



Positive Results from Phase 2 Clinical Study of NKTR-102 in Metastatic Breast Cancer Presented in Oral Session at the ASCO 2011 Breast Cancer Symposium

NKTR-102 Phase 3 BEACON Clinical Trial Design Highlighted in Presentation

SAN FRANCISCO, Sept. 9, 2011 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today that positive results from the company's Phase 2 clinical study of NKTR-102 in patients with metastatic breast cancer were presented at the ASCO 2011 Breast Cancer Symposium in San Francisco, California. NKTR-102 is a novel topoisomerase I inhibitor designed using Nektar's proprietary polymer conjugate technology, and is being developed in multiple tumor settings.

"NKTR-102 exhibits a very high response rate and excellent clinical benefit rate in patients with metastatic breast cancer, and importantly, this anti-tumor activity is maintained in each of the poor prognosis subsets within the study," said presenter and NKTR-102 study investigator, Dr. Agustin Garcia, Associate Professor of Clinical Medicine at USC Norris Comprehensive Center. "The data from the Phase 2 study also shows highly promising PFS of 5.3 months and OS of 13.1 months in the every three week dose schedule, which was also very well-tolerated. As a novel topoisomerase I inhibitor in breast cancer, NKTR-102 holds great therapeutic potential and allows us to address the challenge of resistance in this setting. The investigators look forward to the initiation of the Phase 3 BEACON study of NKTR-102 in patients with metastatic breast cancer."

More than one million women worldwide are diagnosed with breast cancer every year and the disease is the leading cause of cancer-related death among women.(1)

Highlights from the Phase 2 Clinical Data Presentation

The randomized Simon two-stage study of single-agent NKTR-102 evaluated two 145 mg/m² dose schedules of NKTR-102, every two weeks (q14d) and every three weeks (q21d), in 70 metastatic breast cancer patients. NKTR-102 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. NKTR-102 also demonstrated a high clinical benefit (CR+PR+SD greater than six months) rate 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. Objective tumor responses were maintained in heavily pretreated and poor prognosis subsets, including patients previously treated with anthracycline/taxane/capecitabine, patients with metastatic triple-negative breast cancer and patients with visceral disease.

NKTR-102 exhibited minimal alopecia, neuropathy and neutropenia, which are significant adverse events associated with existing and recently-approved breast cancer therapies. Side effects were generally manageable; most common Grade 3 toxicity was diarrhea (17-23%) typically occurring after three months of therapy for both schedules.

Eighty-nine percent (62/70) of patients in the study received a prior anthracycline/taxane with or without capecitabine. A total of 66 of the 70 patients treated with single-agent NKTR-102 in the Phase 2 clinical study were assessable for the primary endpoint of objective tumor response rate (ORR).

The slide presentation from today's oral session at the ASCO 2011 Breast Cancer Symposium is available on Nektar's website at http://www.nektar.com/product_pipeline/oncology_nktr-102.html.

BEACON Study Design

The company also announced today the design of the planned Phase 3 clinical trial of NKTR-102 in metastatic breast cancer patients. The BEACON study (BrEast Cancer Outcomes with NKTR-102) plans to enroll approximately 840 metastatic breast cancer patients who have had prior treatment with anthracycline, taxane and capecitabine in either the adjuvant or metastatic setting. Patients will be randomized on a 1:1 basis to receive single-agent NKTR-102 once every three weeks or a single agent of physician's choice. The primary endpoint of the study will be overall survival, and secondary endpoints will include progression-free survival and objective tumor response rates. The global BEACON study, which will include over 130 investigator sites, is expected to begin in December 2011.

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 NKTR-102

NKTR-102 is a next generation topoisomerase I inhibitor with a unique pharmacokinetic profile that provides a continuous exposure to active drug with reduced peak concentrations. NKTR-102 is a new chemical entity designed by Nektar using its polymer conjugate technology platform. NKTR-102 has been evaluated in two separate Phase 2 studies for the treatment of platinum-refractory/resistant ovarian cancer and metastatic breast cancer patients. In addition, NKTR-102 is also being tested as a single agent in a Phase 2 clinical trial in patients with second-line colorectal cancer and a Phase 1 clinical trial evaluating NKTR-102 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 has a robust R&D pipeline of potentially high-value therapeutics in oncology, pain and other areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for NKTR-118, an investigational drug candidate, being evaluated in Phase 3 clinical studies as a once-daily, oral tablet for the treatment of opioid-induced constipation. The agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of NKTR-118 and an opioid. NKTR-181, a novel mu-opioid analgesic molecule, is being evaluated in Phase 1 clinical studies. In oncology, NKTR-102, a novel topoisomerase I-inhibitor, is being evaluated in Phase 2 clinical studies for the treatment of breast, ovarian and colorectal cancers.

Nektar's technology has enabled seven 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 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>.

Forward-Looking Statements

This press release contains forward-looking statements that reflect management's current views regarding NKTR-102 and certain other drug candidates in Nektar's pipeline. These forward-looking statements involve numerous risks and uncertainties, including but not limited to: (i) Nektar's product candidates and those of its 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 preclinical and clinical studies; (ii) the timing of the commencement or end of clinical trials and the successful commercial launch of our drug candidates may be delayed or unsuccessful due to slower than anticipated patient enrollment, 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; (iii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of Nektar's technology platform to potential new drug candidates is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (iv) 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; (v) the outcome of any future intellectual property or other litigation related to Nektar's proprietary product candidates or complex commercial agreements; and (vi) certain other important risks and uncertainties set forth in Nektar's reports and other filings with the Securities and Exchange Commission, including without limitation, those risks and uncertainties set forth in Nektar's Form 10-Q for the quarter ended June 30, 2011, filed on August 5, 2011. 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.

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

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