



October 13, 2023

Nektar Presents New Responder Data for Repegaldesleukin, a First-in-Class Selective Regulatory T-cell Therapy, in Late-Breaking News Oral Presentation at 2023 EADV Congress

– Dose-Dependent Efficacy Reported Across All Endpoints for REZPEG Demonstrating a Rapid Onset of Action and Continuing Benefit for 36 Weeks After 12-Week Treatment Period –

– New Data Presented Show Encouraging Proportion of Patient-Reported Responder Outcomes for DLQI and POEM Endpoints –

SAN FRANCISCO, Oct. 13, 2023 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) today announced new data for repegaldesleukin (REZPEG), a first-in-class selective regulatory T-cell (Treg) therapy, in patients with atopic dermatitis (AD) at the 2023 European Academy of Dermatology and Venereology (EADV) Congress. These data were presented by Dr. Jonathan Silverberg, Professor of Dermatology at The George Washington University School of Medicine and Health Sciences and Director of Clinical Research and Contact Dermatitis in a late-breaking oral presentation.

"Data from this presentation demonstrate consistent benefit with REZPEG across multiple clinician and patient-reported outcomes, which were maintained through 36 weeks after treatment ended," said Dr. Jonathan Silverberg. "The sustained post-treatment benefit observed with REZPEG has the potential to alter the need for frequent maintenance dosing for patients with atopic dermatitis. Together with the observed safety profile, these promising results potentially open the door for a new therapeutic class."

In the Phase 1b study, patients with moderate-to-severe AD that were treated with REZPEG showed dose-dependent improvements in Eczema Area and Severity Index (EASI), Validated Investigator Global Assessment (vIGA), Body Surface Area (BSA), and Itch Numeric Rating Scale (NRS) over 12 weeks of treatment compared to placebo, which were sustained post-treatment over an additional 36 weeks. At the highest studied dose, the proportion of Daily Life Quality Index (DLQI) responders was 75% and the proportion of Patient Oriented Eczema Measure (POEM) responders was 65% at week 12. The proportion of responders were generally sustained after treatment ended through the 36-week follow-up. This durability highlights REZPEG's disease remittive potential.

REZPEG was well tolerated with no patients in the REZPEG groups experiencing severe, serious, or fatal adverse events, and no anti-REZPEG antibodies were detected. Pharmacodynamic data observed in the Phase 1b study corroborate the clinical efficacy signal observed in patients. Compared with placebo, there were sustained increases in absolute numbers of circulating total (FoxP3⁺CD25⁺) and CD25^{bright} Tregs in the REZPEG treatment arms. The peak increase in CD25^{bright} Treg number was 10-fold above baseline in the 24 µg/kg group.

Based on these data, the company is initiating two Phase 2 studies in atopic dermatitis and in alopecia areata. These trials are expected to initiate in October of this year and in early 2024, respectively. The trial design for the study in patients with moderate-to-severe atopic dermatitis was presented in an ePoster at EADV earlier this week.

"The findings presented today confirm our previously-reported data demonstrating the efficacy and rapid onset of action of REZPEG and continue to reinforce the promise of REZPEG as a novel therapeutic for patients with moderate-to-severe atopic dermatitis," said Jonathan Zalevsky, Ph.D., Senior Vice President and Chief Research & Development Officer at Nektar. "We look forward to advancing the program into our robust Phase 2b study in this indication and exploring its therapeutic potential in other autoimmune indications, including alopecia areata."

Highlight of the new patient-reported outcomes for the Phase 1b study in atopic dermatitis presented at EADV 2023 for the first time:

Proportion of Patients Who Achieved a DLQI Greater than or Equal to a 4-point Reduction from Baseline (NRI* calculation)

Study Arm	12 weeks	48 weeks
Placebo	30 %	33 %
12 µg/kg	46 %	25 %
24 µg/kg	75% (<i>p</i> = 0.0426)	56 %

*NRI: non-responder imputation

Proportion of Patients Who Achieved a POEM Greater than or Equal to a 4-point Reduction from Baseline (NRI* calculation)

Study Arm	12 weeks	48 weeks
Placebo	30 %	33 %
12 µg/kg	50 %	22 %
24 µg/kg	65 %	70 %

*NRI: non-responder imputation

Details of the presentations at EADV are as follows:

Efficacy and Safety of Single Agent Repegaldesleukin, a Selective Regulatory T-Cell-Inducing Interleukin-2 Conjugate, in the Treatment of Atopic Dermatitis: Final Results from a Randomized Phase 1b Study (Abstract #6685, Session: DT301.3: Late Breaking News. Friday, October 13, 14:30 – 14:45 CET)

A Phase 2b, Randomized, Double-Blinded, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Repegaldesleukin in Adults with Moderate-to-Severe Atopic Dermatitis (Abstract #6218/ePoster #P0559. Trial in Progress)

2023 EADV presentations are available for download at <http://www.nektar.com/science/scientific-posters>.

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. It is wholly-owned by Nektar Therapeutics.

About Nektar

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>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "could," "develop," "potential," "advance," "expect," "initiate" 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, repegaldesleukin. 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 repegaldesleukin are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) repegaldesleukin 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) repegaldesleukin 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 Annual Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 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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