Nektar Therapeutics Announces Dosing of First Patients in Phase 1/2 Study of its IL-15 Agonist, NKTR-255, in Combination with Cetuximab in Patients with Head and Neck Squamous Cell Carcinoma or Colorectal Cancer

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SAN FRANCISCO, Dec. 15, 2020 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) today announced that the first patient has been dosed in the Phase 1/2 trial of NKTR-255, Nektar's investigational IL-15 pathway agonist, in patients with relapsed or refractory (R/R) head and neck squamous cell carcinoma (HNSCC) or colorectal cancer (CRC) at the START Center for Cancer Care in San Antonio, TX. The study is evaluating NKTR-255 plus cetuximab in up to 80 patients at approximately 15 investigator sites in the United States and European Union.

NKTR-255 is designed to activate the IL-15 pathway and expand Natural Killer (NK) cells as well as promote the survival and expansion of CD8+ T cells without inducing suppressive regulatory T cells. Cetuximab is a monoclonal antibody against epidermal growth factor receptor (EGFR) and is approved for the treatment of advanced HNSCC and CRC.

"An NK-cell agent such as NKTR-255 is a perfect and unique complement to monoclonal antibody therapies which induce antibody-dependent cellular cytotoxicity," said Wei Lin, MD, Head of Development at Nektar. "Our body of preclinical and clinical data for NKTR-255 demonstrates that this novel agent not only induces NK cell proliferation but also enhances their cytotoxic immune effector function. With this new Phase 1/2 study in HNSCC and CRC, we are excited to expand our NKTR-255 development program beyond the hematological setting into solid tumors."

Nektar recently presented the first clinical data for NKTR-255 at the most recent 2020 Society for Immunotherapy in Cancer (SITC) Annual Meeting in November. The data demonstrated that NKTR-255 was well tolerated and biologically active, and treatment resulted in consistent expansion of lymphocytes, with durable and sustained increases in NK and CD8+ T cells in a highly refractory population of patients with multiple myeloma (MM) and non-Hodgkin lymphoma (NHL).

The new Phase 1b/2 study will test the combination of NKTR-255 with cetuximab in two groups of patients. One group will consist of R/R head and neck cancer patients who have progressed after treatment with platinum-based chemotherapy and a checkpoint inhibitor. The second group will include patients with metastatic colorectal cancer who have received two prior treatments for metastatic disease. The trial will begin with a dose-finding portion for the combination, which will then be expanded into dedicated cohorts for head and neck and colorectal cancer patients.

About NKTR-255

NKTR-255 is an investigational IL-15 receptor agonist designed to activate the IL-15 pathway and expand NK cells and promote the survival and expansion of memory CD8+ T cells without inducing suppressive regulatory T cells. Through optimal engagement of the IL-15Rα/IL-2Rβγ receptor complex, NKTR-255 enhances functional NK cell population and formation of long-term immunological memory, which may lead to sustained anti-tumor immune response. NKTR-255 is uniquely designed to overcome the challenges of recombinant IL-15 and other IL-15 agonists, which are rapidly cleared from the body and have shown diminishing response to successive doses.[1] NKTR-255 is wholly-owned by Nektar.

About Nektar

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology, immunology, and virology as 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," "enhance," "may," "test," "evaluate" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the expected benefits of NKTR-255 (both alone as a single agent as well as in combination with other agents, such as cetuximab), the ability to obtain useful data from the Phase 1b/2 clinical study of NKTR-255, and the future clinical development plans for NKTR-255. 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, 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-255 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 1b/2 clinical study notwithstanding positive preclinical findings; (ii) clinical study outcomes, including the Phase 1b/2 clinical study outcome of NKTR-255, remain very unpredictable and it is possible that a clinical study could fail due to efficacy, safety or other important clinical findings; (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-255) is therefore highly uncertain and unpredictable; (v) patents may not issue from our patent applications for NKTR-255, 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 6, 2020. 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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1. Blood 2018 Jun 7;131(23):2515-2527

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