Nektar Announces Publication in The Lancet of Positive Phase 2b REZOLVE-AD 16-Week Induction Results of Rezpegaldesleukin in Moderate-to-Severe Atopic Dermatitis

August 25, 2026

REZOLVE-AD study met all primary and key secondary endpoints, including EASI-75, EASI-90, Itch NRS, vIGA-AD and BSA, on rezpegaldesleukin 24 µg/kg q2w

First large, placebo-controlled trial to support T-reg modulation as a clinical mechanism for immunoregulation of chronic inflammatory disease

Findings support the continued development of rezpegaldesleukin in the ongoing Phase 3 ZENITH AD clinical program

SAN FRANCISCO, Aug. 25, 2026 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced the publication of peer-reviewed data from the 16-week induction period of REZOLVE-AD, a global, randomized, double-blind, placebo-controlled Phase 2b study evaluating rezpegaldesleukin in adults with moderate-to-severe atopic dermatitis (AD). The publication in *The Lancet*, a world-leading medical journal, provides the medical and scientific community with the full reporting of efficacy, safety, pharmacodynamics, pharmacokinetics, and biomarker findings from the 16-week induction period of the Phase 2b trial.

Bold immune science.
Transformative immune health.

Rezpegaldesleukin is a first-in-class regulatory T-cell (T-reg) biologic designed to address imbalances in the immune system that underlie many autoimmune disorders and chronic inflammatory conditions. It targets the IL-2 receptor complex to preferentially stimulate the proliferation of T-regs to restore immune balance.

"These results represent the first large, randomized, placebo-controlled trial to demonstrate that selectively expanding regulatory T cells can translate into clinically meaningful improvements across both physician-assessed and patient-reported outcomes in patients with atopic dermatitis," said Jonathan I. Silverberg, M.D., Ph.D., M.P.H., Professor of Dermatology at George Washington University School of Medicine and Principal Investigator of the REZOLVE-AD study. "The rapid onset of efficacy, paired with consistency of responses across disease severity and a good safety profile, highlights the unique promise of rezpegaldesleukin. With a T-reg mechanism that works upstream of currently available targeted agents, we have the opportunity with rezpegaldesleukin to alter the treatment paradigm and provide a novel alternative for the many patients with moderate-to-severe atopic dermatitis who are inadequately treated today."

The REZOLVE-AD trial was conducted across 107 sites in 10 countries, analyzing 393 biologic- and JAK inhibitor-naive adults with moderate-to-severe atopic dermatitis. Patients were randomized to one of three rezpegaldesleukin dosing regimens (24 µg/kg every two weeks, 18 µg/kg every two weeks, or 24 µg/kg every four weeks) or placebo for a 16-week induction period, with the primary endpoint of mean percent change from baseline in Eczema Area and Severity Index (EASI) at Week 16.

"We are pleased to share these important data with the broader medical and scientific community through publication in The Lancet," said Jonathan Zalevsky, Ph.D., Chief Research and Development Officer of Nektar Therapeutics. "In 2025, the discovery of T-regs was recognized by the Nobel Prize in Physiology and Medicine. These REZOLVE-AD study results demonstrate, for the first time, that modulation of T-regs represents a novel mechanism for chronic inflammatory disease with no evidence of immunosuppression observed. Unlike current therapeutic strategies available and in late-stage development, which largely focus on inhibiting cytokines to suppress inflammation, rezpegaldesleukin showed no increased risk for viral or bacterial infections in the clinical trials completed to-date in over 1,000 study participants. These findings further strengthen the scientific foundation for our ongoing Phase 3 ZENITH AD program in patients with atopic dermatitis."

Highlights from the REZOLVE-AD study

- **All three dosing regimens met the primary endpoint:** Patients treated with rezpegaldesleukin showed statistically significant, dose-dependent improvement in mean percent reduction in EASI from baseline at Week 16: 61%, 58%, and

53% for the 24 µg/kg q2w, 18 µg/kg q2w, and 24 µg/kg q4w arms, respectively, compared with 31% for placebo (p<0.0001, p<0.0001, and p=0.0002, respectively).

- **Key secondary endpoints were met:** Significant improvements over placebo were observed in EASI-75 (42% vs. 17%), EASI-90 (25% vs. 9%), Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) 0/1 response (20% vs. 8%), Itch Numerical Rating Scale (NRS) 4-point reduction (42% vs. 16%), and body surface area (BSA) change from baseline (-54% vs. -17%), all favoring rezpegaldesleukin 24 µg/kg q2w.
- **Key Patient-Reported Outcome (PRO) Assessments:** Rezpegaldesleukin demonstrated statistically significant improvements in patient reported outcomes over placebo at week 16 including ≥ 4-point reduction in Daily Life Quality Index (DLQI) (72% vs. 54%), ≥ 5-point reduction in Atopic Dermatitis Control Tool (ADCT) (67% vs. 35%), ≥ 4-point reduction in Pain Numeric Rating (Pain NRS) (45% vs. 22%) and ≥ 1.25-point reduction in Atopic Dermatitis Sleep Scale (ADSS) item 1 (57% vs. 30%), all favoring rezpegaldesleukin 24 µg/kg q2w.
- **Rapid onset with deepening responses over time:** Significant EASI improvement was observed as early as Week 2 in the 24 µg/kg dose arms and by Week 4 across all rezpegaldesleukin arms, with responses continuing to deepen through Week 16, indicating potential for further benefit with extended induction treatment.
- **Consistent efficacy across baseline disease severity:** Rezpegaldesleukin demonstrated similar efficacy in patients with moderate (vIGA-AD score 3) and severe (vIGA-AD score 4) disease at baseline.
- **Meaningful itch relief, including in patients with severe itch:** Among patients with a baseline Itch NRS score of 7 or greater, Itch NRS response rates were 54% and 49% for the 24 µg/kg q2w and 18 µg/kg q2w arms, respectively, compared with 24% for placebo.
- **Favorable and differentiated safety profile:** Safety data for rezpegaldesleukin for the 16-week induction period were consistent with the previously observed and reported safety profile.[1-3] Serious adverse events were rare (2%), with no deaths reported during the 16-week induction period and no increased risk of infections, conjunctivitis, or other safety signals associated with currently approved AD therapies.
- **Biomarker data support mechanism of action:** Rezpegaldesleukin dose-dependently reduced key AD biomarkers including TARC/CCL17, periostin, MDC/CCL22, and interleukin-19 in patients with elevated baseline levels, consistent with upstream immunomodulation through T-reg restoration. The results from this trial, corroborated by biomarker evidence of rezpegaldesleukin's mechanistic activity, support a central role of T-reg imbalance in the pathogenesis of atopic dermatitis and IL-2 receptor agonism as an important therapeutic target.
- **Phase 3 program underway:** Based on T-reg pharmacodynamic findings and overall benefit-risk profile, the 24 µg/kg q2w induction dosing and monthly and quarterly maintenance dosing regimens have been selected for the ZENITH AD Phase 3 program, which is currently enrolling.

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Rezpegaldesleukin is currently in Phase 3 development. The registrational program in atopic dermatitis includes three global, randomized, double-blind, placebo-controlled trials: ZENITH AD-1 and ZENITH AD-2 initiated in July 2026, which are currently enrolling biologic and systemic JAK inhibitor treatment-naive patients, and ZENITH AD-3, which will enroll patients with prior systemic biologic and/or JAK inhibitor treatment experience when the study initiates in September 2026. In early 2027, we also plan to initiate a single registrational Phase 3 trial in alopecia areata, based upon strong data from our randomized, placebo-controlled Phase 2b REZOLVE-AA study.

About *The Lancet*

The Lancet is a world-leading source of clinical, public health, and global health knowledge. Lancet journals have an extensive global reach with more than 33.9 million annual visits and 169.9 million downloaded articles.[4]

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 disease modifying 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 powerful inhibitory immune 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. 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, including atopic dermatitis, alopecia areata and Type 1 diabetes. 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[5]. 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 atopic dermatitis, alopecia areata, and Type 1 diabetes mellitus. Nektar's pipeline also includes 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 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: "will", "can," "develop," "potential," "expand," "address," "may," "plan" and similar references to future periods. Examples of forward-looking statements include, among others, statements regarding the safety and efficacy profile and therapeutic potential of, and future development plans for, rezpegaldesleukin, NKTR-0165, NKTR-0166, and NKTR-422, and potential patient preferences and market adoption related thereto, and plans and timing of future clinical trials and data releases. 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 and NKTR-422 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 and NKTR-422 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 and NKTR-422 are in various stages of preclinical and clinical development, the risk of failure is high and can unexpectedly occur at any stage of development, and there can be no assurance that any such drug candidate will obtain regulatory approval; (iv) data reported from ongoing clinical trials may be preliminary or interim and may change as additional patient data become available or as continuing observations, verifications and analysis are completed; (v) the timing of the initiation or completion 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 filings with the Securities and Exchange Commission (SEC), including the risks and uncertainties described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K or Quarterly Report, as such risks and uncertainties may be amended or supplemented by our other filings with the SEC . 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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