Nektar Therapeutics Presents Biomarker and Clinical Data from PIVOT-02 Phase 2 Study of Bempegaldesleukin with Nivolumab at 2019 ASCO Annual Meeting

June 1, 2019

CHICAGO, June 1, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today that biomarker and clinical data from PIVOT-02 is being presented at the 2019 American Society of Clinical Oncology (ASCO) Meeting in Chicago, Illinois.

New baseline biomarker analyses and updated clinical study efficacy and safety results were shared in a presentation titled, *"Baseline tumor-immune signatures associated with response to bempegaldesleukin (NKTR-214) and nivolumab*" (Abstract #2623/Poster Board #267) by Michael Hurwitz, Ph.D., M.D. who serves as Assistant Professor of Medicine, Medical Oncology at Yale Cancer Center during the "Developmental Immunotherapy and Tumor Immunobiology" poster session on Saturday, June 1, 2019.

"The Stage IV melanoma patients enrolled in the ongoing PIVOT-02 study continue to experience both deepening and durability of response over time," said Jonathan Zalevsky, Ph.D., Chief Scientific Officer at Nektar Therapeutics. "This translated into a 34% rate of complete response at a 12-month follow-up for the 38 efficacy-evaluable patients in this cohort. Further, 42% of patients achieved a 100% reduction in target lesions. Finally, corresponding lymphocyte data highlight the benefit of replenishing and stimulating T cells continuously over the course of treatment with an I-O doublet regimen."

Bempegaldesleukin (NKTR-214, bempeg) is an investigational, CD122-preferential IL-2 pathway agonist designed to provide sustained signaling through the IL-2 beta-gamma receptor. PIVOT-02 is an ongoing Phase 2 study evaluating bempeg in combination with nivolumab in solid tumors.

Highlights from the biomarker, clinical efficacy and safety data presented at ASCO 2019 are provided below:

Biomarkers and Mechanism of Action:

- Exploratory biomarker analyses of PIVOT-02 baseline tumor biopsies identified immune signatures that potentially enrich for response in patients with 1L metastatic melanoma and not 1L metastatic urothelial carcinoma.
- Notable response rates were seen in both 1L metastatic melanoma and 1L metastatic urothelial cancer patients (ASCO 2019 and ASCO-GU 2019), regardless of PD-L1 status or unfavorable tumor microenvironments.

12 Month Follow-Up for 1L Melanoma Cohort in PIVOT-02:
(*Response measured by RECIST 1.1 by independent central radiology review for 38 efficacy-evaluable patients per protocol which were treated at the recommended Phase 2 dose in PIVOT-02 and with ≥1 on treatment scan. Data cut as of March 29, 2019)*:

- At a median time of follow-up of 12.7 months, confirmed objective response rate (ORR) was 53% (20/38) in efficacy-evaluable patients, with 34% (13/38) of patients achieving confirmed complete responses. 42% (16/38) of patients achieved a maximum reduction of 100% in target lesions. DCR, also known as disease control rate (CR+ PR + SD) was 74%.
- Median time to response was 2 months. Median duration of response was not reached. At the 12.7 month median follow-up, data were too immature to calculate median progression-free survival (PFS).
- 80% (16/20) of patients with responses have ongoing responses. Amongst the 35 patients with known pre-treatment PD-L1 status, ORR in PD-L1 negative patients was 6/14 (43%) and in PD-L1 positive patients was 13/21 (62%). One of three patients with unknown PD-L1 baseline status experienced a CR.
- The most common (>30%) treatment-related adverse events (TRAEs) were grade 1-2 fatigue (65.9%), pyrexia (61.0%), rash (56.1%), pruritus (48.8%), nausea (41.5%), influenza like illness (39.0%), arthralgia (36.6%), chills (34.1%) and myalgia (31.7%). A total of 6/41 (14.6%) of patients experienced a Grade 3 (G3) or higher TRAE with 4/41 (9.8%) patients discontinuing treatment due to a TRAE. A total of 41 patients have been treated at the RP2D with 3 patients discontinuing prior to 1st scan due to an unrelated treatment-emergent adverse event (n=1) and patient decision (n=2).

A Phase 3 trial evaluating bempeg in combination with nivolumab versus nivolumab in first-line advanced melanoma patients is currently recruiting patients (NCT03635983). A Phase 2 pivotal trial evaluating bempeg in combination with nivolumab in first-line metastatic urothelial cancer is currently recruiting patients (NCT03785925).

Details of the poster presentation are provided below and a link to a copy of the poster presentation is available on Nektar's corporate website: https://www.nektar.com/download_file/701/0.

Abstract #2623/Poster Board #267
Title: *"Baseline tumor-immune signatures associated with response to bempegaldesleukin (NKTR-214) and nivolumab",* Hurwitz,

M., et al.
Date: Saturday, June 1, 2019, 8:00 a.m. – 11:00 a.m. Central Time
Location: McCormick Place, Exhibit Hall A

About Nektar
Nektar Therapeutics is a research-based, development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, auto-immune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. 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," "designed" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of bempegaldesleukin (NKTR-214) in combination with nivolumab, the ability of biomarker data to enrich for response to bempegaldesleukin and nivolumab in certain patient populations, the availability of results and outcomes from clinical studies involving bempegaldesleukin, and our future clinical development plans. 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 observations to date from ongoing clinical studies; (ii) bempegaldesleukin is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the cancer indications being studied prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other factors that negatively impact drug development; (iii) data reported from ongoing clinical trials is necessarily interim data only and the final results will change based on continuing observations from patients that currently remain enrolled in the trials and/or new observations from patients enrolling in the trials; (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) 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 Nektar's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 2019. 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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