February 17, 2021

Nektar Announces Collaboration with SFJ Pharmaceuticals® for Bempegaldesleukin in Head and Neck Cancer

Nektar to receive up to $150 million in development funding through a novel financing collaboration agreement

SAN FRANCISCO, Feb. 17, 2021 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cancer and auto-immune disease, today announced a financing and co-development collaboration with SFJ Pharmaceuticals to support the development of Bempegaldesleukin (BEMPEG), an investigational CD122-preferential IL-2–pathway agonist. SFJ Pharmaceuticals is a global drug development company backed by Abingworth and Blackstone Life Sciences.

The collaboration between SFJ and Nektar will support a new Phase 2/3 registrational clinical study of BEMPEG plus pembrolizumab in patients with head and neck cancer whose tumors express PD-L1 (Combined Positive Score [CPS] ≥1). Under the terms of the agreement, SFJ has agreed to fund up to $150 million to support the study and manage clinical trial operations. Nektar will serve as the sponsor of the Phase 2/3 study.

"This innovative collaboration with SFJ provides Nektar with substantial non-dilutive funding to broaden the registrational program for BEMPEG," said Howard Robin, President and CEO of Nektar Therapeutics. "SFJ's global drug development and clinical trial management expertise, coupled with a track record of success in accelerating and advancing late-stage development programs for global pharmaceutical companies, make them an ideal partner."

Under the terms of the new agreement, SFJ will fund up to $150 million for the Phase 2/3 study until its completion. In return, Nektar agrees to pay SFJ success-based annual milestone payments over a period of seven to eight years, which are contingent upon receipt of certain U.S. regulatory approvals for specified indications for BEMPEG and will begin following completion of the head and neck study that is projected to be in 2024. If BEMPEG does not receive regulatory approval for one or more of the specified indications, Nektar will not owe any future payments linked to an indication that is not approved.

"We are excited to be partnering with Nektar under this novel financing and co-development agreement," said Bob DeBenedetto, Chief Executive Officer of SFJ. "Based on the strength of the clinical data generated to date for BEMPEG in melanoma and other tumor types, and following an extensive diligence process conducted in conjunction with our partners at Blackstone Life Sciences and Abingworth, we believe that BEMPEG has great potential to help cancer patients. We look forward to supporting the Phase 3 study and working closely with the Nektar team."

Morgan Stanley & Co. LLC acted as the sole structuring agent to Nektar on the transaction.

About Bempegaldesleukin (BEMPEG; NKTR-214)

Bempegaldesleukin (BEMPEG: NKTR-214) is an investigational CD122-preferential IL-2–pathway agonist that leverages the clinically validated IL-2 pathway to stimulate an antitumor immune response.[1] BEMPEG was engineered to deliver a controlled, sustained, and preferential IL-2 pathway signal, with the goals of stimulating an antitumor immune response while minimizing toxicity, thereby allowing for outpatient administration.[1,2] In a phase 1 trial of BEMPEG in combination with the checkpoint inhibitor nivolumab (NIVO; PIVOT-02), the combination was well tolerated and produced durable responses that deepened over time in multiple advanced solid tumor types.[3]

In February of 2018, Nektar and Bristol-Myers Squibb entered into a global strategic development and commercialization collaboration for BEMPEG. Under the terms of the agreement, Nektar is eligible to receive $1.45 billion in regulatory filing and approval milestones for BEMPEG. Nektar will book revenue for worldwide sales of BEMPEG and the companies will split global profits for BEMPEG with Nektar receiving 65% and Bristol-Myers Squibb 35%. The agreement allows Nektar to develop BEMPEG with other checkpoint inhibitor therapies in tumor types outside of the Nektar-Bristol-Myers Squibb joint clinical development program for BEMPEG plus NIVO.

In July of 2019, Bristol-Myers Squibb and Nektar announced that the U.S. Food and Drug Administration granted Breakthrough Therapy Designation for investigational agent bempegaldesleukin in combination with nivolumab for the treatment of patients with previously untreated unresectable or metastatic melanoma.

The joint clinical development program for BEMPEG plus NIVO includes registrational and other studies of BEMPEG plus NIVO in melanoma, renal cell carcinoma or RCC, and bladder cancer. This includes a Phase 3 trial in first-line advanced melanoma (NCT03635983), a Phase 3 trial in adjuvant melanoma (NCT04410445), a Phase 3 trial in advanced RCC (NCT03729245), a Phase 3 trial in muscle-invasive bladder cancer (NCT04209114), a Phase 2 trial in cisplatin-ineligible urothelial carcinoma (NCT03785925), a Phase 1/2 trial in combination with a tyrosine kinase inhibitor in advanced RCC (NCT04540705) and a Phase 1/2 trial in children, adolescents and young adults with recurrent or treatment-resistant cancer (NCT04730349).

BEMPEG is also being evaluated separately in the PROPEL study in combination with pembrolizumab in patients with first-line metastatic non-small cell lung cancer (NCT03138889) and in collaboration with Vaccibody in the DIRECT-01 study in combination with VB10.NEO in squamous cell carcinoma of the head and neck (NCT03548467).

About Head and Neck Cancer

Squamous cell carcinoma of the head and neck, which forms in the tissues of the moist, mucosal surfaces inside the mouth, nose and throat, is the sixth most common cancer worldwide. In 2020, there were more than 850,000 cases leading to 440,000 deaths, according to The Global Cancer Observatory. The incidence of SCCHN continues to rise and is expected to increase by about 40% by 2040. According to data from the SEER registry, 5-year survival rate was estimated to be 66% for patients diagnosed with SCCHN and 40% for patients with metastatic disease, during the period 2010-2016.

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology, immunology and virology. 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.

About the SFJ Pharmaceuticals Group

SFJ is a global drug development company, which provides a unique and highly customized co-development partnering model for the world's top pharmaceutical and biotechnology companies. SFJ provides at-risk funding and the global clinical development management and oversight necessary for regulatory submission for some of the most promising drug development programs of Pharmaceutical and Biotechnology companies. SFJ's mission is to leverage its financial strength and global team of pharmaceutical development experts to accelerate the development of life-saving and life-enhancing drugs for the benefit of physicians and the patients they serve.

1. Bentebibel S-E, et al. A First-in-Human Study and Biomarker Analysis of NKTR-214, a Novel IL2Rβγ -Biased Cytokine, in Patients with Advanced or Metastatic Solid Tumors. *Cancer Discovery* 2019;9:711-21.
2. Charych D, et al. Modeling the receptor pharmacology, pharmacokinetics, and pharmacodynamics of NKTR-214, a kinetically controlled interleukin-2 (IL2) receptor agonist for cancer immunotherapy. *PLoS ONE* 2017;12.
3. Diab A, et al. Bempegaldesleukin (NKTR-214) plus nivolumab in patients with advanced solid tumors: Phase 1 dose-escalation study of safety, efficacy and immune activation (PIVOT-02). *Cancer Discovery* 2020

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "will," "develop," "may," "provide," "deliver" 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 (such as nivolumab and pembrolizumab), the availability of results from clinical studies, and the potential benefits of co-development collaborations. 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) projected costs for completing clinical trials are estimates only and the actual costs will vary and can be higher depending on a number of factors, such as unexpected changes in healthcare costs over time, the need to increase the number of clinical trial sites, and the length of time the trial is conducted; (vii) 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 (viii) 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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