

Nektar starts Phase 3 programme for T-reg biologic in atopic dermatitis

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The ZENITH AD programme will evaluate rezpegaldesleukin across treatment-naïve and treatment-experienced patients with moderate-to-severe disease.



Nektar Therapeutics has initiated the first two global registrational trials in its Phase 3 ZENITH AD programme for rezpegaldesleukin in moderate-to-severe atopic dermatitis.

The programme is evaluating rezpegaldesleukin in patients aged 12 years and older. ZENITH AD-1 and ZENITH AD-2 will enrol patients who are naïve to systemic biologics and JAK inhibitors, while ZENITH AD-3 will enrol treatment-experienced patients and is expected to begin in September.

Rezpegaldesleukin is a first-in-class regulatory T-cell biologic. It targets the IL-2 receptor complex to preferentially stimulate regulatory T-cell proliferation, with the aim of restoring immune balance in autoimmune and chronic inflammatory diseases.

This is relevant because many patients with moderate-to-severe atopic dermatitis fail to achieve adequate control or lose response over time on available therapies. A T-reg-directed mechanism could provide a differentiated route compared with therapies focused mainly on blocking downstream inflammatory pathways.

The ZENITH AD programme includes global, randomised, double-blind, placebo-controlled trials. Initial Phase 3 topline data are expected in mid-2028, with a Biologics License Application submission targeted for 2029.

The programme design follows End-of-Phase 2 meetings with the U.S. FDA and scientific advice from the European Medicines Agency. Nektar said the programme is intended to support registration in both the United States and Europe.

The company also plans to start a registrational Phase 3 trial of rezpegaldesleukin in alopecia areata in early 2027, based on prior Phase 2b data. A Phase 2 study in type 1 diabetes is also expected to produce initial data in 2027.

Rezpegaldesleukin positions Nektar around immune restoration rather than broad immune suppression, with atopic dermatitis serving as the first Phase 3 test of the company's T-reg biologic strategy.