Nektar Therapeutics Announces New Clinical Study Collaboration with Cellular Biomedicine Group Inc. to Evaluate NKTR-255 in Combination with C-TIL051 in Advanced Non-Small Cell Lung Cancer

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SAN FRANCISCO, Sept. 27, 2023 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today that it has entered into a new clinical study collaboration with Cellular Biomedicine Group Inc. ("CBMG"). The study will evaluate Nektar's NKTR-255, a novel interleukin-15 (IL-15) receptor agonist, in combination with CBMG's C-TIL051, a tumor-infiltrating lymphocyte (TIL) therapy, in advanced non-small cell lung cancer (NSCLC) patients that are relapsed or refractory to anti-PD-1 therapy.

NKTR-255 is a novel polymer-conjugated human IL-15 receptor agonist currently being studied in two separate Phase 2 studies in combination with cell therapies and immunotherapies. Preclinical and early clinical data suggest that IL-15 can improve proliferation and persistence of cellular therapies including TIL, TCR, and CAR-T therapies to increase specific anti-tumor activity.

"Early results have shown that NKTR-255 has the potential to emerge as a valuable adjuvant therapy for a range of cell therapy platforms," said Mary Tagliaferri, M.D., Chief Medical Officer at Nektar Therapeutics. "We are excited to partner with CBMG, a leader in the development of the next generation of cell therapies, to evaluate this novel combination in the clinical setting of lung cancer. Combining NKTR-255 and C-TIL051 could have the potential to deliver deep and durable objective responses with a well-tolerated regimen to patients battling relapsed or refractory NSCLC."

C-TIL051 is an autologous adoptive cell therapy being developed by CBMG that is comprised of a patient's *ex vivo* expanded lymphocytes using CBMG's proprietary manufacturing process. The development of C-TIL051 was based on initial NSCLC TIL studies demonstrating encouraging safety and efficacy results (NCT03215810, NCT03645928). In October of last year, CBMG received clearance of an Investigational New Drug (IND) application for C-TIL051 for late-stage NSCLC patients that are relapsed or refractory to anti-PD-1 therapy.

Under the new collaboration, CBMG will add NKTR-255 to its ongoing CBMG-sponsored Phase 1 clinical trial evaluating C-TIL051 in NSCLC patients who have relapsed on or were refractory to anti-PD-1 therapy, which is being conducted at Duke Cancer Institute (NCT05676749). The study is expected to enroll a total of 20 patients. Nektar will contribute NKTR-255 supply for the study. Nektar and CBMG will each maintain existing global rights to their respective investigational medicines.

About NKTR-255

NKTR-255 is a biologic that targets the IL-15 pathway in order to activate the body's innate and adaptive immunity. Through optimal engagement of the IL-15 receptor complex, NKTR-255 is designed to enhance functional NK cell populations and formation of long-term immunological memory, which may lead to sustained and durable anti-tumor immune response.

Preclinical and early clinical findings suggest IL-15 can improve proliferation and persistence of cellular therapies including TIL, TCR, and CAR-T therapies to increase specific anti-tumor activity.

NKTR-255 is currently being studied in two separate Phase 2 studies in combination with cell therapies and immunotherapy. A Phase 2/3 study is underway that combines NKTR-255 with approved CAR-T cell therapies in patients with diffuse large B-cell lymphoma, which is currently recruiting (NCT05664217). NKTR-255 is also being studied in a Phase 2 study in combination with avelumab as a maintenance treatment in patients with locally advanced or metastatic urothelial carcinoma in the Merck KGaA-sponsored JAVELIN Bladder Medley trial (NCT05327530), as well as in combination with durvalumab in patients with locally advanced NSCLC in an IST conducted at M.D. Anderson Cancer Center.

In addition, there are two ongoing investigator sponsored trials (ISTs) evaluating NKTR-255 as adjunct therapy following a CAR-T cell therapy. Fred Hutchinson Cancer Center is conducting a Phase 1 study evaluating NKTR-255 following lisocabtagene maraleucel treatment in patients with relapsed/refractory large B-cell lymphoma (NCT05359211), and Stanford University is conducting a Phase 1 study evaluating NKTR-255 following an investigational CD19/22 CAR-T cell therapy in patients with relapsed or refractory B-cell acute lymphoblastic leukemia (NCT03233854).

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in immunology and oncology as well as a portfolio of approved partnered medicines. Nektar is headquartered in San Francisco, California, with additional manufacturing operations in Huntsville, Alabama. 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: "will," "may," "evaluate," "develop," "provide," "potential" and similar references to future periods. Examples of forward-looking statements include, among others, statements regarding the therapeutic potential of, and future development plans for NKTR-255, and our other drug candidates in research programs, the prospects and plans for our collaborations with other companies, the timing of the initiation of clinical studies and the data readouts for our drug candidates. 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-255, and our other drug candidates are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) NKTR-255 and our other drug candidates are investigational agents and continued research and development for these drug candidates 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-255 and our other drug candidates 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; (iv) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to challenges caused by the COVID-19 pandemic, 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) we may not achieve the expected cost savings we expect from our 2022 corporate restructuring and reorganization plan or our 2023 cost restructuring plan and we may undertake additional restructuring and cost-saving activities in the future, (vi) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vii) certain other important risks and uncertainties set forth in our Annual Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2023. 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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