Nektar Therapeutics Receives Fast Track Designation for Rezpegaldesleukin for the Treatment of Moderate-to-Severe Atopic Dermatitis

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SAN FRANCISCO, Feb. 10, 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 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. Rezpegaldesleukin is an investigational biologic therapy that targets the interleukin-2 receptor complex in the body in order to stimulate proliferation of inhibitory immune cells known as regulatory T cells (Tregs).

In patients with moderate-to-severe atopic dermatitis, rezpegaldesleukin has been shown to rapidly improve measurable exploratory disease outcomes during a 12-week induction treatment phase and for at least 36 weeks after ceasing treatment, demonstrating proof-of-concept in this indication.[1] Proof-of-concept efficacy and safety data from a Phase 1b study of rezpegaldesleukin in atopic dermatitis patients were presented at the 2023 EADV Congress in October 2023 (Presentation Link).

"We are pleased that rezpegaldesleukin has been designated a Fast Track product," said Jonathan Zalevsky, Ph.D., Senior Vice President and Chief Research & Development Officer at Nektar. "Rezpegaldesleukin has the potential to address a significant unmet need for the millions of patients living with moderate-to-severe atopic dermatitis. We remain on track to announce topline data from the induction period of our Phase 2b REZOLVE-AD study in the second quarter of this year. This designation will now allow us to collaborate closely with the agency on the design of the registrational program for rezpegaldesleukin once we've completed 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-AD
The REZOLVE-AD (NCT06136741) study enrolled 398 patients with moderate-to-severe atopic dermatitis who had not previously received treatment with biologic or JAK inhibitor therapies. Patients randomized across three different dose regimens of rezpegaldesleukin and placebo for a 16-week induction treatment period. Following this period, patients who meet an Eczema Area and Severity Index (EASI) score threshold for advancement to maintenance are re-randomized to one of two maintenance regimens at their original dose level to receive maintenance therapy either once a month or once every three months.

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).

This trial was initiated in October 2023. Patients were enrolled across approximately 110 sites globally with: 67% enrolled in the European countries of Poland, Bulgaria, Germany, Czechia, Spain, Croatia and Hungary; 17% enrolled in the United States; 11% enrolled in Canada; and 5% enrolled in Australia. Patient randomization was stratified based on baseline disease severity measured by vIGA-AD and geographic region.

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 at both screening and randomization. Patients who experienced an unstable course of atopic dermatitis between screening and randomization per investigator assessment were excluded from the study.

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 in order 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.

Rezpegaldesleukin is being developed as a self-administered injection for a number of autoimmune and inflammatory diseases. In addition to the REZOLVE-AD study, it is also being evaluated in the REZOLVE-AA study, a randomized, double blind, placebo-controlled Phase 2b clinical trial for treatment of patients with severe-to-very-severe alopecia areata (NCT06340360). Rezpegaldesleukin 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.[2] 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 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 Nektar on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "announce," "potential," "may," "allow," "can," and similar references to future periods. Examples of forward-looking statements include, among others, statements regarding the potential benefits from Fast Track designation, the therapeutic potential of, and future development plans for, rezpegaldesleukin, and the timing for the announcement of rezpegaldesleukin clinical data. 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) a Fast Track designation does not increase the likelihood that rezpegaldesleukin will receive marketing approval in the United States; (ii) 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; (iii) 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); (iv) rezpegaldesleukin is in clinical development, and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval; (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, 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) 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 November 8, 2024. 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.

For Investors:

Vivian Wu of Nektar Therapeutics
628-895-0661

For Media:

Madelin Hawtin
LifeSci Communications
603-714-2638
mhawtin@lifescicomms.com

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