Nektar Announces Clinical Trial Agreement to Evaluate Rezpegaldesleukin in Patients with New Onset Type 1 Diabetes Mellitus

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-- TrialNet to conduct the Phase 2 randomized, placebo-controlled clinical study --

SAN FRANCISCO and NEW YORK, Feb. 24, 2025 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) and TrialNet, an international clinical trial network at the forefront of diabetes research, today announced a new collaboration agreement to evaluate Nektar's rezpegaldesleukin in patients with new onset stage 3 type 1 diabetes mellitus (T1D).

Rezpegaldesleukin is a novel agonistic T regulatory (Treg) cell biologic that is designed to both dampen the inflammatory response and simultaneously restore immune balance by directly expanding functional Treg cells and engaging multiple immunoregulatory pathways. Tregs are known to play a key role in the pathogenesis of T1D.[1]

Under the agreement, TrialNet will conduct the Phase 2 randomized, double-blind, placebo-controlled, clinical trial to investigate the safety and potential efficacy of rezpegaldesleukin in approximately 70 adults and children with new onset stage 3 T1D. Nektar will supply rezpegaldesleukin for the trial and will provide support for the study, including pharmacokinetic and other analyses. Nektar will retain all rights to the rezpegaldesleukin program under the collaboration.

"We are looking forward to collaborating with the exceptional team at TrialNet to advance rezpegaldesleukin in an important clinical study to evaluate its potential in patients with newly-diagnosed type 1 diabetes," said Jonathan Zalevsky, PhD, Senior Vice President and Chief Research & Development Officer of Nektar. "Our goal is to initiate this study in 2025. We are proud to support TrialNet's mission of advancing innovative mechanisms aimed at slowing or stopping the progression of type 1 diabetes."

The new study will use a mixed meal tolerance test (MMTT) to measure the efficacy of rezpegaldesleukin or placebo for preserving C-peptide area under the curve over a 12-month duration comprised of a 6-month treatment period and a 6-month follow-up. Secondary objectives include pharmacokinetics, pharmacodynamics, and additional disease assessments including HbA1c levels and patient insulin requirements.

"We are excited to explore the potential of the Treg stimulator rezpegaldesleukin as a novel investigational candidate in people with type 1 diabetes," said Kevan C. Herold, MD, TrialNet Chair and C.N.H. Long Professor of Immunobiology and Medicine at Yale University. "Rezpegaldesleukin provides an important opportunity to evaluate the therapeutic potential of using Tregs to directly target T-cell and cytokine-mediated destruction of beta-cells in the pancreas."

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. It is currently 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). In addition to the REZOLVE-AD study, it is also being evaluated in the REZOLVE-AA study, a randomized, double blind, placebo-controlled Phase 2b clinical trial for treatment of patients with severe-to-very-severe alopecia areata (NCT06340360).

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 Type 1 Diabetes (T1D)

T1D is an immune-mediated disease in which insulin-producing beta cells are completely, or almost completely, destroyed, resulting in life-long dependence on exogenous insulin.[2] It is a chronic and potentially disabling disease that represents a major public health and clinical concern. Most individuals with newly diagnosed T1D have 10%–20% of beta-cell function remaining at the time of diagnosis.[3] Preservation of residual beta-cell function at diagnosis may improve glycemic control and reduce longer-term complications.[4]

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 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. Our pipeline also includes a preclinical candidate NKTR-0165, which is a bivalent tumor necrosis factor receptor type II agonist antibody. 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 us on LinkedIn.

About TrialNet

TrialNet is sponsored and funded by the National Institutes of Health (NIH), primarily through the Special Statutory Funding Program for Type 1 Diabetes through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). TrialNet is the largest clinical trial network ever assembled to change the course of type 1 diabetes, and its mission is to prevent T1D and stop disease progression by preserving insulin production before and after diagnosis. Visit www.trialnet.org to learn more. The content in this press release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Nektar Therapeutics Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "could," "aim," "potential," "advance," "estimate," "evaluate" 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 (vi) 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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