# Nektar Announces Agreement for Phase 2/3 Study of IL-2 Pathway Agonist, Bempegaldesleukin, in Combination with Merck's KEYTRUDA® (pembrolizumab) in Patients with Squamous Cell Carcinoma of the Head and Neck (SCCHN)

February 17, 2021

SAN FRANCISCO, Feb. 17, 2021 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) announced today that it has entered into a clinical trial collaboration and supply agreement with Merck (known as MSD outside the United States and Canada) for a Phase 2/3 study of bempegaldesleukin (NKTR-214, BEMPEG), Nektar's investigational IL-2 pathway agent, in combination with Merck's KEYTRUDA® (pembrolizumab) for first-line treatment of patients with metastatic or unresectable recurrent squamous cell carcinoma of the head and neck (SCCHN) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥1). The study is planned to start in the second half of 2021.

"We are excited to advance the combination of BEMPEG plus KEYTRUDA to a Phase 2/3 study in first-line squamous cell carcinoma of the head and neck," said Jonathan Zalevsky, PhD, Chief R&D Officer at Nektar. "Earlier studies of BEMPEG in combination with immune checkpoint inhibitors, also known as ICIs, evaluated in patients with immune-sensitive cancers have shown the potential to increase and deepen treatment responses as compared to historical rates for ICIs alone. This collaboration with Merck will enable us to further explore the combination of BEMPEG with the leading checkpoint inhibitor therapy in the setting of advanced head and neck cancer."

Under the terms of the agreement, Nektar will conduct the Phase 2/3 study, which is expected to enroll 500 patients with metastatic or recurrent SCCHN with PD-L1 expressing tumors. Patients will be randomized to receive either the combination of BEMPEG plus pembrolizumab or pembrolizumab alone. The Phase 2 portion of the study will include an interim analysis of overall response rate (ORR) after the first 200 patients enrolled have a minimum follow up of 4 months. If the ORR passes a prespecified futility boundary, the study will continue, and the remaining 300 patients will be enrolled to the Phase 3 portion of the study. The primary endpoints of the trial are ORR and overall survival (OS); progression free survival (PFS) is a secondary endpoint.

**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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

**Cautionary Note Regarding Forward-Looking Statements**
This press release contains forward-looking statements which can be identified by words such as: "will," "develop," "may" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of bempegaldesleukin (BEMPEG) in combination with other agents (immune checkpoint inhibitors), and the availability of results from clinical studies. 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) our statements regarding the therapeutic potential of bempegaldesleukin are based on preclinical and clinical findings and the expected therapeutic potential for bempegaldesleukin is subject to change as research and development continue; (ii) bempegaldesleukin is in clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the indications being studied prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other factors that impact drug development; (iii) data reported from ongoing preclinical and clinical trials are necessarily interim data only and the final results will change based on continuing observations; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of potential new drug candidates (such as bempegaldesleukin) is therefore very uncertain and unpredictable; (v) the timing of the commencement or end of clinical studies 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, delays caused by our collaboration partners and the COVID-19 pandemic, and enrollment competition; (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 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.

**Contact:**
**For Investors:**
Vivian Wu of Nektar Therapeutics
628-895-0661

**For Media:**

Dan Budwick of 1AB
973-271-6085
dan@1abmedia.com

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