May 31, 2014

Positive Data from Phase 2 Trial of NKTR-102 in Patients with Avastin®-Refractory High-Grade Glioma Presented at 50th ASCO Meeting

Single agent NKTR-102 exceeds primary endpoint with fifty-five percent of patients achieving six-week progression-free survival and fifteen percent of patients achieving partial response

SAN FRANCISCO, May 31, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) announced today new data from an investigator-sponsored Phase 2 study of NKTR-102 (etirinotecan pegol) in patients with Avastin-refractory high-grade glioma conducted at Stanford Cancer Institute under the direction of Lawrence Recht, M.D., Professor of Neurology and Neurosurgery, with co-investigator Seema Nagpal, M.D., Clinical Assistant Professor of Neurology and Neurological Sciences, Stanford School of Medicine.

"Patients with Avastin-refractory high-grade glioma currently have little to no treatment options to help them manage their disease," said Dr. Recht. "Patients progress rapidly once resistance develops, objective responses are rarely seen. In this study we saw three patients - 15%, all with glioblastoma - with confirmed partial responses on single-agent NKTR-102 according to RANO criteria and an additional eight patients - 40% -- who had stable disease as a best response."

The trial enrolled 20 patients with high-grade glioma from August 2012 to May 2013. Patients had a median KPS of 70 and had received a median of three lines of prior therapy, including recurrence following treatment with Avastin. Avastin-refractory was defined as progression by RANO criteria within 60 days of prior Avastin (bevacizumab) treatment. Ninety percent of patients in the trial had glioblastoma. Patients received a median of three cycles (1-22) of NKTR-102 once every three weeks as monotherapy. Six-week progression-free survival in at least 25% of the patients was needed to reject the null hypothesis for the primary endpoint.

Study Results
The primary endpoint was met and exceeded with fifty-five percent (95% CI: 31%-75%) of patients in the study achieving six-week progression-free survival. Response and disease progression were assessed by RANO criteria in the trial. Three patients, or 15%, achieved partial responses with NKTR-102 monotherapy with maximum percent reductions in tumor area of 86%, 72%, and 59%. An additional eight patients, or 40%, achieved stable disease as best response. Two of the three patients with RANO responses experienced a long duration of response of 14 and 20 months. Secondary endpoints include median progression-free survival (2.2 months), median survival from time of first NKTR-102 infusion (4.5 months) and median overall survival from date of pathologic diagnosis or confirmation of high-grade glioma (17.1 months). NKTR-102 monotherapy was well-tolerated in patients with Avastin-refractory high-grade glioma with low toxicity in spite of being heavily pre-treated and neurologically symptomatic. Only one patient (5%) had Grade 3 toxicity (diarrhea with dehydration) attributable to NKTR-102 as a result of not taking anti-diarrheal medication. Hematologic toxicity was mild. As of May 31, 2014, there is one patient in the study who is continuing on NKTR-102 monotherapy.

"Though participants in this trial were heavily pre-treated and more neurologically symptomatic than many clinical trial patients, we observed low toxicity with three partial responses," said Dr. Nagpal. "In addition, two of the three patients with responses experienced a long duration of response of 14 and 20 months, respectively. These results warrant further investigation of NKTR-102 in high-grade glioma, including glioblastoma as single-agent and in combination with bevacizumab, which could theoretically enhance retention of NKTR-102 in the tumor."

The ASCO 2014 data presentation can be accessed at the link below:
http://www.nektar.com/pdf/pipeline/NKTR-102/NKTR-102_ASCO_Poster_2014.pdf

About High-Grade Gliomas
High-grade gliomas, including anaplastic astrocytomas, anaplastic oligodendrogliomas, and glioblastomas, are the most common and most aggressive primary brain tumors. Recurrence after initial therapy with temozolomide and radiation is nearly universal. Since May 2009, the majority of patients in the U.S. with an initial recurrence of high-grade glioma receive bevacizumab. Avastin has initial response rates from 32-62%[1], however, the response is short-lived and nearly 100% of patients eventually progress. Patients with high-grade gliomas who have progressed through bevacizumab represent a population in dire need of new therapies.

About NKTR-102 (etirinotecan pegol)

NKTR-102, a novel topoisomerase I inhibitor, is believed to penetrate the vasculature of the tumor environment more readily than normal vasculature, increasing the concentration of active drug within tumor tissue to enhance anti-tumor activity. The unique pharmacokinetic profile of NKTR-102 provides continuous exposure of active drug throughout the entire chemotherapy cycle, with reduced peak exposures that can be associated with toxicities. NKTR-102 is currently being evaluated in a pivotal Phase 3 clinical study in patients with advanced breast cancer (the BEACON study). In November 2012, NKTR-102 was designated a Fast Track development program by the U.S. FDA for the treatment of patients with locally recurrent or metastatic breast cancer progressing after treatment with ATC. Additional investigator-sponsored studies at Roswell Park Cancer Institute and University of Pennsylvania Abramson Cancer Center are ongoing to evaluate NKTR-102 in patients with small cell lung cancer and non-small cell lung cancer, respectively.

About Nektar
Nektar Therapeutics (NASDAQ: NKTR) is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar has a robust R&D pipeline of potentially high-value therapeutics in pain, oncology and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for naloxegol (NKTR-118), an investigational drug candidate, which has been filed for regulatory approvals in the U.S., Europe and Canada as a once- daily, oral tablet for the treatment of opioid-induced constipation. This agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of naloxegol and an opioid. NKTR-181, a novel mu-opioid analgesic molecule for chronic pain conditions, has completed Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-171, a new sodium channel blocker being developed as an oral therapy for the treatment of peripheral neuropathic pain, is in Phase 1 clinical development. In oncology, etirinotecan pegol (NKTR-102) is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer and is also in Phase 2 studies for the treatment of ovarian, colorectal, lung and brain cancers. In anti-infectives, Amikacin Inhale is in Phase 3 studies conducted by Bayer Healthcare as an adjunctive treatment for intubated and mechanically ventilated patients with Gram-negative pneumonia. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a long-acting PEGylated rFVIII program, which is in Phase 3 clinical development for patients with hemophilia A.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia.

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" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "could," "potential," "may" and similar references to future periods. Examples of forward-looking statements include those statements regarding the therapeutic potential of etirinotecan pegol and the potential of certain of our other drug candidates and those of our collaboration partners. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, observations and assumptions regarding the potential of our drug candidates and our technology. 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) etirinotecan pegol is still in clinical development and the risk of failure is high and can unexpectedly occur at any time prior to regulatory approval for numerous reasons including safety and efficacy findings from the ongoing BEACON clinical study program; (ii) the timing of the commencement or end of clinical trials, target timeframe for the availability of clinical results, and the successful commercial launch of our drug candidates may be delayed or unsuccessful due to manufacturing challenges, changing standards of care, regulatory delay, 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; (iii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of our technology platform to potential new drug candidates such as etirinotecan pegol is therefore very uncertain and unpredictable and could unexpectedly fail at any time; (iv) patents may not issue from our patent applications for etirinotecan pegol, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (v) the outcome of any existing or future intellectual property or other litigation related to our proprietary drug candidates including etirinotecan pegol. Other important risks and uncertainties are detailed in our reports and other filings with the Securities and Exchange Commission ("SEC"), including without limitation, those risks and uncertainties set forth in our most recent quarterly report on Form 10-Q filed with the SEC on May 8, 2014. 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. Chamberlain MC. Bevacizumab for recurrent malignant gliomas: efficacy, toxicity, and patterns of recurrence. Neurology. 2009; 72(8): 772-3; author reply 3-4.

DEFINITIONS:
RANO: Revised Assessment in Neuro-Oncology (RANO) criteria is used for assessing disease progression and treatment response in glioblastoma multiforme (GBM)
KPS: Karnofsky Performance Status Scale: A standard way of measuring the ability of cancer patients to perform ordinary tasks. The Karnofsky Performance scores range from 0 to 100. A higher score means the patient is better able to carry out daily activities. KPS may be used to determine a patient's prognosis, to measure changes in a patient's ability to function, or to decide if a patient could be included in a clinical trial.

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