November 7, 2012

Nektar Announces that FDA Grants Fast Track Designation to Etirinotecan Pegol (NKTR-102) for the Treatment of Metastatic Breast Cancer

SAN FRANCISCO, Nov. 7, 2012 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) announced today that the U.S. Food and Drug Administration (FDA) has designated etirinotecan pegol (NKTR-102) as a Fast Track development program for the treatment of patients with locally recurrent or metastatic breast cancer progressing after treatment with an anthracycline, a taxane, and capecitabine (ATC). Etirinotecan pegol is a unique, targeted topoisomerase I inhibitor designed using Nektar's proprietary polymer conjugate technology. The drug candidate is currently being evaluated in a Phase 3 study in women with metastatic breast cancer.

"We are very pleased that the etirinotecan pegol development program in breast cancer has been granted Fast Track designation and we look forward to continuing to work closely with the FDA on this program," said Robert Medve, MD, Chief Medical Officer of Nektar Therapeutics. "Patients with advanced breast cancer who have progressed following ATC therapies have limited treatment options to manage their disease. As a novel targeted topoisomerase I inhibitor, etirinotecan pegol is a different mechanism of action than currently approved therapies and has the potential to deliver improved efficacy while offering a more tolerable therapy for women with this aggressive disease."

Nektar requested Fast Track designation from the FDA for etirinotecan pegol based upon what is known about its safety and efficacy profile to-date from the nonclinical, Phase 1 and Phase 2 clinical studies, as well as etirinotecan pegol's potential to deliver better efficacy and a more tolerable therapy for patients with locally recurrent or metastatic breast cancer progressing after treatment with ATC. Etirinotecan pegol, a new topoisomerase I inhibitor, was designed to improve the efficacy of irinotecan by modifying the distribution of the drug candidate within the body. As a new topoisomerase I inhibitor, etirinotecan pegol has a non-overlapping mechanism of action with other agents used to treat breast cancer which may mitigate potential cancer cross-resistance and reduce overlapping toxicities.

Under the FDA Modernization Act of 1997, the Fast Track program facilitates interactions with the FDA before and during the submission of a New Drug Application (NDA) for therapeutics being investigated as a treatment for serious or life-threatening conditions, which demonstrate the potential to address an unmet medical need for such conditions. The Fast Track program enables a company to file sections of an NDA on a rolling basis as data becomes available. This permits the FDA to review portions of the NDA as they are received, rather than waiting for the entire NDA filing prior to commencing the review process. With a Fast Track designation, there is the possibility of a priority review and a more opportunity for more frequent interactions with the FDA, which could decrease the typical development time and review period.

About the Phase 3 BEACON Study of Etirinotecan Pegol

The BEACON Study (**B**r**EA**st **C**ancer **O**utcomes with **N**KTR-102) will enroll approximately 840 metastatic breast cancer patients who have had prior treatment with ATC in either the adjuvant or metastatic setting. The primary endpoint of the BEACON study is overall survival (OS). Secondary endpoints include progression-free survival (PFS), objective tumor response rates (ORR), clinical benefit rate, duration of response, pharmacokinetic (PK) data, safety, quality-of-life measurements, and measurement of healthcare resource utilization for the two study arms. Exploratory objectives of the study include collecting specific biomarker data which will be correlated with efficacy outcome measures. Enrollment in the BEACON study began in December 2011 and is expected to be completed by the end of 2013.

About Metastatic Breast Cancer

More than one million people 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 of 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 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 is being evaluated in Phase 3 clinical studies 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.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including Affymax's OMONTYS® for anemia, 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 has completed Phase 1/2 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.

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," "could," "potential," "may" and similar references to future periods. Examples of forward-looking statements include our current views as to the potential of etirinotecan pegol as a potential new therapy for patients with metastatic breast cancer; the expected enrollment completion date for the BEACON trial; the value of our polymer conjugate technology platform; and the potential of certain of our other drug candidates and those of our collaboration partners. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, observations and assumptions regarding the potential of our drug candidates and our technology. 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) 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; (ii) 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; (iii) 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; (iv) 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 such as etirinotecan pegol is therefore very uncertain and unpredictable and could unexpectedly fail at any time; (v) patents may not issue from our patent applications for etirinotecan pegol, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vi) the outcome of any existing or future intellectual property or other litigation related to our proprietary drug candidates. Other important risks and uncertainties are detailed in our reports and other filings with the Securities and Exchange Commission ("SEC"), including without limitation, those risks and uncertainties set forth in our quarterly report on Form 10-Q for the quarter ended June 30, 2012, filed with the SEC on August 9, 2012. 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) 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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