First-in-Human Data Presented from Phase 1a Study of NKTR-358, a Novel T Regulatory Cell Stimulator, at Annual European Congress of Rheumatology

June 13, 2019

MADRID and SAN FRANCISCO, June 13, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced the results of the first-in-human Phase 1a study evaluating single-ascending doses of NKTR-358, a first-in-class T regulatory cell stimulator in clinical development for the treatment of autoimmune and other chronic inflammatory conditions.

The data, which were presented during an oral session at the Annual European Congress of Rheumatology (EULAR 2019) in Madrid, show that NKTR-358 was safe and well-tolerated and led to a marked and selective dose-dependent expansion of T regulatory cells with no measurable effect on conventional CD4+ and CD8+ T cells (Tcons). NKTR-358 was discovered by Nektar and is being co-developed and commercialized in partnership with Eli Lilly and Company.

NKTR-358 is designed to correct the underlying immune system imbalance in people with autoimmune conditions, which are 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 (IL-2) alpha-beta-gamma receptor complex in the body to stimulate proliferation of Treg cells and their suppressive functional activity.

"The data presented at EULAR 2019 demonstrate its meaningful and targeted effect of selective proliferation of Treg cells," said Brian Kotzin, M.D., Senior Vice President, Clinical Development and NKTR-358 Program Lead at Nektar Therapeutics. "This first-in-human single ascending dose study also demonstrated a favorable safety and tolerability profile. NKTR-358 is designed to help the body regulate and control pathogenic auto-reactive T cells and restore normal self-tolerance mechanisms and these data provide strong support to study NKTR-358 as a potential treatment for a range of autoimmune and inflammatory diseases."

The double-blind, single-ascending dose Phase 1a study evaluated 100 healthy volunteers who received subcutaneous doses of NKTR-358 ranging from 0.3 to 28 µg/kg. Subjects were followed for 50 days following administration.

Key highlights from today's data presentation include:

- NKTR-358 was safe and well tolerated in this first-in human study
- Preliminary data suggest dose-proportional pharmacokinetics for NKTR-358 and prolonged exposure with a half-life of 8-9 days
- NKTR-358 resulted in marked and selective dose-dependent expansion of $CD25^{bright}$ Treg cells
- NKTR-358 induced elevated Treg levels for > 20 days after a single dose administration
- No measurable changes in numbers and percentages of CD4+ and CD8+ Tcons at all doses and only low-level increases of NK cell numbers at highest doses tested

Nektar will host a call today for analysts and investors to review the data presented at EULAR 2019. Details of the call are as follows:

Date and Time: Thursday, June 13, 2018 at 8:00 a.m. Eastern Daylight Time
Dial-in: (877) 881-2183 (toll-free) or (970) 315-0453 (access code 4438228)

The call will include immunology expert, Dr. David Klatzmann, Professor of Immunology, Head of Department at Sorbonne University. Investors and analysts can view slides and listen to the live audio webcast of the presentation at https://edge.media-server.com/m6/p/kpe7mjmo. The event will also be available for replay for two weeks on the company's website, www.nektar.com.

About NKTR-358
Autoimmune diseases cause the immune system to mistakenly attack healthy cells in a person's body. A failure of the body's self-tolerance mechanisms enables the formation of the pathogenic auto-reactive 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 patients with many autoimmune conditions. It targets the interleukin (IL-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 diseases. A Phase 1b study evaluating the safety, tolerability, pharmacokinetics and immunological effects of multiple ascending doses of NKTR-358 in patients with systemic lupus erythematosus (SLE) is ongoing and additional studies in other inflammatory diseases are planned.

About Nektar
Nektar Therapeutics is a research-based, development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, autoimmune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. 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.

Forward-Looking Statements
This press release contains forward-looking statements which can be identified by words such as: "will," "may," "designed," "planned" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential and future development plans of NKTR-358. 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, 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 NKTR-358 are based on preclinical and clinical findings and observations to date from ongoing clinical studies; (ii) NKTR-358 is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the autoimmune indications being studied prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other factors that negatively impact drug development; (iii) data reported from the Phase 1a study of NKTR-358 may not be predictive of results obtained from future clinical studies; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future regulatory approval of potential new drug candidates (such as NKTR-358) is therefore very uncertain and unpredictable; (v) 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 Nektar's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 2019. 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.

Contact:

For Investors:
Jennifer Ruddock of Nektar Therapeutics
415-482-5585

For Media:
Katie Engleman of 1AB
919-333-7722
katie@1abmedia.com

View original content:http://www.prnewswire.com/news-releases/first-in-human-data-presented-from-phase-1a-study-of-nktr-358-a-novel-t-regulatory-cell-stimulator-at-annual-european-congress-of-rheumatology-300867034.html

SOURCE Nektar Therapeutics