Nektar Therapeutics Announces Phase 1b Clinical Study to Evaluate Bempegaldesleukin for Treatment of Patients Diagnosed with Mild COVID-19

October 27, 2020

Study Designed to Evaluate Whether BEMPEG's Ability to Increase Lymphocyte Production Could Improve Treatment Regimens for COVID-19 Patients

SAN FRANCISCO, Oct. 27, 2020 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today announced that it has received FDA clearance for an Investigational New Drug (IND) application for its investigational IL-2 pathway agent, bempegaldesleukin (BEMPEG, NKTR-214), to be evaluated in a Phase 1b clinical study in adult patients who have been diagnosed with mild COVID-19 infection. The study is designed to evaluate whether BEMPEG's ability to stimulate lymphocyte production could improve treatment regimens for COVID-19 patients. Enrollment in the Phase 1b, randomized, double-blind, placebo-controlled study is planned to start in early November.

The company will hold an analyst and investor conference call this morning, Tuesday, October 27, 2020, at 8:30 a.m. Eastern Daylight Time (EDT). The call will include Nektar COVID-19 Study Steering Committee Co-Chairs: Dr. Richard Bucala MD, PhD, Waldemar Von Zedtwitz Professor of Medicine, Pathology, and Epidemiology and Chief of Rheumatology, Allergy & Immunology at the Yale School of Medicine and Dr. Robert Gallo, co-founder and director of the Institute of Human Virology at the University of Maryland School of Medicine.

BEMPEG is an investigational CD122-preferential IL-2 pathway agonist that stimulates the immune system through the proliferation of lymphocytes. It is currently being evaluated in six separate late-stage clinical studies in patients diagnosed with melanoma, renal cell carcinoma and bladder cancer.

"Decreased levels of lymphocytes have been associated with increased mortality in hospitalized COVID-19 patients. Providing these patients with an agent like BEMPEG that can drive anti-viral adaptive immunity has the potential to improve these outcomes," said Dr. Bucala. "We believe this development program is important to determine whether stimulating the adaptive immune response with BEMPEG improves patient outcomes, and to hopefully bring this treatment to patients afflicted with COVID-19."

The Phase 1b, randomized, double-blind, placebo-controlled study is designed to assess the safety, tolerability, and pharmacokinetic/pharmacodynamic profile of BEMPEG in adult patients with mild COVID-19. Eligibility criteria include symptoms such as fever, cough, sore throat, malaise, headache, and muscle pain without evidence of severe dyspnea or acute respiratory distress syndrome. Patients who meet the eligibility criteria will be randomized and treated with either a single dose of BEMPEG or placebo in combination with current standard of care treatment for patients with mild COVID-19. Primary and secondary endpoints include change over time in absolute lymphocyte counts and measurements of clinical progression based upon the WHO Clinical Progression Scale. The trial will enroll up to three cohorts of ten patients each, who will receive increasing doses of BEMPEG with the aim of evaluating safety and tolerability and to identify the recommended dose for future studies. The clinical trial will be conducted at various investigator sites in the United States.

"After many months of evaluating the emerging body of data on the correlation of decreased lymphocyte levels and the severity of disease in patients with COVID-19, Nektar and our scientific and clinical advisors made the decision to proceed with this important study of our cytokine investigational therapy BEMPEG," said Dr. Jonathan Zalevsky, Ph.D., Chief Research & Development Officer at Nektar. "Recovery in hospitalized COVID-19 patients has been linked to a robust T cell response, and our objective with the introduction of BEMPEG investigational therapy is to help the patient mount a comprehensive cellular and humoral immune response to the virus. The study design allows us to evaluate whether early intervention with BEMPEG's adaptive immune-stimulating mechanism that promotes priming and proliferation of T cells and NK cells could be useful in the emerging treatment armamentarium for COVID-19. Following the successful completion of this initial Phase 1b study, our plan is to advance development into COVID-19 patients who present with lymphopenia. We are hopeful that this unique approach could ultimately lead to a reduction in the severity of disease and in long-term hospitalizations and mortality."

Analyst Call Details

Date and Time: Tuesday, October 27, 2020 at 8:30 a.m. Eastern Daylight Time
Dial-in: (877) 881-2183 (toll-free) or (970) 315-0453 (Conference ID: 1418007)
Investors and analysts can also view slides and listen to the live audio webcast of the presentation at https://edge.media-server.com/mmc/p/tc46muyj. The event will also be available for replay for two weeks on the company's website, www.nektar.com.

Dr. Richard Bucala

Richard Bucala, MD, PhD, is a Professor of Medicine, Pathology, and Epidemiology & Public Health at the Yale School of Medicine. He studies the mechanisms by which protective immune responses lead to immunopathology, focusing on MIF-family cytokines and their genetics, which his group first cloned and characterized. Currently, his laboratory is leading multidisciplinary efforts to develop immunotherapies tailored to an individual's genetic makeup. An anti-MIF antibody developed by his group is undergoing clinical evaluation in oncology and additional MIF antagonists are in advanced clinical testing for different inflammatory indications. Dr. Bucala also is credited with the discovery of the fibrocyte, which is being targeted therapeutically in different fibrosing disorders. He is a co-founder of MIFCOR, a biotechnology startup begun as a student-advised project. Dr. Bucala was elected to the American Society for Clinical Investigation and the Association of American Physicians. He is the former Editor-in-Chief of *Arthritis & Rheumatology* and has served on numerous advisory boards for the NIH, the pharmaceutical industry, academia, and private foundations.

Dr. Robert Gallo

Robert C. Gallo, MD is the co-founder of The Institute of Human Virology (IHV) at the University of Maryland School of Medicine. He led the team that

discovered IL-2 and identified the first retroviruses in humans. He became world famous in 1984 when he co-discovered HIV as the cause of AIDS, and his team developed the first blood test for HIV. Little was known then of the mysterious disease that was fast becoming the deadliest in medical history. Since then, Dr. Gallo has spent much of his career trying to put an end to this raging epidemic and other viral, chronic illnesses. Lifetime achievements in Dr. Gallo's legendary career include discoveries that have led to both diagnostic and therapeutic advances in cancer, AIDS and other viral disorders while his vision remains unprecedented in the field of virology.

About Bempegaldesleukin (BEMPEG; NKTR-214)

BEMPEG is an investigational, first-in-class, CD122-preferential IL-2 pathway agonist designed to provide rapid activation and proliferation of cytotoxic immune cells, known as CD8+ effector T cells and natural killer (NK) cells, without over activating the immune system. The agent is designed to stimulate these immune cells in the body by targeting CD122 specific receptors found on the surface of these immune cells. CD122, which is also known as the Interleukin-2 receptor beta subunit, is a key signaling receptor that is known to increase proliferation of these effector T cells.[1] In clinical and preclinical studies, treatment with BEMPEG resulted in expansion of these cells and mobilization into the tumor micro-environment.[2,3] Bempegaldesleukin has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines being used to treat a range of cancers.

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology and immunology 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: "may," "design," "potential," "evaluate," "plan," "will," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of, and future development plans for, bempegaldesleukin, and the timing of the initiation of clinical studies for bempegaldesleukin. 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 bempegaldesleukin in patients who have been diagnosed with COVID-19 infection are based on data that is evolving and does not include clinical testing of bempegaldesleukin for this intended patient population, and there is no guarantee that the clinical evaluation of bempegaldesleukin in COVID-19 patients will support the use of bempegaldesleukin in this patient population; (ii) bempegaldesleukin 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) as bempegaldesleukin is currently in clinical development, the risk of failure is high and failure 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, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (v) 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 (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 August 7, 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.

1. Boyman, J., et al., Nature Reviews Immunology, 2012, 12:180-90.

2. Charych, D., et al., Clin Can Res, 2016, 22(3):680-90.

3. Diab, A., et al., Journal for ImmunoTherapy of Cancer, 2016, 4(Suppl 1):P369

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View original content:http://www.prnewswire.com/news-releases/nektar-therapeutics-announces-phase-1b-clinical-study-to-evaluate-bempegaldesleukin-for-treatment-of-patients-diagnosed-with-mild-covid-19-301160116.html

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