieved: IGA 0/1 and ≥ 2 -point reduction (47.7% vs. 17.6%), EASI-75 (74.2% vs. 34.4%), EASI-90 (43.0% vs. 14.5%), and ≥ 3 -point Pruritus NRS reduction (54.7% vs. 27.5%). By Week 52, efficacy further improved in rademikibart group: IGA 0/1 and ≥ 2 -point reduction (87.1%), EASI-75 (96.6%), EASI-90 (85.3%), and ≥ 3 -point Pruritus NRS reduction (91.2%). TEAEs occurred in 60.9% (rademikibart) vs. 64.9% (placebo) by Week 16, and 82.2% (rademikibart) by Week 52. SAEs and permanent discontinuations due to TEAEs at week 16 were low in rademikibart group vs. placebo group (2.3% vs. 0% and 0.8% vs. 0%, respectively), and remained low at week 52 (5.5% and 0.8%, respectively).

Conclusions

Rademikibart 300mg Q2W significantly improved moderate-to-severe AD signs/symptoms by Week 16, with sustained and enhanced benefits through Week 52. Long term safety profile was consistent with that observed in the double-blind phase, with low serious adverse events and treatment discontinuations. These findings demonstrate the potential of rademikibart to offer best-in-class efficacy in moderate to severe AD patients.

Disclosures

Jianzhong Zhang has no relevant financial relationships to disclose.

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