Nektar Therapeutics Announces Phase 1b Data for Novel T Regulatory Cell Stimulator NKTR-358 (LY3471851) in Patients with Atopic Dermatitis

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SAN FRANCISCO, Dec. 15, 2021 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today announced that its partner Eli Lilly & Company presented preliminary results from a Lilly-sponsored Phase 1b proof-of-concept study of NKTR-358 (LY3471851*), a novel T regulatory (Treg) cell stimulator, in patients with moderate-to-severe atopic dermatitis during its Investment Community Meeting.

NKTR-358 is designed to treat autoimmune and inflammatory conditions by correcting the immune system imbalance that results from increased levels of inflammatory T cells and reduced numbers and impaired function of immune regulating Treg cells. NKTR-358 works by targeting the interleukin-2 receptor complex to selectively stimulate the proliferation and overall abundance of Tregs and increase their suppressive functional activity.

Key conclusions from today's preliminary data presentation of the Phase 1b study of NKTR-358 in patients with moderate-to-severe atopic dermatitis include:

- The proof-of-concept data show that NKTR-358 (Q2W for 12-week treatment duration) resulted in a dose dependent reduction in Eczema Area and Severity Index (EASI) scores in patients with moderate-to-severe atopic dermatitis
- Treatment with NKTR-358 at the 24 ug/kg dose resulted in a 70% maximum reduction in EASI scores at week 12
- Treatment with NKTR-358 over a 12-week period at the 24 ug/kg Q2W dose resulted in sustained disease control for at least 6 months after last dose demonstrating the potential for NKTR-358 to differentiate from standard of care

"This is a truly remarkable result which demonstrates the potential for NKTR-358 to differentiate from current standard of care for patients with atopic dermatitis and supports Lilly's planned Phase 2 study in this indication," said Jonathan Zalevsky, Ph.D., Senior Vice President and Chief Research & Development Officer at Nektar Therapeutics. "These proof-of-concept data presented today show that, in patients with moderate to severe atopic dermatitis, NKTR-358 given every two weeks over a 12-week period resulted in a dose-dependent reduction in EASI scores. Importantly, at the highest dose tested, the majority of patients maintained this disease reduction for at least 6 months after the last dose of NKTR-358."

"NKTR-358 has demonstrated that it can drive expansion of Tregs, which we believe could help to regulate and control pathogenic T cells, to potentially modify disease through restoration of normal self-tolerance mechanisms," continued Zalevsky. "We are especially excited because we have now demonstrated the potential benefit of NKTR-358 in two different dermal disease settings. NKTR-358 produced a reduction in CLASI scores in lupus patients in our Phase 1b study, and here showed a reduction in EASI in Lilly's study in atopic dermatitis."

NKTR-358 exhibited a similar tolerability profile in the Phase 1b study in atopic dermatitis as shown in prior studies conducted in patients with mild-to-moderate SLE and healthy volunteers.

Today's presentation can be found on Eli Lilly's website at https://investor.lilly.com/events/event-details/investment-community-meeting-0.

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.

In 2020, Nektar presented results from a first-in-human Phase 1b single-ascending dose study of NKTR-358 in patients with systemic lupus erythematosus (SLE) at the Annual College of Rheumatology Meeting. These results showed that NKTR-358 selectively stimulated and expanded Treg cells. NKTR-358 also resulted in a dose-dependent reduction in CLASI-A composite clinical scores after only 3 treatment cycles as compared to placebo in patients with mild to moderate SLE and CLASI-A scores of ≥4 at baseline. A Phase 2 study is currently underway in moderate-to-severe SLE patients being conducted by Lilly.

Nektar entered into a strategic collaboration with Lilly in 2017 to develop and commercialize NKTR-358.

A total of four Lilly-sponsored studies are ongoing or completed for NKTR-358: a Phase 2 trial of NKTR-358 in patients with SLE (NCT04433585), a Phase 2 trial of NKTR-358 in patients with moderately-to-severely active ulcerative colitis (NCT 04677179) and two Phase 1b studies in patients with atopic dermatitis (NCT04081350) and psoriasis (NCT04119557).

About the Phase 1b Study in Atopic Dermatitis

The Phase 1b study is a double-blind, randomized, placebo-controlled multiple-dose study evaluating 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 biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology, immunology and virology 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: "potential," "design," "can," "provide," "may," "will," "suggest," 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 ability to obtain useful data from the 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) our statements regarding the therapeutic potential of NKTR-358 are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (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) NKTR-358 is in early clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval; (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, and competitive factors; (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 November 5, 2021. 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.

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