Nektar Therapeutics Initiates Phase 3 BEACON Trial of NKTR-102 in Women with Metastatic Breast Cancer

Study Design Highlighted at 2011 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) in Trials in Progress Session

SAN FRANCISCO, Dec. 12, 2011 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today that the company has initiated its pivotal Phase 3 global clinical trial evaluating NKTR-102 as a single agent in women with metastatic breast cancer. NKTR-102 is a next-generation topoisomerase I inhibitor designed using Nektar's proprietary polymer conjugate technology, and is being developed in multiple tumor settings. The BEACON Study (**B**r**EA**st **C**ancer **O**utcomes with **N**KTR-102) is designed to include approximately 840 metastatic breast cancer patients who have had prior treatment with anthracycline, taxane and capecitabine in either the adjuvant or metastatic setting.

"We are pleased to begin the enrollment in this important pivotal study of NKTR-102 for women with metastatic breast cancer," said Dr. Javier Cortes, Director of the Breast Cancer Program at Vall d'Hebron University Hospital in Spain and lead investigator in the European Union for the BEACON Study. "The study design builds on the highly positive data from the Phase 2 study of NKTR-102 presented at the 2011 ASCO Meeting. BEACON will investigate the inhibition of topoisomerase I as a new mechanism of action to treat breast cancer, which could address the challenge of resistance from treatment with anthracyclines and taxanes for women with this devastating disease."

Dr. Edith Perez, Deputy Director of the Mayo Clinic Cancer Center, will serve as the lead investigator in the United States for the BEACON study. Dr. Perez is also Director of the Breast Program at Mayo Clinic, and a Serene M. and Frances C. Durling Professor of Medicine with College of Medicine, Mayo Clinic.

BEACON is a Phase 3, open-label, randomized, multicenter study of NKTR-102 and will be conducted in approximately 160 sites worldwide including North America, Eastern and Western Europe, and certain countries in Asia/Pacific. Patients will be 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 physician's choice. The physician's choice agents will include: ixabepilone, vinorelbine, gemcitabine, eribulin, or a taxane. Randomization will be stratified by geographic region, prior use of eribulin and receptor status.

The primary endpoint of the BEACON study will be overall survival, and secondary endpoints will 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 will include collecting specific biomarker data to correlate with objective tumor response rates, progression-free survival, overall survival and selected toxicities.

"In our Phase 2 study, NKTR-102 resulted in a 30% RECIST response rate and excellent clinical benefit for patients with very aggressive disease," said Robert Medve, MD, Chief Medical Officer of Nektar Therapeutics. "Women with metastatic breast cancer who have progressed after treatment with anthracycline, taxane and capecitabine, have limited treatment options to help them manage their disease. Recognizing this high unmet need, we are excited about the opening of enrollment for our pivotal study of single-agent NKTR-102 in this setting."

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)

The design of the BEACON study was presented during the *Trials in Progress Session* at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium, which was held from December 6 through December 10, 2011 in San Antonio, Texas. The presentation is available on Nektar's website at http://www.nektar.com/pdf/pipeline/NKTR-102/SABCS_2011_NKTR-102_BEACON_poster.pdf

The phase 3 trial has been designed by Nektar in collaboration with internationally renowned experts in the field of metastatic breast cancer, including Drs. Perez and Cortes, Dr. Ahmad Awada, Head of the Medical Oncology Clinic at Institut Jules Bordet in Brussels, Belgium, Dr. Hope Rugo, Director of Breast Oncology and Clinical Trials Education and Professor of Medicine at the UCSF Helen Diller Comprehensive Cancer Center in San Francisco, California, and Dr. Joyce O'Shaughnessy, Co-Director of Breast Cancer Research for US Oncology's Research and the Celebrated Women Chair in Breast Cancer Research at the

Baylor-Sammons Cancer Center.

Information about enrolling in the BEACON study will be made available on www.clinicaltrials.gov.

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. In addition, NKTR-102 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. 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 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 that have the potential to overcome the problem of drug resistance to prior therapies.(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 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, has completed Phase 1 single and multiple dose clinical studies, and is being prepared to start Phase 2. In oncology, NKTR-102, a novel topoisomerase I inhibitor, is also being evaluated in Phase 2 clinical studies for the treatment of 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 4, 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.

Nektar Investor Inquiries:	
Jennifer Ruddock/Nektar Therapeutics	(650) 283-6253
Susan Noonan/SA Noonan Communications, LLC	(212) 966-3650
Nektar Media Inquiries:	
Karen Bergman/BCC Partners	(650) 575-1509
Michelle Corral/BCC Partners	(415) 794-8662

(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

SOURCE Nektar Therapeutics