Nektar Therapeutics Announces It Will Regain Full Rights to Rezpegaldesleukin (REZPEG, NKTR-358), a Novel, First-in-Class Selective Regulatory T-cell (Treg) Therapy in Clinical Development

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Company plans to move REZPEG forward into Phase 2 clinical study in atopic dermatitis

SAN FRANCISCO, April 27, 2023 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that it will be regaining the full rights to REZPEG from Eli Lilly and Company.

As announced in a press release issued on April 17, Nektar plans to move forward with REZPEG and will initiate a Phase 2b study in patients with moderate-to-severe atopic dermatitis in 2023. The company will also explore other auto-immune indications for the development plan for REZPEG.

Phase 1b data for REZPEG in atopic dermatitis were presented at an investment presentation made by Eli Lilly and Company in December 2021 and at the 2022 European Academy of Dermatology (EADV). REZPEG evidenced a dose-dependent improvement over placebo for key efficacy measures of mean change in EASI, EASI-75, vIGA-AD scores, and Itch NRS ≥4-point scales. These improvements were observed for an additional 36 weeks following the 12-week treatment period.

"The promising Phase 1b data presented at the 2022 EADV conference warrant moving REZPEG forward into Phase 2 development," said Jonathan Silverberg, MD, PhD, MPH, Associate Professor of Dermatology at The George Washington University School of Medicine and Health Sciences in Washington, DC and the Director of Clinical Research and Contact Dermatitis. "The durability of the response may offer an opportunity for a quarterly maintenance dosing regimen and improved long-term disease control."

The proof-of-concept data presented to-date on REZPEG also evidenced REZPEG's ability to stimulate Tregs to target an immune system imbalance resulting in an improvement of disease activity in patients. In addition, REZPEG data were recently highlighted in a talk by Eric Lawrence Simpson, MD, FAAD at the 2023 American Academy of Dermatology (AAD) Annual Meeting on March 17, 2023 in the scientific session covering atopic dermatitis, as a potential future remittive therapy.

"We are pleased to be regaining full rights to REZPEG," said Howard W. Robin, President and CEO of Nektar. "We plan to work quickly to initiate a Phase 2b study in atopic dermatitis. We believe the strong data generated to-date for REZPEG in atopic dermatitis show the significant potential for REZPEG to emerge as an innovative new mechanism with the possibility of disease resolution in a growing biologic treatment field. We are excited about REZPEG's immune-modulatory profile and believe it could offer great hope in the future to patients who are managing this common and debilitating condition. We look forward to demonstrating this in the clinic as quickly as possible."

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in immunology and oncology as well as a portfolio of approved partnered medicines. Nektar is headquartered in San Francisco, California, with additional manufacturing 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.

About Rezpegaldesleukin (REZPEG, NKTR-358)

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 an investigational, potential first-in-class T regulatory cell stimulator that may address this underlying immune system imbalance in people with many autoimmune and inflammatory conditions. It is designed to target 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.

About Atopic Dermatitis

Atopic dermatitis is a chronic skin disease characterized by intense itching, dry skin and inflammation that can be present on any part of the body.[1] Atopic dermatitis is a heterogeneous disease and may be characterized by a highly variable appearance in which flares occur in an unpredictable manner.[2] It is estimated that 16.5 million U.S. adults are affected by the disease with nearly 40% being diagnosed with moderate to severe disease.[3]

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "may," "advance," "support," "develop," "provide," "expect," "aim," "potential" 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, and our other drug candidates in research programs, the prospects and plans for our collaborations with other companies, the timing of the initiation of clinical studies and the data readouts for our drug candidates. 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, and our other drug candidates are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) rezpegaldesleukin and our other drug candidates are investigational agents and continued research and development for these drug candidates is subject to substantial risks, including negative safety and efficacy findings in ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) rezpegaldesleukin and our other drug candidates are in various stages of 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 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.

1. Weidinger S, Novak N. Lancet. 2016;387:1109-1122.
2. Langan SM, et al. Arch Dermatol. 2008;142:1109.
3. Chiesa Fuxench, Z. C. et al. J. Invest. Dermatol. 2019;139(3): 583-590.

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