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Nektar Therapeutics Initiates Clinical Study of NKTR-358, a First-in-Class Regulatory T Cell Stimulator, Being Developed for the Treatment of Immune and Inflammatory Disorders

NKTR-358 is designed to correct the underlying immune system dysfunction common to many auto-immune diseases

SAN FRANCISCO, March 27, 2017 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today announced that it has begun dosing in a Phase 1 clinical study evaluating NKTR-358, the company's new biologic therapy, which is being developed to treat a wide range of auto-immune diseases and inflammatory disorders. NKTR-358 selectively stimulates the growth and activation of regulatory T cells in the body in order to restore the body's self-tolerance mechanisms. Unlike immunosuppressant medicines that treat the symptoms of auto-immune disease by inhibiting the entire immune system which can cause unwanted side effects, NKTR-358 is designed to correct the underlying immune system dysfunction found in patients with immune disorders. The Phase 1 study will evaluate single-ascending doses of NKTR-358 in approximately 50 healthy subjects.

"NKTR-358 has the potential to be a first-in-class key resolution therapeutic in immunology," said Jonathan Zalevsky, Ph.D., vice president of biology at Nektar Therapeutics. "Data from non-human primate studies show that NKTR-358 drives proliferation and increased functional activity of Regulatory T cells (Tregs). Suboptimal Treg numbers and their lack of activity underlie many autoimmune diseases, including lupus, Crohn's disease, psoriasis, rheumatoid arthritis and multiple sclerosis. As the first potential medicine to restore appropriate Treg levels and function, NKTR-358 could address a critical unmet need for patients with serious and debilitating immune disorders."

The Phase 1 study is a dose-finding trial for NKTR-358 and will measure observed changes and functional activity of regulatory T cells. The objective of the trial is to establish a range of dose levels that could be advanced in further clinical trials. The Phase 1 study will also evaluate pharmacokinetics and safety. A multiple-ascending dose trial evaluating NKTR-358 in patients with systemic lupus erythematosus (SLE) is planned for the second half of 2017.

More than 23 million Americans have an autoimmune disease - nearly eight percent of the U.S. population - and the prevalence is continuing to rise.[i,ii] There are more than 80 known types of autoimmune diseases, including lupus, Crohn's disease, psoriasis and rheumatoid arthritis.[iii]

Autoimmune diseases cause the immune system to mistakenly attack healthy cells in a person's body.[iv] 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 works by optimally targeting the interleukin-2 (IL-2) receptor complex in order to stimulate proliferation and activation of regulatory T cells. By increasing the number of regulatory T cells, the pathogenic auto-reactive T cells can be controlled and the proper balance of effector and regulatory T cells can be achieved to restore the body's self-tolerance mechanisms.

In preclinical studies, NKTR-358 has demonstrated that it could suppress antigen-driven inflammation in a model of cutaneous hypersensitivity. NKTR-358 has also shown that it reduces markers of progression in a mouse model of systemic lupus erythematosus (SLE).

NKTR-358 is being developed as a once or twice-monthly self-administered injection for a number of auto-immune diseases.

About Nektar Therapeutics
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, auto-immune 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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "potential," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the expected ability to obtain useful data from the Phase 1 clinical study to evaluate NKTR-358, the timing and availability of clinical data for NKTR-358, the future clinical development plans for NKTR-358, the timing of planned regulatory filings, the commercial and therapeutic potential of NKTR-358, and the potential of our technology and drug candidates in our research and development pipeline. 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) clinical study outcomes, including the Phase 1 clinical study outcome of NKTR-358, remain very unpredictable and it is possible that a clinical study could fail due to efficacy, safety or other important clinical findings; (ii) NKTR-358 is in early-stage clinical development and there are substantial risks that can unexpectedly occur for numerous reasons including negative safety and efficacy findings in the Phase 1 clinical study notwithstanding positive findings in preclinical studies; (iii) our drug candidates are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval for numerous reasons including negative safety and efficacy findings even after positive findings in previous preclinical studies; (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) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of applying our technology platform to potential new drug candidates (such as NKTR-358) is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (vi) patents may not issue from our patent applications for NKTR-358, 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-K for the year ended December 31, 2016 filed with the Securities and Exchange Commission on March 1, 2017. 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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[i] The American Autoimmune Related Diseases Association. Autoimmune Statistics. https://www.aarda.org/autoimmune-information/autoimmune-statistics/

[ii] Johns Hopkins University. Autoimmune Disease Research Center. http://autoimmune.pathology.jhmi.edu/faqs.cfm

[iii] The American Autoimmune Related Diseases Association. Autoimmune Statistics. https://www.aarda.org/autoimmune-information/autoimmune-statistics/

[iv] The American Autoimmune Related Diseases Association. Autoimmune Statistics. https://www.aarda.org/autoimmune-information/autoimmune-statistics/

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