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Nektar Presents Data on Target-Specific Biomarkers from Circulating Tumor Cell Sub-Study of Phase 3 BEACON Study of Etirinotecan Pegol (NKTR-102) in Patients with Advanced Breast Cancer

-- Findings Presented at 2014 San Antonio Breast Cancer Symposium (SABCS) --

SAN ANTONIO and SAN FRANCISCO, Dec. 11, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today presented biomarker data from a sub-study of the Phase 3 BEACON study of etirinotecan pegol (NKTR-102) which collected and analyzed circulating tumor cell (CTC) samples from patients in the study. A total of 80% of the 852 patients enrolled in the BEACON trial participated in the CTC sub-study. Among the 627 patients who participated and had evaluable baseline samples, CTCs were detected in 97% of these samples.

For the 611 evaluable baseline patient samples which yielded CTCs, potential NKTR-102 target-specific pharmacodynamic biomarkers (Top1, Top2, and Ki67) were detected in the majority of samples. The pharmacodynamic biomarkers assessed in the CTC sub-study were chosen because of their potential ability to predict response to topoisomerase 1 inhibition as well as to measure chemo-sensitivity in metastatic cancer patients.^{1,2,3,4}

"We were encouraged to find that the CTC sub-study confirmed the presence of several potential target-specific pharmacodynamic biomarkers, such as topoisomerase 1, in the patients enrolled in our study," said Ivan Gergel, MD, senior vice president drug development and chief medical officer of Nektar Therapeutics. "The analysis from the BEACON CTC sub-study could help us better understand which additional patient populations would benefit from NKTR-102. We expect topline results from the BEACON study to be available in the first quarter of 2015."

The data were presented during the 2014 San Antonio Breast Cancer Symposium (SABCS) in San Antonio.

NKTR-102 is the first long-acting topoisomerase 1 inhibitor with an extended half-life and a unique molecular structure that is designed to concentrate the drug in tumors. It is currently being evaluated in the Phase 3 BEACON (BrEAst Cancer Outcomes with NKTR-102) study in patients with locally recurrent or metastatic breast cancer who previously have been treated with anthracycline, taxane or capecitabine (ATC). CTCs 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 patients.

Study Design and Results

In this CTC sub-study of the BEACON study, 7.5 mL whole blood samples from patients were drawn and analyzed for the number of CTCs, the percent of cells staining positive for a given biomarker, and the mean fluorescence intensity, reflecting the normalized intensity of the specific biomarker in the biomarker positive CTCs. Results showed that CTCs were detected in 97 percent of 627 evaluable baseline samples. The median number of CTCs per 7.5 mL blood draw was 472, which permitted evaluation of biomarkers at baseline and over the course of treatment.

Poster Presentation Details

Details of the NKTR-102 poster presentation follow.

- **Poster Title:** Etirinotecan Pegol (NKTR-102) Target-specific Pharmacodynamic Biomarkers in Circulating Tumor Cells from Patients with Metastatic Breast Cancer, Dr. Edith Perez, et al.
- **Poster Number:** P3-10-03
- **Session Title/Track:** Treatment: Advanced Chemotherapy
- **Date and Time:** Thursday, December 11, 2014, 5:00-7:00 p.m. Central Time,
- **Location:** Henry B. Gonzalez Convention Center, Exhibit Halls A-B

About Etirinotecan Pegol (NKTR-102)

Etirinotecan pegol (NKTR-102) is the first long-acting topoisomerase 1 inhibitor with an extended half-life and a unique structure that is designed to concentrate the drug in tumors. In patients, NKTR-102 leads to greatly prolonged plasma SN38 exposure compared with irinotecan (elimination half-life of 50 days compared with 2 days) yet peak SN38 concentrations are at

least 5- to 10-times less, which may also result in a favorable tolerability profile.

About the BEACON Study

NKTR-102 is currently being evaluated in the Phase 3, open-label, randomized, multicenter BEACON study. BEACON enrolled 852 women with locally recurrent or metastatic breast cancer who previously have been treated with anthracycline, taxane and capecitabine (ATC). The study is being conducted at approximately 150 sites worldwide including in North America, Western Europe, and the Republic of Korea. Nearly half of the patients enrolled in BEACON are 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 the physician's choice, including 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, 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 Nektar

Nektar Therapeutics has a robust R&D pipeline in pain, oncology, hemophilia and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for MOVANTIK™ (naloxegol), the first FDA-approved once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC), in adult patients with chronic, non-cancer pain. The product is also approved in the European Union as MOVENTIG® and is indicated for adult patients with OIC who have had an inadequate response to laxatives. The AstraZeneca agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of MOVANTIK™ and an opioid. NKTR-181, a wholly-owned mu-opioid analgesic molecule for chronic pain conditions, has completed Phase 2 development. NKTR-171, a wholly-owned 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, NKTR-102 is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer. In hemophilia, BAX 855, a longer-acting PEGylated Factor VIII therapeutic is in Phase 3 development conducted by partner Baxter. 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 nine approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including AstraZeneca's MOVANTIK™, 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>.

MOVANTIK™ is a trademark of the AstraZeneca group of companies.

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 (NKTR-102), the potential of specified biomarkers to predict a patient's response to topoisomerase I inhibition, and the value and potential of our technology and 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 BEACON study is currently ongoing and the outcome of this study will not be known until topline data is available, which we do not currently expect to occur until sometime the first quarter of 2015; (ii) 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; (iii) the timing of the commencement or end of clinical trials and the commercial launch of 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; (iv) acceptance, review and approval decisions for new drug applications by health authorities is an uncertain and evolving process and health authorities retain significant discretion at all stages of the regulatory review and approval decision process; (v)

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 is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (vi) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (viii) the outcome of any existing or future intellectual property or other litigation related to our drug candidates and those of our collaboration partners. Other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2014. 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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