Data Presented from Phase 1b Study of NKTR-358, a Novel T Regulatory Cell Stimulator, at Annual European Congress of Rheumatology (EULAR 2020)

June 4, 2020

SAN FRANCISCO, June 4, 2020 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) today announced the presentation of results from the Phase 1b study evaluating multiple ascending doses of NKTR-358, a first-in-class T regulatory cell stimulator, which is being developed as a potential therapeutic for a range of autoimmune disorders, including systemic lupus erythematosus (SLE).

The data, which were presented during the Annual European Congress of Rheumatology (EULAR 2020) in a virtual congress format, show that NKTR-358 was safe and well tolerated in patients with mild-to-moderate SLE and led to a marked and selective, dose-dependent expansion of regulatory T cells (Tregs) that was maintained over multiple administrations.

NKTR-358 is designed to correct an underlying immune system imbalance in patients with autoimmune conditions, which is associated with reduced numbers and impaired function of powerful inhibitory immune cells, known as T regulatory (Treg) cells. NKTR-358 works by targeting the interleukin-2 (IL-2) receptor complex in the body to stimulate proliferation of the body's own Treg cells and increase their suppressive functional activity.

NKTR-358 was discovered by Nektar and is being co-developed in partnership with Eli Lilly and Company.

"The results in patients with lupus presented at this year's EULAR Congress further support the potential of NKTR-358, through its stimulation of immune-inhibitory Treg cells, to restore normal self-tolerance mechanisms that are out of balance in patients with systemic lupus erythematosus," said Brian Kotzin, Senior Vice President, Clinical Development and Head of Immunology at Nektar. "Based upon these data, Nektar and our partner Lilly are advancing NKTR-358 into a Phase 2 study in patients with moderate to severe SLE, which will be initiated this summer."

The randomized, double-blind, multiple-ascending dose Phase 1b study being presented at 2020 EULAR evaluated safety, pharmacokinetics (PK) and pharmacodynamics (PD) in a total of 48 SLE patients across 4 separate ascending dose cohorts who received subcutaneous Q2W doses of NKTR-358 (n=9 per cohort) or placebo (n=3 per cohort). Subjects were treated for a total of six weeks.

Key highlights from today's data presentation include:

- NKTR-358 was safe and well tolerated in patients with mild-to-moderate SLE
  - Safety profile was similar between single and repeat administrations
- Data show dose-proportional pharmacokinetics and prolonged exposure, with a half-life of 10–13 days
- NKTR-358 elicited a marked and selective, dose-dependent expansion of $CD25^{bright}$ Tregs in patients with mild-to-moderate SLE, which was maintained through multiple administrations
  - Similar extent and magnitude of induction as observed in the SAD study in healthy volunteers

Nektar will host a call tomorrow for analysts and investors to review the data presented at EULAR 2020. Details of the call are as follows:

Date and Time: Friday, June 5, 2020 at 11:00 a.m. Eastern Daylight Time

Dial- in: (877) 881-2183 (toll-free) or (970) 315-0453 (access code 1170058)

Investors and analysts can also view slides and listen to the live audio webcast of the presentation at https://edge.media-server.com/mmc/p/aaf3wx35. The event will also be available for replay for two weeks on the company's website, www.nektar.com.

About NKTR-358 (LY3471851*)

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. NKTR-358 is a potential first-in-class resolution therapeutic that may address this underlying immune system imbalance in people with different 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, NKTR-358 may act to bring the immune system back into balance. Nektar entered into a strategic collaboration with Lilly in 2017 to develop and commercialize NKTR-358.

NKTR-358 is being developed as a self-administered injection for a number of autoimmune and inflammatory diseases. It is currently being evaluated in two separate Phase 1b studies in patients with atopic dermatitis (NCT04081350) and psoriasis (NCT04119557).

About Nektar

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 and Hyderabad, India. 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: "may," "can," "develop," "design," "will," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make concerning the therapeutic potential of NKTR-358, and future development plans for this drug candidate. 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) the extent and duration of the impact of the COVID-19 pandemic on our business, regulatory efforts, research and development, clinical trials (including those being led by us and our partner), and corporate development activities will depend on future developments that are highly uncertain and cannot be accurately predicted, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, as well as the effectiveness of actions taken globally to contain and treat the disease; (ii) NKTR-358 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 ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) 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, decisions and policies of our partner, 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; (iv) 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 (v) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 8, 2020. 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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View original content:http://www.prnewswire.com/news-releases/data-presented-from-phase-1b-study-of-nktr-358-a-novel-t-regulatory-cell-stimulator-at-annual-european-congress-of-rheumatology-eular-2020-301071068.html

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