September 13, 2023

Nektar Therapeutics Announces Promising New Data from Phase 1b Study of Rezpegaldesleukin in Moderate-to-Severe Atopic Dermatitis

New Statistically Significant Results Reported for Clinical Efficacy Endpoints of BSA, DLQI and POEM from Phase 1b Study

New Phase 2a Study Also Being Planned for Rezpegaldesleukin in Alopecia Areata

SAN FRANCISCO, Sept. 13, 2023 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced new data for rezpegaldesleukin in patients with atopic dermatitis, including new clinical efficacy endpoints from the Phase 1b study. Rezpegaldesleukin is Nektar's novel, first-in-class selective regulatory T-cell (Treg) therapy, which is being developed for the treatment of atopic dermatitis.

The company is presenting the new Phase 1b clinical efficacy endpoints for rezpegaldesleukin at its investor and analyst event today. The new data highlight rezpegaldesleukin's important promise to help patients battling atopic dermatitis, a chronic skin condition that afflicts nearly 10% of Americans.[1] The company will also present the trial designs for its Phase 2b study starting in October of rezpegaldesleukin in atopic dermatitis and its new planned Phase 2a study starting in early 2024 in alopecia areata.

"These new data announced today for rezpegaldesleukin in atopic dermatitis demonstrate that, in addition to the strong previously reported efficacy for EASI-related endpoints, rezpegaldesleukin has the potential to be a differentiated therapeutic that could greatly improve quality-of-life for patients," said Jonathan Zalevsky, Ph.D., Chief R&D Officer of Nektar Therapeutics. "We look forward to advancing rezpegaldesleukin into our robust Phase 2b study in biologic-naïve patients with moderate to severe atopic dermatitis in October of this year. In addition, we are excited to announce that we are also initiating a Phase 2a study of rezpegaldesleukin in patients with alopecia areata in early 2024."

The double-blind, randomized, placebo-controlled Phase 1b study of rezpegaldesleukin in atopic dermatitis evaluated safety, tolerability, and pharmacokinetics over a 12-week induction treatment period. Patients with ≥EASI-50 response at Week 19 were followed for an additional 36 weeks after the end of the treatment period or until EASI-25 response criteria were no longer met. The first study evaluated 44 patients with moderate-to-severe AtD who had progressed on topical corticosteroids.

Highlights of final efficacy endpoints for the Phase 1b study in atopic dermatitis:

TABLE 1:

Study Arm	*LS Mean % improvement in EASI score from baseline at 12 weeks*	p-value
Placebo	47	-
12 µg/kg	65	NS
24 µg/kg	83	0.0020

EASI Improvement results are least squares (LS) mean percent change from baseline obtained from Mixed Model for Repeated Measures (MMRM) as specified in the statistical analysis plan (SAP) defined in the protocol (generated by independent statistical audit firm). P-value confirmed by independent statistical audit.

TABLE 2:

Study Arm	*Proportion of Patients Who Achieved an EASI-75 Score at 12 weeks (NRI* calculation)*	*Proportion of Patients Who Achieved an EASI-75 Score at 12 weeks (as observed)*
Placebo	20 %	29 %
12 µg/kg	25 %	33 %
24 µg/kg	41 %	58 %

*NRI: non-responder imputation

TABLE 3:

Study Arm	*LS mean % Improvement in Affected Body Surface Area from Baseline at 12 weeks (BSA)*	*p-value*

Placebo	36	-
12 µg/kg	55	NS
24 µg/kg	72	0.0158

BSA Improvement results are least squares (LS) mean percent change from baseline obtained from Mixed Model for Repeated Measures (MMRM) as specified in the statistical analysis plan (SAP) defined in the protocol.

TABLE 4:

Study Arm	*LS mean % Improvement in Dermatology Life Quality Index (DLQI) from baseline at 12 weeks*	*p-value*
Placebo	9	-
12 µg/kg	48	NS
24 µg/kg	78	0.0043

DLQI Improvement results are least squares (LS) mean percent change from baseline obtained from Mixed Model for Repeated Measures (MMRM) as specified in the statistical analysis plan (SAP) defined in the protocol.

TABLE 5:

Study Arm	*LS mean % Improvement in Patient-Oriented Eczema Measure (POEM) from baseline at 12 weeks*	*p-value*
Placebo	15	-
12 µg/kg	44	NS
24 µg/kg	58	0.0100

POEM Improvement results are least squares (LS) mean percent change from baseline obtained from Mixed Model for Repeated Measures (MMRM) as specified in the statistical analysis plan (SAP) defined in the protocol.

Investor & Analyst Event

The company is hosting a virtual investor and analyst today Wednesday, September 13, 2023 at 11:00 a.m. EST / 8:00 a.m. PST to discuss these final Phase 1b data of rezpegaldesleukin (REZPEG) in patients with atopic dermatitis, the atopic dermatitis treatment landscape and the potential role of rezpegaldesleukin, Nektar's novel, first-in-class selective regulatory T-cell (Treg) therapy, in the treatment of atopic dermatitis.

Invited speakers include:

- 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
- Dr. David Rosmarin, Chair of the Department of Dermatology at Indiana University and Kampen-Norins Scholar in Dermatology;
- Dr. Raj Chovatiya, Board Certified Dermatologist at Northwestern University.

To access the conference call, please pre-register at Nektar Call Registration. All registrants will receive dial-in information and a PIN allowing them to access the live call.

Investors and analysts can also view slides and listen to the live audio webcast of the presentation here. The event will also be available for replay through October 13, 2023 on Nektar's website: www.nektar.com.

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical 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.

Nektar 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," "plan" 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 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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1. *Eczema stats.* National Eczema Association. (2023, September 5). https://nationaleczema.org/research/eczema-facts/