Nektar Therapeutics Announces Initiation of Phase 2b Clinical Study Evaluating Rezpegaldesleukin in Patients with Severe to Very Severe Alopecia Areata

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SAN FRANCISCO, March 5, 2024 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR), a biotechnology company developing medicines for the treatment of auto-immune disorders, today announced the initiation of its Phase 2b clinical trial evaluating rezpegaldesleukin in patients with severe to very severe alopecia areata.

Rezpegaldesleukin (REZPEG) is a novel agonistic T regulatory cell biologic that is designed to both dampen the inflammatory response and simultaneously restore immune balance by directly expanding functional T reg cells and engaging multiple immunoregulatory pathways.

"The start of this Phase 2b study is another significant milestone for Nektar as we advance REZPEG, a potentially transformative new mechanism for alopecia areata and other auto-immune disorders," said Mary Tagliaferri, M.D., Chief Medical Officer at Nektar Therapeutics. "Alopecia areata is a disease where a patient's own immune system attacks hair follicles and the resulting hair loss can be devastating for patients. Current treatments available have high relapse rates and carry potential safety challenges. As a result, there is a high unmet need for durable and well-tolerated treatment options that target the underlying dysfunction of the immune system in these patients. We believe there's an opportunity for REZPEG to emerge as a novel biologic mechanism for alopecia patients and we look forward to our topline data from this study expected in the first half of 2025."

Nektar's global, randomized, double-blind, placebo-controlled, dose-ranging Phase 2b study will investigate the efficacy and safety of REZPEG in 84 participants with severe to very severe alopecia areata over a 36-week induction treatment period. The induction treatment period will compare two different dosing regimens of REZPEG against placebo. Participants will be followed for an additional 24 weeks after the end of the treatment period to evaluate durability. Initial results from the study are anticipated in the first half of 2025.

The primary efficacy endpoint will evaluate mean percent improvement in the Severity of Alopecia Tool (SALT) at week 36. Secondary endpoints include proportion of participants with greater than or equal to 50% reduction in SALT at week 36 and other assessed timepoints and mean percent improvement in SALT at other assessed timepoints.

About Alopecia Areata

The lifetime incidence of alopecia areata is 2% in both men and women.[1] 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.[2] It is often associated with other auto-immune conditions as well as depression and anxiety.[1] The disease has a tremendous impact on quality of life for patients.[3] 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 REZPEG

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. REZPEG 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, REZPEG may act to bring the immune system back into balance.

REZPEG is being developed as a self-administered injection for a number of autoimmune and inflammatory diseases. In addition to this clinical trial in patients with severe to very severe alopecia areata, REZPEG is also being evaluated in a Phase 2b study in the treatment of adult patients with moderate-to-severe atopic dermatitis (REZOLVE-AD; NCT06136741). REZPEG is wholly-owned by Nektar Therapeutics.

About Nektar Therapeutics

Nektar Therapeutics is a biotechnology company with a robust, wholly owned R&D pipeline of investigational medicines in oncology and immunology as well as a portfolio of approved partnered medicines. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama. Further information about the company and its drug development programs and capabilities may be found online at http://www.nektar.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "expect," "develop," "potential," "advance," "anticipate," 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 challenges caused by the COVID-19 pandemic, 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) we may not achieve the expected cost savings we expect from our 2022 corporate restructuring and reorganization plan or our 2023 cost restructuring plan and we may undertake additional restructuring and cost-saving activities in the future, (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, 2023. 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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