Clinical Data Presented from PIVOT-02 Study of Bempegaldesleukin (NKTR-214) with Nivolumab in Triple-Negative Breast Cancer Patients at the 2019 CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference

September 26, 2019

Analyst conference call with breast cancer specialist to be held at 2:30 p.m. Central European Summer Time (CEST)/8:30 a.m. Eastern Daylight Time (EDT) today

SAN FRANCISCO, Sept. 26, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today a presentation of new clinical data for bempegaldesleukin (bempeg, NKTR-214) in combination with nivolumab in patients with advanced or metastatic triple-negative breast cancer (TNBC) at the 2019 CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference in Paris, France.

"Among all the breast cancer types, triple-negative breast cancer has the poorest prognosis and new treatment options are needed for our patients," said Sara M. Tolaney, M.D., MPH, Associate Director of the Susan F. Smith Center for Women's Cancers at Dana-Farber Cancer Institute and Assistant Professor of Medicine at Harvard Medical School. "While checkpoint inhibitors in combination with taxanes have been shown to provide survival benefit to advanced TNBC patients whose tumors are positive for PD-L1, more effective treatment combinations are needed, particularly for those patients whose tumors are PD-L1 negative."

TNBC is a type of breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein. It accounts for up to 20% of all breast cancer cases, occurring more frequently in young premenopausal women.*

"The data presented today in patients with metastatic TNBC demonstrate the promising clinical activity of bempeg plus nivolumab, most notably in patients with PD-L1 negative baseline tumors," said Mary Tagliaferri, M.D., Chief Medical Officer at Nektar Therapeutics. "Responses were prolonged and occurred in patients with multiple negative predictive factors for clinical benefit with a checkpoint inhibitor, including prior treatment with taxane therapy and multiple sites of metastases. These data support potential future development of this doublet in combination with chemotherapy in the population of TNBC patients with the highest unmet medical need."

The preliminary results from patients enrolled in the TNBC cohort in the ongoing PIVOT-02 Phase 1/2 study were shared in a poster presentation today titled, "Clinical activity of BEMPEG plus NIVO observed in metastatic TNBC: preliminary results from the TNBC cohort of the Ph1/2 PIVOT-02 study" by Sara M. Tolaney, M.D., MPH, et al.

Highlights from the CRI-CIMT-EATI-AACR presentation in metastatic TNBC patients include:

Clinical Efficacy:
Investigator-assessed response measured per RECIST 1.1 for efficacy-evaluable patients treated at the recommended Phase 2 dose (RP2D) and with ≥1 post-treatment scan as of July 1, 2019[1]*:*

- All patients had at least one or more poor prognostic features or negative predictive clinical factors (high LDH, # of metastatic sites, prior taxane, early relapser) for checkpoint inhibitor (CPI) benefit, including those who were baseline PD-L1 negative.[2-4]
- Confirmed overall objective response rate (ORR) was 13% (5/38) in all efficacy-evaluable patients.[5] 24 of 38 efficacy-evaluable patients were relapsed/refractory to prior chemotherapy regimens in the metastatic setting (≥2/3L metastatic setting). All 5 confirmed responders had received at least one line of chemotherapy for metastatic disease prior to study entry. One patient with a confirmed partial response (PR) had a 100% reduction in RECIST target lesions and went off therapy as a result of achieving maximal clinical benefit at 20.7 months; the remaining four responders are ongoing treatment with prolonged responses.
- ORR was 21% (5/24) in the ≥2/3L metastatic patients, with an ORR of 23% (3/13) in ≥2/3L metastatic patients who had a PD-L1 negative baseline tumor status.
- Among the 34 patients with known pre-treatment PD-L1 status, ORR in PD-L1 negative patients was 14% (3/22) and in PD-L1 positive patients was 17% (2/12).
- Disease control rate (DCR) in the overall efficacy-evaluable population was 45% (defined as complete response (CR) + PR

+ stable disease (SD)).

- In patients with RECIST response, no patients discontinued due to disease progression.

Clinical Safety:

- The combination of bempegaldesleukin and nivolumab was well tolerated, and treatment-related adverse events (TRAEs) were similar to what was previously reported. A total of 26%(11/43) patients experienced a Grade 3/4 TRAE, with 2 patients discontinuing due to a TRAE. The most common Grade 3/4 TRAEs were dehydration (4.7%), hypotension (4.7%), and myalgia (4.7%).

- A copy of Dr. Tolaney's poster presentation of PIVOT-02 data is available on Nektar's corporate website at https://www.nektar.com/download_file/713/0.

Analyst Call with Nektar Management and Breast Cancer Specialist, Dr. Sara Tolaney of Dana-Farber Cancer Institute
Nektar will webcast an analyst conference call today, Thursday, September 26, 2019, at 2:30 p.m. CEST. The conference call may be accessed by dialing 877-881-2183 (toll-free) or 970-315-0453 (international) with the conference call passcode 1998093. The webcast and slides for the conference call can be accessed through a link posted on the Investors section of the Nektar website at https://ir.nektar.com/. The webcast of the conference call will be available for replay through December 26, 2019.

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 cancer-killing 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 cancer-killing 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.[6] In clinical and preclinical studies, treatment with bempegaldesleukin resulted in expansion of these cells and mobilization into the tumor micro-environment.[7,8] Bempegaldesleukin has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

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, autoimmune 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 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" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential bempegaldesleukin in combination with other therapeutic agents. 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 new observations from patients enrolling in the trials; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future regulatory approval 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 August 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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*BioScience Reports (2016) 36, e00432

[1] Efficacy-evaluable defined per protocol as patients with at least one post-baseline scan. As of 7/1/2019, five patients were not evaluable: three had clinical progression and 2 were deaths due to progressive disease before the first tumor assessment.

[2] Defined as <1% tumor staining by 28-8 PharmDx

[3] Emens, L., et al., JAMA Oncol. 2019;5(1):74-82 September 13, 2018

[4] Planes-Laine, G., et al., Cancers 2019, 11, 1033 July 22, 2019

[5] ORR by primary investigator assessment includes only confirmed responses.

[6] Boyman, J., et al., Nature Reviews Immunology, 2012, 12, 180-190.

[7] Charych, D., et al., Clin Can Res; 22(3) February 1, 2016

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

View original content:http://www.prnewswire.com/news-releases/clinical-data-presented-from-pivot-02-study-of-bempegaldesleukin-nktr-214-with-nivolumab-in-triple-negative-breast-cancer-patients-at-the-2019-cri-cimt-eati-aacr-international-cancer-immunotherapy-conference-300925662.html

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