Nektar Therapeutics Announces Completion of Target Enrollment in REZOLVE-AA Phase 2b Clinical Trial of Rezpegaldesleukin in Patients with Severe-to-Very Severe Alopecia Areata

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SAN FRANCISCO, Feb. 26, 2025 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced the company has completed target enrollment in its REZOLVE-AA Phase 2b study of rezpegaldesleukin in patients with severe-to-very-severe alopecia areata.

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). Results from multiple clinical trials showed that rezpegaldesleukin safely and dose-dependently increased Tregs.[1]

"We are grateful to the patients and physicians whose enthusiasm for this novel mechanism enabled us to achieve our 84-patient target enrollment in the rezpegaldesleukin alopecia study," said Howard W. Robin, President and CEO of Nektar Therapeutics. "Rezpegaldesleukin has demonstrated activity in multiple inflammatory skin disease settings. There is a high unmet need for better treatment options in alopecia areata as the standard of care therapies available have significant relapse rates and carry potential long-term safety challenges. This creates an opportunity for rezpegaldesleukin to emerge as the first novel treatment option targeting T regulatory cell dysfunction in the hair follicles of patients battling this chronic condition. We look forward to reporting our topline data from this study in the fourth quarter of this year."

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

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 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 wholly-owned by Nektar Therapeutics. It is being developed as a self-administered injection for a number of autoimmune and inflammatory diseases. In addition to the REZOLVE-AA study, it is also being evaluated in the REZOLVE-AD study, a randomized, double blind, placebo-controlled Phase 2b clinical trial for treatment of patients with moderate-to-severe atopic dermatitis (NCT06136741). 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.

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 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," "advance," "anticipate," "can," 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. 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 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.

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