Nektar Therapeutics Announces Positive Initial Results from Phase 2 Study of NKTR-102 in Metastatic Breast Cancer

SAN CARLOS, Calif., June 9, 2010 /PRNewswire via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced positive preliminary initial results from a two-stage Phase 2 clinical study evaluating single-agent NKTR-102 in women with advanced/metastatic breast cancer patients who have received a prior taxane. The increased use of taxanes in breast cancer often renders tumors resistant to these drugs by the time the disease recurs, thereby underscoring the urgent need for new treatment options with novel mechanisms of action for metastatic disease.

The single-agent NKTR-102 study recently completed enrollment with a total of 70 patients with metastatic breast cancer. A significant majority of the women had been treated with prior anthracycline/taxane with or without capecitabine. Of the 70 patients, 66 patients are currently evaluable per RECIST for the imaging-based primary endpoint of objective response rate. Confirmed and unconfirmed RECIST responses were 21% (14/66) overall for single-agent NKTR-102, with 18% (6/33) for the q14d dose regimen and 24% (8/33) for the q21d dose regimen. There are a significant number of patients in the study still on therapy with NKTR-102.

"This is a very promising result in patients with metastatic breast cancer who have failed prior taxanes and in most cases, prior anthracyclines," said Prof. Ahmad Awada, Head of the Gynecologic Oncology Clinic at the Institut Jules Bordet in Brussels, Belgium. "I have patients who have not responded to any prior therapy but who have experienced a good response to NKTR-102. These data are quite encouraging, and NKTR-102 should be taken forward as a single agent and in combination therapy in patients with difficult-to-treat disease such as triple-negative breast cancer and anthracycline/taxane failures."

Of the 70 patients enrolled in the study, approximately 85% had received prior anthracycline/ taxane, either with or without capecitabine therapy. The drug has been well-tolerated to-date. The most commonly observed grade 3 or grade 4 side effects in the study to date (every 14 day/every 21 day dose schedule) were diarrhea (14%/6%) and neutropenia (9%/6%). There were low rates of alopecia observed with single-agent NKTR-102, with only a small number of women experiencing Grade 2 alopecia.

"We are highly encouraged by the compelling preliminary activity observed to-date in the patients from our study," said Lorianne Masuoka, M.D., Senior Vice President and Chief Medical Officer. "This, combined with our recent results presented at the 2010 ASCO meeting for single-agent NKTR-102 in women with platinum-resistant and refractory ovarian cancer, make us very excited about the future of NKTR-102 as a novel anti-cancer agent."

About the Study

The Phase 2 study is evaluating two dose regimens (q14 day and q21 day) of single-agent NKTR-102 in women with metastatic breast cancer. The study employs a two-stage design, with 40 patients in the first stage and 30 patients in the second stage. Secondary endpoints of the Phase 2 study include progression-free survival and safety.

About Metastatic Breast Cancer

Breast cancer is one of the most common cancers among every major ethnic group of women in the United States. The chance of developing invasive breast cancer at some time in a woman's life is a little less than 1 in 8 (12%). According to the American Cancer Society, nearly 200,000 new cases of invasive breast cancer were diagnosed in women in 2009. Anthracyclines and taxanes 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 be 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.(1) There are currently no FDA-approved topoisomerase-I inhibitors to treat breast cancer.

About NKTR-102

Nektar is developing NKTR-102, a topoisomerase I inhibitor-polymer conjugate with reduced peak concentrations and a continuous concentration profile. NKTR-102 was invented by Nektar using its advanced polymer conjugate technology platform,

and is the first oncology product candidate to leverage Nektar's releasable polymer technology platform.

In addition to the fully-enrolled Phase 2 studies in platinum-resistant ovarian cancer and metastatic breast cancer, NKTR-102 is also being tested in a separate Phase 2 clinical trial in patients with second-line colorectal cancer and a Phase 1 clinical trial of NKTR-102 evaluating it in combination with 5-FU therapy.

About Nektar

Nektar Therapeutics is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar's technology and drug development expertise have enabled nine approved products in the U.S. or Europe for leading biopharmaceutical company partners, including UCB's Cimzia(R) for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS(R) for hepatitis C and Amgen's Neulasta(R) for neutropenia.

Nektar has created a robust pipeline of potentially high-value therapeutics to address unmet medical needs by leveraging and expanding its technology platforms to improve and enable molecules. In addition to the releasable polymer technology, Nektar is the first company to create a permanent small molecule-polymer conjugate with enhanced oral bioavailability and restricted entry into the CNS. Nektar is currently conducting clinical and preclinical programs in oncology, pain and other therapeutic areas. Nektar recently entered into an exclusive worldwide license agreement with AstraZeneca for its oral NKTR-118 program to treat opioid-induced constipation and its NKTR-119 program for the treatment of pain without constipation side effects. NKTR-102 is being evaluated in Phase 2 clinical studies for the treatment of ovarian, breast and colorectal cancers. NKTR-105 is in a Phase 1 clinical study in cancer patients with refractory solid tumors.

Nektar is headquartered in San Carlos, California, with additional R&D 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.

This press release contains forward-looking statements that reflect Nektar's current views regarding the potential of Nektar's technology platform, the potential of NKTR-102 for breast cancer patients, and preliminary initial results from the Phase 2 clinical trial of NKTR-102 in metastatic breast cancer. These forward-looking statements involve substantial risks and uncertainties, including but not limited to one or more of the following: (i) NKTR-102 is in early stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage for one or more of the cancer indications being studied (i.e. ovarian cancer, breast cancer, and colorectal cancer) due to efficacy, safety or other unpredictable factors; (ii) the initial preliminary RECIST response data for the NKTR-102 clinical trial in breast cancer reported in this press release is subject to substantial change and such substantial change could be material and adverse--in particular, there is no way to predict whether unconfirmed responses will become confirmed responses as the clinical trial progresses; (iii) the Phase 2 results for NKTR-102 in breast cancer described in this press release remain subject to data audit confirmation procedures, and the reported results may change materially and adversely after such review is completed; (iv) additional important data will be reported by Nektar in the future regarding the NKTR-102 clinical study in breast cancer including but not limited to confirmed/unconfirmed RECIST response rates, progression-free survival, overall survival and further safety information regarding the frequency and severity of adverse events observed in the study, and therefore the complete and final results for the Phase 2 breast cancer trial may differ materially and adversely from these preliminary initial results; (v) the timing or success of the commencement or end of clinical trials and commercial launch of new drugs may be delayed or unsuccessful due to regulatory delays, clinical trial design, slower than anticipated patient enrollment, drug manufacturing challenges, changing standards of care, clinical outcomes, or delay or failure in obtaining regulatory approval in one or more important markets; (vi) this early preliminary data from the NKTR-102 clinical study for breast cancer is not necessarily predictive of the outcomes for other cancer indications for which NKTR-102 is being studied (i.e. ovarian and colorectal cancers); (vii) the data package required and the timing for regulatory approval of a new drug application is very uncertain and difficult to predict due to broad regulatory discretion, changing standards of care, available approved therapies, the size of the completed clinical trials and the statistical significance of the results, the potential need for comparative clinical studies against approved therapies, and other important variables that are not within the control of Nektar; (viii) Nektar's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required in the future; (ix) the uncertain outcome of any future intellectual property, commercial or other litigation related to Nektar's proprietary product candidates, including without limitation NKTR-102; (x) if Nektar is unable to establish and maintain collaboration partnerships on attractive commercial terms, our business, results of operations and financial condition could suffer; and (xi) certain other important risks and uncertainties set forth in Nektar's Current Report on Form 8-K filed today, the Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed on May 6, 2010, and the most recent Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 3, 2010. Actual results could differ materially from the forward-looking statements contained in this press release. Nektar undertakes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise including without limitation future clinical and regulatory developments.

Nektar Investor Inquiries:

Jennifer Ruddock (650) 283-6253
Susan Noonan/SAN Group (212) 966-3650
Nektar Media Inquiries:
Karen Bergman/BCC Partners (650) 575-1509
Michelle Corral/BCC Partners (415) 794-8662

(1) Alvaro and Perez, Mayo Clin Proc. 2009; 84(6):533-545

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