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Nektar Presents New Preclinical Data for NKTR-358, a First-in-Class Regulatory T Cell Stimulator, at 13th World Congress of Inflammation in London

SAN FRANCISCO, July 10, 2017 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today announced positive preclinical results for NKTR-358, a first-in-class resolution therapeutic for autoimmune disease. The new preclinical data demonstrate that treatment with NKTR-358 induces profound regulatory T cell effects and suppresses inflammation in multiple preclinical models. The data were highlighted in an oral presentation at the 13th Annual World Congress on Inflammation on July 9, 2017.

"These studies show that NKTR-358 increases the suppressive capacity and prolongs activation and proliferation of regulatory T cells with limited effects on conventional T cells in order to address the imbalance found in many autoimmune diseases," said Jonathan Zalevsky, PhD, Senior Vice President, Biology and Preclinical Development at Nektar Therapeutics. "NKTR-358 also demonstrated suppression of antigen-driven inflammation in multiple preclinical models including systemic lupus erythematosus. We are very excited about NKTR-358's potential as a resolution therapy in autoimmune disease."

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 demonstrates attenuated and optimized affinity for human IL-2 receptors to promote biological activity favoring activation of regulatory T cells over conventional T cells. This preferential activity combined with prolonged exposure *in vivo* led to significant Treg mobilization in blood and spleen following a single subcutaneous administration in rodents. Increases in regulatory T cells were sustained for 7 to 10 days, and were concomitant with increases in cytometric markers of activation and increased suppressive capacity.

In non-human primates, a single administration of NKTR-358 led to increases in Treg mobilization and activity sustained for over 14 days, a response greatly superior in magnitude, duration and specificity compared to an equivalent total dose of rhIL-2 administered daily for five days. In a mouse model of cutaneous hypersensitivity, NKTR-358 administration significantly suppressed antigen-induced inflammatory responses, an effect which was antigen-specific and associated with establishment of Treg memory. Similar results were achieved in analogous model using non-human primates. Finally, NKTR-358 was efficacious in a spontaneous mouse model of systemic lupus erythematosus (SLE). Repeat administration over 12 weeks result in sustained Treg elevation with corresponding significantly reduced blood urea nitrogen. In addition, NKTR-358 resulted in a return to normal of urine protein levels and kidney histopathology in the treated animals.

About NKTR-358

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 autoimmune 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.

NKTR-358 is being developed as a once or twice monthly self-administered injection for a number of autoimmune diseases and is currently in a Phase 1 dose-finding trial. The Phase 1 study will measure observed changes and functional activity of regulatory T cells in approximately 50 healthy subjects. 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.

About Nektar
Nektar Therapeutics is a research-based 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 therapeutic potential of NKTR-358, the timing and availability of clinical data for NKTR-358, the future clinical development plans for NKTR-358, 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) our statements regarding the therapeutic potential of NKTR-358 are based on findings and observations from preclinical findings and ongoing clinical studies; (ii) NKTR-358 is in early-stage clinical development and the risk of failure remains high and failure can unexpectedly occur due to efficacy, safety or other unpredictable factors even after positive findings in previous preclinical 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, 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) 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; (v) 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 (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q with the Securities and Exchange Commission on May 10, 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/news-information/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/news-information/statistics/

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

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