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Nektar Presents New Clinical Data from Two Studies of NKTR-214, a CD122-Biased Agonist, at 2017 American Society of Clinical Oncology (ASCO) Annual Meeting

CHICAGO and SAN FRANCISCO, June 5, 2017 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that it presented new findings from two Phase 1 clinical studies of NKTR-214, Nektar's lead immuno-oncology candidate, a CD122-biased agonist, at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

NKTR-214 is an investigational immuno-stimulatory therapy designed to expand specific cancer-fighting CD8+ effector T cells and natural killer (NK) cells directly in the tumor micro-environment and increase expression of PD-1 on these immune cells.

"We are very excited about the initial data emerging from the PIVOT study evaluating NKTR-214 in combination with nivolumab," said Mary Tagliaferri, M.D., Senior Vice President of Clinical Development at Nektar Therapeutics. "The combination is showing early clinical benefit in patients with both melanoma and renal cell carcinoma. We've observed RECIST responses in 3 of 4 patients with BRAF-positive Stage IV melanoma in the study, including a durable complete response that occurred at week 6 on treatment. These patients had very poor prognosis coming into the study, including high baseline LDH levels and liver metastases. In addition, the combination treatment has a favorable safety profile and we have not observed any grade 3 or higher treatment-related AEs to-date. We look forward to identifying a Phase 2 dose and initiating the expansion cohorts for the PIVOT trial in our 8 target indications in the third quarter of 2017."

New findings were presented in patients from an ongoing Phase 1 dose-escalation study evaluating monotherapy NKTR-214 in patients with solid tumors in a poster session at the 2017 American Society of Clinical Oncology Annual Meeting in Chicago:

- Confirmed partial responses (PRs) were observed in 3 of 4 patients with Stage IV renal cell carcinoma (RCC) who were immuno-oncology (I-O) treatment naïve who experienced stable disease (SD) with tumor shrinkage while on NKTR-214 monotherapy (range of 3-8 cycles) and then received sequential therapy with nivolumab. All three patients with confirmed PRs experienced rapid responses at first 8-week scan after initiating sequential therapy with nivolumab. The fourth patient experienced SD at first 8-week scan. All four patients had progressed on one or more prior tyrosine-kinase inhibitor (TKI) therapies and all are continuing on therapy with nivolumab.
- Two heavily pre-treated Stage IV patients are continuing treatment with monotherapy NKTR-214. One patient with BRAF-mutated melanoma, who was previously treated with ipilimumab and vemurafenib, continues on NKTR-214 therapy with SD for greater than 15 months. One patient with RCC who was previously treated with high-dose IL-2 and subsequently refractory to single agent treatments with OX40 and nivolumab, continues on NKTR-214 therapy with SD for greater than 10 months.
- NKTR-214 monotherapy demonstrated a favorable safety profile with no immune-related adverse events (AEs) (N=28, Stage IV patients)
- Data from blood and tumor samples show that NKTR-214 increases immune cells in the blood and tumor microenvironment even in subjects who have failed multiple prior immunotherapeutic agents.

Initial data were presented from the ongoing PIVOT dose-escalation trial evaluating NKTR-214 in combination with nivolumab in patients with melanoma, renal cell carcinoma and non-small cell lung cancer. As of June 1, 2017, 20 patients were enrolled in the dose-escalation phase of the ongoing PIVOT study in a number of dose cohorts. Findings from the first patients enrolled in the ongoing study are as follows:

- Clinical benefit data (evaluable scans) were available for initial patients enrolled in the trial:
  - Responses (RECIST 1.1) were observed in 3 of 4 patients with BRAF-mutated Stage IV melanoma (1 CR, 2 *u*PR). Time to response for these patients, respectively, was 6 weeks, 7 weeks and 20 weeks. All three patients with responses are ongoing treatment in the trial.
  - Two patients with RCC who were I-O naïve were evaluable for at least two scans. A confirmed PR (-39%) was observed in one of these patients (PD-L1 negative) who progressed on prior TKI therapy. Time to response was 15 weeks. The second patient, who progressed on prior bevacizumab therapy, experienced SD and is continuing on treatment.
  - 4 additional RCC IO naïve patients were evaluable for one scan. All four had SD in their target lesions and are continuing on treatment in the study.

- On treatment tumor biopsies from the PIVOT trial show robust expansion of ICOS+ CD4 and CD8 T cells with the combination of NKTR-214 and nivolumab.
- All dose cohorts of NKTR-214 and nivolumab demonstrate a favorable safety profile and are well-tolerated. In the study to-date, there are no dose-limiting toxicities, no grade 3 or higher treatment-related AEs, and no immune-related AEs (such as colitis, dermatitis, pneumonitis or endocrinopathies).
- The dose-escalation portion of the trial is enrolling with the last dose cohort recently initiated (NKTR-214 0.009 mg/kg q3w + nivo 360 mg q3w) in order to identify a recommended Phase 2 dose.

NKTR-214 preferentially binds to the CD122 receptor on the surface of cancer-fighting immune cells in order to stimulate their proliferation. In clinical and preclinical studies, treatment with NKTR-214 resulted in expansion of these cells and mobilization into the tumor micro-environment.[1,2] NKTR-214 has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

About Nektar
Nektar Therapeutics is a research-based 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: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of NKTR-214, observations from early data emerging from ongoing clinical trials of NKTR-214, the anticipated timing of starting the expansion cohorts for the PIVOT study, and the potential of our technology and drug candidates in our research and development pipeline. 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 NKTR-214 are based on findings and observations from preclinical findings and ongoing clinical studies; (ii) NKTR-214 is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur due to efficacy, safety or other unpredictable factors; (iii) the initial preliminary RECIST response data reported in this press release is subject to change—in particular, there is no way to predict whether unconfirmed responses will become confirmed responses as the clinical studies progress; (iv) the preliminary clinical results from the NKTR-214 clinical studies described in this press release remain subject to change as a result of final data audit confirmation procedures to be conducted following completion of the studies; (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, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (vi) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of applying our technology platform to potential new drug candidates (such as NKTR-214) is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (vii) patents may not issue from our patent applications for our drug candidates including NKTR-214, 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 our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2017. 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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1. Charych, D., et al., Clin Can Res; 22(3) February 1, 2016
2. Diab, A., et al., Journal for ImmunoTherapy of Cancer 2016, 4(Suppl 1):P369