Nektar Therapeutics Announces Initiation of Two Clinical Studies of Novel T Regulatory Cell Stimulator NKTR-358 (LY3471851) in Patients with Psoriasis and Atopic Dermatitis

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SAN FRANCISCO, Oct. 7, 2019 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today announced the initiation of two Phase 1b studies of NKTR-358 (LY3471851*), a novel T regulatory (Treg) cell stimulator, one in patients with psoriasis and one in patients with atopic dermatitis. NKTR-358 is designed to treat autoimmune and inflammatory conditions by correcting the immune system imbalance that results from reduced numbers and impaired function of immune regulating Treg cells. NKTR-358 works by targeting the interleukin-2 receptor complex to stimulate the proliferation and suppressive functional activity of Treg cells. Nektar entered into a strategic collaboration with Eli Lilly and Company in 2017 to develop and commercialize NKTR-358. The two Phase 1b studies are Lilly-sponsored studies.

"Dysfunctions in Treg cell biology are implicated in the breakdown of immune self-tolerance, which is one of the underlying mechanisms involved in autoimmune and inflammatory diseases such as lupus, atopic dermatitis and psoriasis," said Brian Kotzin, M.D., Senior Vice President, Clinical Development and NKTR-358 Program Lead at Nektar Therapeutics. "NKTR-358 has demonstrated that it can drive expansion of Tregs, which we believe could help to regulate and control pathogenic T cells and restore normal self-tolerance mechanisms. We are excited to start these clinical studies to explore NKTR-358 for the treatment of psoriasis and atopic dermatitis, two common inflammatory diseases."

Earlier this year, Nektar presented initial results of a first-in-human Phase 1a single-ascending dose study of NKTR-358 in healthy volunteers at the Annual European Congress of Rheumatology (EULAR). The data showed that NKTR-358 was 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. Nektar plans to present additional data from the single-ascending dose study at the 2019 Annual Meeting of the American College of Rheumatology in November 2019.

Atopic dermatitis (AD), also known as eczema, is a chronic, inflammatory skin disease which results in widespread rashes and patches of itchy skin, which can become thickened, cracked, raw or leak fluid when scratched. About 6.6 million adults report moderate-to-severe symptoms of AD[1]. AD is commonly associated with an individual or family history of asthma, hay fever, food allergy and/or other allergic diseases.

Psoriasis is an immune-mediated skin disease that causes raised, red, scaly patches to appear on the skin typically affecting the outsides of the elbows, knees or scalp. According to the World Psoriasis Day consortium, 125 million people worldwide—2 to 3 percent of the total population—have psoriasis[2].

NKTR-358 is also being evaluated in a double-blind, randomized, placebo-controlled Phase 1b study in adults with systemic lupus erythematosus (SLE). The study will evaluate the safety, tolerability, pharmacokinetics and immunological effects of multiple ascending doses of NKTR-358 in approximately 50 adults with SLE. For more information, please visit clinicaltrials.gov and search NCT03556007.

About the Phase 1b Study in Psoriasis

The Phase 1b study is a double-blind, randomized, placebo-controlled multiple-dose study of NKTR-358 and will evaluate the safety, tolerability and pharmacokinetics of NKTR-358 in approximately 40 adults with plaque psoriasis. Exploratory objectives include assessment of disease activity and biomarkers.

About the Phase 1b Study in Atopic Dermatitis

The Phase 1b study is a double-blind, randomized, placebo-controlled multiple-dose study of NKTR-358 and will evaluate the safety, tolerability and pharmacokinetics of NKTR-358 in approximately 40 adults with atopic dermatitis. Exploratory objectives include assessment of disease activity and biomarkers. For additional information visit clinicaltrials.gov and search NCT04081350.

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 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, NKTR-358 may act to bring the immune system back into balance.

NKTR-358 is being developed as a self-administered injection for a number of autoimmune and inflammatory 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, 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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "believe," "design," "could," "plan," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the expected benefits of NKTR-358, the ability to obtain useful data from clinical studies of NKTR-358, and the future clinical development plans for 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, 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) 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 clinical studies notwithstanding positive findings in prior studies; (ii) clinical study outcomes of NKTR-358 remain very unpredictable and it is possible that a given clinical study could fail due to efficacy, safety or other important clinical findings, wherein any failure of a clinical trial for NKTR-358 in particular indication could prevent further development for all indications; (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, and competitive factors; (iv) scientific discovery of new therapeutics 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; (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 Nektar's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 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.

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*NKTR-358 is referred to as LY3471851 under Lilly-sponsored studies.

[1] Fuxench, Zelma C. Chiesa, et al. "Atopic Dermatitis in America Study: a cross-sectional study examining the prevalence and disease burden of atopic dermatitis in the US adult population." Journal of Investigative Dermatology 139.3 (2019): 583-590.
[2] National Psoriasis Foundation, https://www.psoriasis.org accessed September 4, 2019.