

New Data from REZOLVE-AD Study of Repegaldesleukin Presented in Late-Breaking Oral Abstract Presentation at ACAAI 2025 Annual Scientific Meeting

November 8, 2025

Statistically significant and clinically meaningful improvements in mean ACQ-5 scores were reported at week 16 versus placebo in patients who had atopic dermatitis and a history of asthma

Extended dosing with repegaldesleukin q2w supports 24-week induction period for planned Phase 3 studies with improvement across major efficacy endpoints from Week 16 to 24, including EASI-75, EASI-90, and vIGA-AD

Data from long-term maintenance portion of REZOLVE-AD with 52 weeks of treatment expected in Q1 2026 from REZOLVE-AD study

Top-line Phase 2b data for repegaldesleukin in alopecia areata to be reported in December 2025

SAN FRANCISCO, Nov. 8, 2025 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today presented new data from the ongoing REZOLVE-AD Phase 2b study in a late-breaking oral abstract presentation at the American College of Allergy, Asthma & Immunology (ACAAI) 2025 Annual Scientific Meeting.

Repegaldesleukin is a first-in-class IL-2 pathway agonist and regulatory T-cell (Treg) biologic currently being studied in a Phase 2b study in moderate-to-severe atopic dermatitis (REZOLVE-AD) and a separate Phase 2b study in patients with severe-to-very-severe alopecia areata (REZOLVE-AA).

"Given that approximately one in four patients with atopic dermatitis also have asthma, improving asthma symptoms is a significant consideration in clinical treatment decisions," said lead author Dr. Jonathan Corren, Associate Clinical Professor of Medicine and Pediatrics at the David Geffen School of Medicine, University of California, Los Angeles. "The results with repegaldesleukin in patients with atopic dermatitis and comorbid asthma demonstrate that promotion of Treg activity may also have benefits to the lower airways, an observation which warrants further investigation."

The Phase 2b REZOLVE-AD trial enrolled 393 patients with moderate-to-severe atopic dermatitis, of which 99 patients also reported having a history of asthma with ACQ-5 data available at both baseline and week 16. A pre-planned analysis in the study evaluated scores from a validated Asthma Control Questionnaire (ACQ-5) at baseline and at the end of the 16-week induction period. For the patients reporting a history of asthma, all three repegaldesleukin doses demonstrated an overall reduction in mean observed ACQ-5 scores at week 16 with two dose arms (24 µg/kg q2w and 24 µg/kg q4w) achieving statistical significance ($p < 0.05$) as compared to placebo. Patients in the placebo arm reported an overall worsening of mean ACQ-5 scores.

Improvements were more pronounced in patients with only partly controlled or uncontrolled asthma:

- In patients with a baseline ACQ-5 score of 0.5 or higher (N=53), at least half of the patients experienced clinically significant improvement (≥ 0.5 point reduction) in ACQ-5 at Week 16 across all treatment arms as compared to 13% in the placebo arm.
- Placebo-adjusted reductions of mean ACQ-5 scores in the subset of patients with baseline ACQ-5 score of 0.5 or higher ranged from 0.7 to 1.0.
- Among the 25 patients with uncontrolled asthma at baseline (≥ 1.5 ACQ-5 score), all three active doses of repegaldesleukin demonstrated a meaningful improvement in mean observed ACQ-5 scores at Week 16 and all dose arms achieved statistical significance ($p < 0.05$) as compared to placebo.
- Placebo-adjusted reductions of mean ACQ-5 scores in this subset of patients with uncontrolled asthma at baseline (≥ 1.5 ACQ-5 score) ranged from 1.0 to 1.4.
- For the 24 µg/kg q2w treatment arm, 75% of patients with uncontrolled asthma at baseline had a clinically significant improvement (≥ 0.5 points reduction) in ACQ-5 at Week 16.

"These observations of improvement in asthma control in REZOLVE-AD support the broad potential of repegaldesleukin's Treg mechanism across multiple T-cell mediated inflammatory diseases," said Jonathan Zalevsky, Ph.D., Chief Research and Development Officer of Nektar. "The data demonstrate that repegaldesleukin could offer a unique and differentiated innovative treatment for atopic dermatitis, particularly as these findings have not been observed with other biologic mechanisms recently approved or in advanced development."

Overall, in REZOLVE-AD, repegaldesleukin 24 µg/kg q2w resulted in statistically significant improvements in the primary and secondary endpoints on all measurements of atopic dermatitis disease control as compared to placebo. Repegaldesleukin resulted in improvement of mean percent change in EASI ($p < 0.001$), EASI-75 ($p < 0.001$), EASI-90 ($p < 0.05$), vIGA-AD 0/1 ($p < 0.05$),

and NRS-Itch response (≥ 4 -point reduction) ($p < 0.01$) at Week 16. This treatment effect was observed across baseline characteristics for severity of disease, region, and asthma comorbidity.

Results presented today also included data for a total of 42 placebo patients who crossed over at Week 16 and continued in the study on a treatment escape arm to receive high dose rezpegaldesleukin (24 $\mu\text{g}/\text{kg}$ q2w). Based on observed data from these patients, EASI-75 response rate at crossover week 24 was 60%; vIGA-AD 0/1 response rate at crossover week 24 was 33%; EASI-90 response rate at crossover week 24 was 37%; and Itch NRS response rate at crossover week 24 was 50% in patients with baseline score ≥ 4 . These data support advancing the dose regimen of rezpegaldesleukin 24 $\mu\text{g}/\text{kg}$ q2w with a 24-week treatment induction period into Phase 3 studies.

Details of the presentation at ACAAI are as follows:

- Abstract ID: 7005
- Oral Presentation: "Rezpegaldesleukin Novel Treg-Inducing Therapy Demonstrates Efficacy in Atopic Dermatitis and Asthma in Phase 2b Trial"
- Session Title: Distinguished Industry & Late-breaking Oral Abstracts - Session 2
- Presentation Date and Time: Saturday, November 8, 2025 at 5:33 PM ET
- Location: Room W231

The full presentation made today at the 2025 ACAAI Scientific Meeting is available on Nektar's website at <http://www.nektar.com> under Scientific Publications.

About REZOLVE-AD Phase 2b Study

The ongoing global Phase 2b REZOLVE-AD study ([NCT06136741](https://clinicaltrials.gov/ct2/show/study/NCT06136741)) enrolled 393 patients with moderate-to-severe atopic dermatitis who had not previously received treatment with biologic or JAK inhibitor therapies. Patients were randomized across three different dose regimens of subcutaneous rezpegaldesleukin or placebo for a 16-week induction treatment period. Following this period, rezpegaldesleukin-treated patients who achieved EASI percent score reductions of >50 (EASI-50) were re-randomized (1:1) to continue at the same dose level on a q4w or q12w regimen through study week 52 in a blinded maintenance period.

The primary endpoint of the Phase 2b study is mean improvement in EASI score at the end of the 16-week induction treatment period. Secondary endpoints include the proportion of patients achieving Validated Investigator Global Assessment (vIGA-AD) of 0 or 1, those achieving EASI-75, and those achieving a greater than or equal to a 4-point improvement in Itch Numeric Rating Scale (NRS). Preplanned exploratory endpoints include a full range of translational biomarker measurements and a change in asthma control questionnaire - 5 (ACQ-5) scores for patients with comorbidity of asthma.

This trial was initiated in October 2023 and enrolled patients across approximately 110 sites globally with: 68% enrolled and treated in Europe, including Poland, Bulgaria, Germany, Czech Republic, Spain, Croatia and Hungary; 16% enrolled and treated in the United States; 11% enrolled and treated in Canada; and 5% enrolled and treated in Australia. Patient randomization was stratified based on baseline disease severity measured by vIGA-AD and geographic region. Key enrollment criteria in the study included a minimum EASI score of 16.0, a minimum Body Surface Area (BSA) of 10% and a minimum vIGA-AD of 3.

About Rezpegaldesleukin

Autoimmune and inflammatory diseases cause the immune system to mistakenly attack and damage healthy cells in a person's body. A failure of the body's self-tolerance mechanisms enables the formation of the pathogenic T lymphocytes that conduct this attack. Rezpegaldesleukin is a potential first-in-class resolution therapeutic that may address this underlying immune system imbalance in people with many autoimmune and inflammatory conditions. It targets the interleukin-2 receptor complex in the body to stimulate proliferation of immune-modulating cells known as regulatory T cells. By activating these cells, rezpegaldesleukin may act to bring the immune system back into balance.

In February 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for rezpegaldesleukin for the treatment of adult and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. In July 2025, the FDA granted Fast Track designation for rezpegaldesleukin for the treatment of severe alopecia areata (AA) in adults and pediatric patients 12 years of age and older who weigh at least 40 kg.

Rezpegaldesleukin is being developed as a self-administered injection for a number of autoimmune and inflammatory diseases. It is wholly owned by Nektar Therapeutics.

About Atopic Dermatitis

Atopic dermatitis is the most common type of eczema, affecting approximately 30 million people in the United States.¹ AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation.

About Nektar Therapeutics

Nektar Therapeutics is a clinical-stage biotechnology company focused on developing treatments that address the underlying

immunological dysfunction in autoimmune and chronic inflammatory diseases. Nektar's lead product candidate, rezpegaldesleukin (REZPEG, or NKTR-358), is a novel, first-in-class regulatory T cell stimulator being evaluated in two Phase 2b clinical trials, one in atopic dermatitis, one in alopecia areata, and in one Phase 2 clinical trial in Type 1 diabetes mellitus. Nektar's pipeline also includes a preclinical bivalent tumor necrosis factor receptor type II (TNFR2) antibody and bispecific programs, NKTR-0165 and NKTR-0166, and a modified hematopoietic colony stimulating factor (CSF) protein, NKTR-422. Nektar, together with various partners, is also evaluating NKTR-255, an investigational IL-15 receptor agonist designed to boost the immune system's natural ability to fight cancer, in several ongoing clinical trials.

Nektar is headquartered in San Francisco, California. For further information, visit www.nektar.com and follow us on [LinkedIn](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "could," "develop," "potential," "target," "address," "may" and similar references to future periods. Examples of forward-looking statements include, among others, statements regarding the therapeutic potential of, and future development plans for, rezpegaldesleukin, NKTR-0165, NKTR-0166, NKTR-422, and NKTR-255. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) our statements regarding the therapeutic potential of rezpegaldesleukin, NKTR-0165, NKTR-0166, NKTR-422 and NKTR-255 are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) rezpegaldesleukin, NKTR-0165, NKTR-0166, NKTR-422 and NKTR-255 are investigational agents and continued research and development for these drug candidates is subject to substantial risks, including negative safety and efficacy findings in future clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) rezpegaldesleukin, NKTR-0165, NKTR-0166, NKTR-422 and NKTR-255 are in clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval; (iv) data reported from ongoing clinical trials are necessarily interim data only and the final results will change based on continuing observations; (v) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (vi) a Fast Track designation does not increase the likelihood that rezpegaldesleukin will receive marketing approval in the United States; (vii) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (viii) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2025. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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1. Eczema stats. National Eczema Association (2022, September 27). <https://nationaleczema.org/research/eczema-facts>

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