June 1, 2013

# Nektar Presents Target-Specific Biomarkers Being Assessed in Ongoing Phase 3 BEACON Study of Etirinotecan Pegol for the Treatment of Metastatic Breast Cancer at the 2013 American Society of Clinical Oncology Annual Meeting

CHICAGO and SAN FRANCISCO, June 1, 2013 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) announced today that it presented a series of target-specific biomarkers that are being evaluated in the development of etirinotecan pegol for the treatment of breast cancer. Etirinotecan pegol is a unique, next generation, targeted topoisomerase I inhibitor currently in Phase 3 clinical development as a potential treatment for patients with locally recurrent or metastatic breast cancer. The BEACON (BrEAst Cancer Outcomes with NKTR-102) Phase 3 Study is a randomized, open-label, international study that is evaluating single agent etirinotecan pegol in patients who have previously received an anthracycline, a taxane and capecitabine (ATC) versus a comparator arm consisting of an active single agent treatment of physician's choice (TPC).

"One of our objectives in treating metastatic breast cancer is to prospectively identify patients that will respond to specific treatments so they can achieve the optimal individualized care," said Hope Rugo, M.D., Director of Breast Oncology and Clinical Trials Education at the UCSF Helen Diller Comprehensive Cancer Center and Member of the BEACON Study investigator steering committee. "The goal of evaluating these important biomarkers in patients enrolled into the BEACON study is to help us understand which breast cancer patients might have the best clinical outcomes from treatment with etirinotecan pegol."

A series of assays for target-specific pharmacodynamic biomarkers for etirinotecan pegol, including the molecular target topoisomerase I, have been established and are being measured in the Phase 3 BEACON study. The biomarkers were identified from Circulating Tumor Cell (CTC) samples which were collected prior to patient treatment. Additional CTC patient samples are being collected at regular intervals during treatment and at the end of treatment. Preliminary results from the initial pre-dose samples found CTCs in over 90% of patient samples, with a median of 200 CTCs per 7.5 mL blood draw. Patient participation in the CTC sub-set of the BEACON study is projected to be over 75%. Measurements of each biomarker expression over time will be analyzed in order to identify potential predictive biomarkers for clinical response to etirinotecan pegol.

"We are pleased to have identified several baseline pharmacodynamic biomarkers, which are target-specific such as topoisomerase 1, and which can be reliably measured over the patient's treatment period," said Robert Medve, M.D., Chief Medical Officer of Nektar Therapeutics. "The measurement of these biomarkers in the BEACON study will help us understand and shape the future treatment of patients with etirinotecan pegol. Enrollment in the BEACON study is well ahead of schedule and we expect to complete the target enrollment of 840 patients in the third quarter of 2013."

Circulating Tumor Cells are cancer cells shed from either the primary tumor or its metastases that circulate in the peripheral blood. CTCs are emerging tumor biomarkers, collected through a minimally invasive blood draw, providing a "liquid" biopsy sample and allowing for post-treatment monitoring of the patient. CTCs provide well-defined targets for the understanding of tumor biology and tumor cell dissemination, which offers a unique approach to identify novel therapeutic targets and understand resistance to established therapies.[1]

**2013 ASCO Presentation Details for Etirinotecan Pegol:**
Abstract Title: *"Etirinotecan pegol (EP) target-specific pharmacodynamic (PD) biomarkers measured in circulating tumor cells (CTCs) isolated from patients participating in BEACON, a Phase 3 study in patients with metastatic breast cancer (mBC)",* Hoch et al.

- Abstract Number: 1087
- Session Title/Track: Breast Cancer — Triple-Negative/Cytotoxics/Local Therapy
- Date: June 1, 2013, 1:15 p.m. — 5:00 p.m. Central Time
- Location: S Hall A2

**About the BEACON Study**
The BEACON (BrEAst Cancer Outcomes with NKTR-102) Study is a phase 3 randomized, open-label, international study of etirinotecan pegol in patients with metastatic breast cancer that is evaluating single agent etirinotecan pegol in patients who have previously received an anthracycline, a taxane and capecitabine versus a comparator arm consisting of an active single agent treatment of physician's choice. The physician's choice agents will include: ixabepilone, vinorelbine, gemcitabine, eribulin, or a taxane.

The primary endpoint of the BEACON study is overall survival, and secondary endpoints include progression-free survival and objective tumor response rates (ORR). Secondary endpoints also include clinical benefit rate, duration of response, PK data, safety profiles, quality-of-life measurements, and pharmacoeconomic implications. Exploratory objectives of the study also include collecting specific biomarker data to correlate with objective tumor response rates, progression-free survival, overall survival and selected toxicities.

**About Etirinotecan Pegol (NKTR-102)**
Etirinotecan pegol is a unique, targeted topoisomerase I inhibitor designed for prolonged tumor cell exposure. 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. The BEACON study is a Phase 3 clinical study currently evaluating etirinotecan pegol for the treatment of locally recurrent or metastatic breast cancer. 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 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 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 and colorectal 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.

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," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of etirinotecan pegol for women with locally recurring or metastatic breast cancer, the predictive potential of prospectively measured biomarkers in the BEACON study to potentially identify patients more likely to benefit from etirinotecan pegol, the projected percentage of patients participating in the CTC sub-set of the BEACON clinical study, the projected timeframe in which we expect the BEACON clinical study to be fully enrolled, and the value and 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) the prospectively measured biomarkers have not previously been linked to more positive clinical outcomes for metastatic breast cancer patients receiving etirinotecan pegol therapy; (ii) etirinotecan pegol is 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 in the BEACON study; (iii) the statements regarding the therapeutic potential of etirinotecan pegol are based on preclinical data and data from the completed Phase 2 clinical study and the future results from the BEACON clinical study may not confirm these earlier findings; (iv) our drug candidates and those of our collaboration partners are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval for numerous reasons including safety and efficacy findings even after positive findings in previous preclinical and clinical studies; (v) the timing of the commencement or end of clinical trials and the commercial launch of our drug candidates 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; and (vi) 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 9, 2013. 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. Lianidou ES, et al., What's new on circulating tumor cells? A meeting report*. Breast Cancer Res* 2010;**12**:307.


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