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## **Nektar Completes Enrollment in Phase 3 BEACON Study of Etirinotecan Pegol in Women With Metastatic Breast Cancer**

### **-Recruitment Completed Five Months Ahead of Schedule-**

SAN FRANCISCO, July 30, 2013 /PRNewswire/-- Nektar Therapeutics (NASDAQ:NKTR) today announced that enrollment is complete in the pivotal clinical study of etirinotecan pegol (NKTR-102) in patients with metastatic breast cancer. The Phase 3 study, also known as the BEACON trial, is evaluating etirinotecan pegol versus a single-agent treatment of physician's choice for the treatment of locally recurrent or metastatic breast cancer. Etirinotecan pegol is the first long-acting topoisomerase I inhibitor designed to concentrate in tumor tissue to provide sustained tumor suppression throughout the entire chemotherapy cycle.

"Strong interest in etirinotecan pegol and the BEACON study from investigators and patients has allowed us to rapidly complete our recruitment and enrollment," said Robert Medve, MD, Senior Vice President and Chief Medical Officer of Nektar Therapeutics. "We recognize the high unmet need for new treatment options in the metastatic breast cancer setting, particularly among patients with HER2-negative breast cancer whose disease has progressed following anthracycline, taxane and capecitabine therapies. The primary endpoint in the BEACON study is survival and as we have previously announced, we plan to conduct an interim futility analysis for the BEACON study in the first quarter of next year with topline survival data to be available around the end of 2014."

Positive Phase 2 data for etirinotecan pegol was previously announced and presented at the ASCO 2011 Breast Cancer Symposium (*Garcia et. al., ASCO 2011*). Etirinotecan pegol achieved a confirmed objective response rate by RECIST of 29 percent. In addition, 71 percent of patients in the study had no tumor progression, defined as complete response (CR), partial response (PR) and stable disease (SD), as measured by RECIST criteria. Etirinotecan pegol also demonstrated a high clinical benefit rate (CR+PR+SD greater than six months) of 46 percent (30 of 66). Six patients experienced 100 percent resolution of all target lesions, with two complete RECIST responses and four near-complete responses. Patients treated exhibited minimal 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 for both schedules.

### **About the BEACON Study**

BEACON is a Phase 3, open-label, randomized, multicenter study of etirinotecan pegol in approximately 840 women with locally recurrent or metastatic breast cancer, who have previously been treated with anthracycline, taxane or capecitabine (ATC) treatments. The trial is being conducted at approximately 150 sites worldwide including North America, Eastern and Western Europe, and certain countries in Asia/Pacific. Patients were randomized on a 1:1 basis to receive 145 mg/m<sup>2</sup> of single-agent etirinotecan pegol 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, and secondary endpoints include progression-free survival, objective tumor response rates (ORR), clinical benefit rate, duration of response, PK data, safety profiles, 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)**

As a new long-acting topoisomerase I inhibitor, etirinotecan pegol has 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, etirinotecan pegol 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 an anthracycline, a taxane, and capecitabine (ATC).

Etirinotecan pegol 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. In addition to metastatic breast

cancer, etirinotecan pegol is also being evaluated for the treatment of ovarian, colorectal, glioma and non-small cell lung cancers.

## **About Metastatic Breast Cancer**

More than one million women worldwide are diagnosed with breast cancer globally every year(1). 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.(2) 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.(3) 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 completed Phase 3 development 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, is in 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.

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. 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.

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 etirinotecan pegol as a potential new therapy for patients with metastatic breast cancer; the potential for etirinotecan pegol to demonstrate a differentiated tolerability profile from existing breast cancer therapies; the estimated timeline for the availability of top-line data for the BEACON clinical study; 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 March 31, 2013, filed with the SEC on May 9, 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) American Cancer Society, 2007 Global Cancer Facts and Figures Report.*

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

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

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