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Etirinotecan Pegol (NKTR-102) Passes Interim Efficacy Analysis for BEACON Pivotal Phase 3 Clinical Study in Patients with Metastatic Breast Cancer

SAN FRANCISCO, Jan. 14, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) announced today that the Independent Data Monitoring Committee (DMC) created to provide safety oversight for the Company's pivotal clinical study for etirinotecan pegol (NKTR-102) has recommended continuation of the BEACON phase 3 trial, based upon the completion of a planned interim efficacy analysis in accordance with the DMC charter. The BEACON trial is evaluating NKTR-102 versus an agent of physician's choice for the treatment of locally recurrent or metastatic breast cancer, with a primary efficacy endpoint of overall survival. NKTR-102 is the first long-acting topoisomerase I-inhibitor designed to concentrate in tumor tissue, provide sustained tumor suppression throughout the entire chemotherapy cycle, and to reduce the peak exposures that are associated with toxicities of other cytotoxics.

The independent DMC performed the pre-defined interim efficacy analysis, which consisted of a review of ongoing efficacy and safety data, including 50% of patient events necessary to evaluate the primary endpoint of overall survival. In August 2013, the BEACON study completed enrollment of 852 patients with advanced breast cancer whose disease has progressed following treatment with anthracycline, taxane and capecitabine therapies (ATC).

"While the results of BEACON remain blinded to Nektar, we are very pleased that the NKTR-102 trial has successfully passed this important interim efficacy analysis," said Howard Robin, President and CEO of Nektar Therapeutics. "We expect final results from the study at the end of 2014 or early 2015, and if positive, we plan to submit filings in the U.S. and Europe in the second half of 2015. There is a high unmet need for new treatment options for patients with advanced breast cancer, particularly for patients with HER2-negative breast cancer and triple-negative breast cancer."

Positive Phase 2 data for NKTR-102 were recently published in Lancet Oncology in November 2013. (1) Etirinotecan pegol achieved a confirmed objective response rate by RECIST of 29 percent. NKTR-102 demonstrated a high clinical benefit rate (CR+PR+SD greater than six months) of 37 percent (13/35) in the 14-day group and 49 percent (17/35) in the 21-day group. Six patients experienced 100 percent resolution of all target lesions, with two complete RECIST responses and four near-complete responses. Patients treated exhibited low rates of alopecia, neuropathy and neutropenia, which are significant adverse events associated with existing breast cancer therapies. Side effects were generally manageable; the most common Grade 3 toxicity was diarrhea (17-23%) typically occurring after three months of therapy.

About the BEACON Study

BEACON is a Phase 3, open-label, randomized, multicenter study of NKTR-102 which enrolled 852 women with locally recurrent or metastatic breast cancer, who have previously been treated with ATC. The trial is being conducted at approximately 150 sites worldwide including North America, Western Europe, Russia and the Republic of Korea. Nearly half of the patients enrolled in BEACON were located in North America. Patients were randomized on a 1:1 basis to receive 145 mg/m2 of single-agent NKTR-102 once every three weeks or a single agent of physician's choice. The physician's choice agents include: ixabepilone, vinorelbine, gemcitabine, eribulin, or a taxane. Randomization was stratified by geographic region, prior use of eribulin and receptor status.

The primary endpoint of the BEACON study is overall survival; secondary endpoints include progression-free survival, objective tumor response rates (ORR), clinical benefit rate, duration of response, pharmacokinetics, safety, quality-of-life measurements, and pharmacoeconomic implications. The study is also evaluating specific biomarker data to assess correlation with objective tumor response rates, progression-free survival, overall survival and selected toxicities.

About Etirinotecan Pegol (NKTR-102)

NKTR-102 is a new therapeutic option in development for advanced breast cancer. It is the first long-acting topoisomerase I inhibitor with a non-overlapping mechanism of action with other agents used to treat breast cancer, which may mitigate potential cancer cross-resistance and reduce overlapping toxicities. 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.

NKTR-102 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 PK 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. In addition to metastatic breast cancer, NKTR-102 is also being evaluated for the treatment of ovarian, colorectal, glioma and lung cancers.

About Metastatic Breast Cancer

More than one million women worldwide are diagnosed with breast cancer globally every year. (2) The chance of developing invasive breast cancer at some time in a woman's life is a little less than one in eight (12%). There are approximately 200,000 new cases of breast cancer in the United States and 430,000 in Europe each year. (3) Metastatic breast cancer refers to cancer that has spread from the breast to distant sites in the body.

Anthracyclines and taxanes (AT) are the most active and widely used chemotherapeutic agents for breast cancer, but the increased use of these agents at an early stage of disease often renders tumors resistant to these drugs by the time the disease recurs, thereby reducing the number of treatment options for metastatic disease. Drugs used to treat patients who progress following AT treatment can have response rates as high as 20-30%; however, resistance develops rapidly and new agents with different mechanisms of action, such as topoisomerase I inhibitors, are needed to allow novel ways to overcome the problem of drug resistance. (4) There are currently no FDA-approved topoisomerase I inhibitors to treat breast cancer.

About Nektar
Nektar Therapeutics 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 oncology, pain 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 candidate for chronic pain conditions, has completed Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-opioid analgesic in development to treat acute pain is in Phase 1 clinical development. 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 longer-acting PEGylated rFVIII program, which is completing Phase 3 clinical development.

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 our current views regarding the potential of etirinotecan pegol as a potential new therapy for patients with metastatic breast cancer that have failed other available therapies; the estimated timeline for the availability of top-line data from the BEACON clinical study and, if the study is successful, the timing of regulatory filings with health authorities; the value of our polymer conjugate technology platform; 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; (ii) the statements regarding the therapeutic potential of etirinotecan pegol are based on preclinical data and data from the completed Phase 2 clinical study and future results from the BEACON clinical study may not confirm these earlier findings; (iii) 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; (iv) 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; (v) 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 (vi) the outcome of any existing or future intellectual property or other litigation related to our proprietary drug candidates. 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 quarterly report on Form 10-Q for the quarter ended September 30, 2013, filed with the SEC on November 7, 2013. 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) Awada et al, Lancet Oncology 2013 Nov;14 (12):1216-25.

(2) American Cancer Society, 2007 Global Cancer Facts and Figures Report.

(3) American Cancer Society, 2009 Global Cancer Facts and Figures Report.

(4) Moreno-Aspitia and Perez, Mayo Clin Proc. 2009; 84(6):533-545

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