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Nektar Publishes Pre-clinical Results for NKTR-214, an Investigational CD122-Biased Immune-Stimulatory Cytokine for the Treatment of Cancer in Clinical Cancer Research

New Paper Documents Durable Anti-Tumor Efficacy, Safety and Immune Mechanism of Action of NKTR-214 in Multiple Tumor Models as well as a Favorable Safety Profile in Non-Human Primates (NHPs)

SAN FRANCISCO, Feb. 1, 2016 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced the publication in *Clinical Cancer Research* of pre-clinical findings for NKTR-214. The paper, titled "*NKTR-214, an Engineered Cytokine with Biased IL2 Receptor Binding, Increased Tumor Exposure, and Marked Efficacy in Mouse Tumor Models*," (Charych et al., Clin Cancer Res, doi:10.1158/1078-0432.CCR-15-1631) documents a broad set of pre-clinical data supporting the clinical advancement of NKTR-214. Among the findings reported, treatment with NKTR-214 led to durable and specific anti-tumor immunity in multiple syngeneic mouse models both as a single agent and as combination therapy with checkpoint inhibitors. In addition, treatment with single-agent NKTR-214 in tumor-bearing mice resulted in a controlled, sustained, and biased T-cell activation leading to a 450:1 mean ratio of CD8-positive effector T cells to T-regulatory cells in the tumor microenvironment, while maintaining more balanced ratios in non-tumor tissues and circulation.

"NKTR-214 allows us to capture and harness the power of the IL-2 biological pathway, which is known to promote T cell growth, to stimulate the body's own immune system to target and fight cancer. The design of NKTR-214 gives it a combination of biophysical, biochemical, and pharmacological properties that translate into a desirable anti-tumor immune profile," said Stephen Doberstein, Ph.D., Senior Vice President and Chief Scientific Officer of Nektar Therapeutics.

The newly published data documented in the paper also support the favorable safety profile of NKTR-214. The compound was well-tolerated in rodents and in non-human primates (NHPs). Importantly, these pre-clinical safety studies showed that NKTR-214 did not lead to hypotension or vascular leak syndrome at predicted clinical therapeutic doses.

As documented in the new publication, in a pre-clinical tumor re-challenge study in an EMT6 mouse breast cancer model, dosing of NKTR-214 in combination with anti-CTLA-4 antibody resulted in durable and complete responses lasting up to 170 days (5.5 months). When tumor-free animals were re-challenged with the same tumors with no additional treatment, the complete responders demonstrated sustained vaccine-like resistance. These results suggest that NKTR-214 provides a complementary mechanism of immune activation when used concurrently with approved antibody therapies.

"We are pleased that the unique mechanism, efficacy and safety of NKTR-214 are now described and published in a prestigious peer-reviewed journal that is widely read by oncologists, scientists and physician-scientists," said Dr. Doberstein. "We are continuing to advance NKTR-214 in an ongoing Phase 1/2 clinical trial in cancer patients and we expect to have preliminary top-line results from the first stage of this study in the second half of 2016."

About the NKTR-214 Phase 1/2 Clinical Study

NKTR-214 is currently being evaluated in a Phase 1/2 clinical study in patients with advanced solid tumors, including melanoma, renal cell carcinoma and non-small cell lung cancer. The ongoing study is being conducted at MD Anderson Cancer Center and Yale Cancer Center and is comprised of two stages. The first stage is an open-label, multi-dose, dose-escalation study evaluating single-agent NKTR-214 treatment in approximately 20 patients with solid tumors. The primary objective of the first stage of the study is to evaluate the safety and efficacy of NKTR-214, and to define the recommended Phase 2 dose. In addition, the study will assess preliminary anti-tumor activity, including objective response rate (ORR). The immunologic effect of NKTR-214 on tumor-infiltrating lymphocytes (TILs) and other immune cells in both blood and tumor tissue will also be assessed. Following the dose-escalation stage of the study, dose expansion cohorts are planned to evaluate NKTR-214 in specific tumor types, including melanoma, renal cell carcinoma and non-small cell lung cancer.

For more information on the ongoing NKTR-214 Study, please visit the "Clinical Trials" section of www.mdanderson.org using identifier 2015-0573 or visit https://medicine.yale.edu/cancer/research/trials/active/858.trial.

About NKTR-214

NKTR-214 is a CD122-biased immune-stimulatory cytokine, which is designed to stimulate the patient's own immune system to kill tumor cells. By biasing activation to the CD122 receptor, NKTR-214 enhances CD8+ effector T cells (tumor-killing cells) in the tumor. In pre-clinical studies, a single dose of NKTR-214 resulted in a 400-fold AUC exposure within the tumor compared with an equivalent dose of the existing IL-2 therapy, enabling, for the first time, an antibody-like dosing regimen for a cytokine.

About Nektar

Nektar Therapeutics has a robust R&D pipeline in pain, oncology, hemophilia and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for MOVANTIK™ (naloxegol), the first FDA-approved once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC), in adult patients with chronic, non-cancer pain. The product is also approved in the European Union as MOVENTIG® (naloxegol) and is indicated for adult patients with OIC who have had an inadequate response to laxatives. The AstraZeneca agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of MOVANTIK and an opioid. NKTR-181, a wholly-owned mu-opioid analgesic molecule for chronic pain conditions, is in Phase 3 development. In hemophilia, Nektar has a collaboration agreement with Baxalta for ADYNOVATE™ [Antihemophilic Factor (Recombinant)], a longer-acting PEGylated Factor VIII therapeutic approved in the U.S. in patients over 12 with hemophilia A. In anti-infectives, Amikacin Inhale is in Phase 3 studies conducted by Bayer Healthcare as an adjunctive treatment for intubated and mechanically ventilated patients with Gram-negative pneumonia.

Nektar's technology has enabled ten approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including AstraZeneca's MOVANTIK™, Baxalta's ADYNOVATE™, UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia.

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: "anticipate," "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-214, the timing of availability of clinical data for NKTR-214, 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-214 are based on preclinical findings and observations, (ii) NKTR-214 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 ongoing Phase 1 clinical study notwithstanding positive findings in preclinical studies; (iii) our drug candidates and those of our collaboration partners 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 and clinical studies; (iv) the timing of the commencement or end of clinical trials and the availability of clinical 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-214) is therefore highly uncertain and unpredictable and one or more research and development programs could fail; and (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 6, 2015. 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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