Nektar Therapeutics Receives Fast Track Designation for Rezpegaldesleukin for the Treatment of Severe-to-Very Severe Alopecia Areata

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SAN FRANCISCO, July 29, 2025 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for rezpegaldesleukin for the treatment of severe-to-very severe alopecia areata (AA) in adults and pediatric patients 12 years of age and older who weigh at least 40 kilograms. Rezpegaldesleukin is an investigational biologic therapy that targets the interleukin-2 receptor complex in the body to stimulate proliferation of inhibitory immune cells known as regulatory T cells (Tregs). Results from multiple clinical trials showed that rezpegaldesleukin safely and dose-dependently increased Tregs.[1]

"We are pleased that rezpegaldesleukin has been granted Fast Track designation for the treatment of alopecia areata, adding to its Fast Track designation in atopic dermatitis," said Jonathan Zalevsky, Ph.D., Senior Vice President and Chief Research & Development Officer at Nektar. "Alopecia areata is a chronic, systemic, immune-mediated inflammatory disease, and there is an urgent need for novel mechanistic approaches that could treat the underlying pathogenesis of this disorder. We remain on track to announce topline data in December from our ongoing REZOLVE-AA Phase 2b study for rezpegaldesleukin in alopecia areata, and we look forward to the opportunity to collaborate quickly with the agency on a potential registrational program following the completion of Phase 2."

The goal of the FDA's Fast Track process is to ensure that important new treatments reach patients as quickly as possible. The designation is granted to investigational therapies that treat serious conditions and have the potential to address an unmet medical need. A drug candidate that receives Fast Track designation is eligible for more frequent meetings and written interactions with the FDA to discuss the drug candidate's development plan as well as possible eligibility for rolling review and priority review.

About REZOLVE-AA

The REZOLVE-AA (NCT06340360) study enrolled approximately 90 patients with severe-to-very severe alopecia areata who have not previously been treated with a JAK inhibitor or other biologic. Patients were randomized across two different dose regimens of rezpegaldesleukin or placebo. The primary efficacy endpoint will evaluate the mean percent change in the Severity of Alopecia Tool (SALT) score at the end of the 36-week induction period. Secondary endpoints include the proportion of participants with greater than or equal to 50% reduction in SALT score at week 36 and other assessed timepoints, the mean percent improvement in SALT score at other assessed timepoints, and the proportion of patients achieving SALT-20 (an absolute SALT score of less than or equal to 20). The Company expects to share these results in December 2025.

This trial was initiated in March 2024. Patients were enrolled across approximately 30 sites globally with: 62% enrolled in Poland; 24% enrolled in Canada; and 14% enrolled in the United States.

Enrollment criteria in the study included a diagnosis of severe-to-very severe alopecia areata (≥ 50% scalp involvement) as measured using the SALT score at both screening and randomization. Patients who experienced an unstable course of alopecia areata over the last 6 months per investigator assessment were excluded from the study. Patients with diffuse alopecia and other forms of alopecia were also excluded. Patient randomization was stratified based on baseline disease severity as measured by the SALT score.

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 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. 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 who weigh at least 40 kilograms with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

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 Alopecia Areata

Alopecia areata is a disease where a patient's own immune system attacks hair follicles resulting in hair loss.[2] The lifetime incidence of alopecia areata is 2% in both men and women.[2] Nearly 6.7 million people in the U.S. and 160 million worldwide develop alopecia areata in their lifetime. About 700,000 people in the U.S. currently have some form of alopecia areata.[3] It is often associated with other auto-immune conditions as well as depression and anxiety.[2] The disease has a tremendous impact on quality of life for patients.[4] Available therapies for alopecia are not durable and have high relapse rates and there is an urgent unmet medical need for novel, more effective therapies for patients.

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 and one in alopecia areata. 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: "will," "could," "forward," "expect," "develop," "potential," "plan," and similar references to future periods. Examples of forward-looking statements include, among others, statements regarding the therapeutic potential and safety profile of, and future development plans for, rezpegaldesleukin, the results and timing for reporting data from REZOLVE-AA, the potential for rezpegaldesleukin to be a first-in-class T regulatory cell therapy, the potential market opportunity in atopic dermatitis and alopecia areata, the advantage of a broad-based Treg mechanism over other immune-modulation approaches in development, and the high unmet need for a new mechanism of action in alopecia areata. 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 are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) rezpegaldesleukin is an investigational agent and continued research and development for this drug candidate 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 is in clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval; (iv) 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; (v) a Fast Track designation does not increase the likelihood that rezpegaldesleukin will receive marketing approval in the United States; (vi) 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 (vii) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 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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