NKTR-102 Demonstrates Superior Activity to Irinotecan in Nonclinical Studies Presented at ESMO 12th World Congress on Gastrointestinal Cancer

BARCELONA, Spain and SAN CARLOS, Calif., July 6, 2010 /PRNewswire via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today that data presented at the European Society for Medical Oncology (ESMO) 12th World Congress on Gastrointestinal Cancer demonstrates that NKTR-102, the company's lead oncology compound, exhibits superior activity compared to irinotecan as part of either a monotherapy or combination regimen in tumor models of gastrointestinal cancers.

NKTR-102 is a novel topoisomerase I inhibitor-polymer conjugate with a sustained exposure profile and a unique macromolecular structure that targets tumor tissue through the enhanced permeation and retention (EPR) effect.

"Data presented today show that NKTR-102 achieves greater and more sustained concentration of active drug in the tumor, leading to superior activity of NKTR-102 in models of gastrointestinal cancers," said Lorianne Masuoka, MD, SVP and Chief Medical Officer of Nektar. "These preclinical results demonstrate the potential for NKTR-102 to be developed as both a single agent and in combination with 5-FU to treat patients with metastatic colorectal cancer, and also support our comprehensive development program for NKTR-102 that includes colorectal, breast and ovarian cancers."

In the studies presented, researchers evaluated the activity of NKTR-102 versus irinotecan alone or administered in combination with 5-FU in nonclinical models of gastrointestinal cancers. Anti-tumor activity was evaluated based on tumor growth delay (TGD) and regression responses. In the first study, NKTR-102 was administered as a single-agent at doses of 60, 100, and 150 mg/kg resulted in maximum TGDs of 362 percent. Regression response rates were dose-related and increased from 30-100 percent, with several animals remaining tumor free at the end-of-study at the 150 mg/kg dose level. In contrast, the irinotecan monotherapy arm of this study was minimally active, yielding slight TGDs of 64 percent, with no regressions and no end-of-study survivors at a maximum-tolerated dose of 60 mg/kg. In the second study, the combination of 100 mg/kg NKTR-102 with 50 mg/kg 5-FU was the most active regimen, yielding the maximum TGD of 232 percent, a 100-percent regression response rate and demonstrating superiority when compared to standard irinotecan in combination with 5-FU. NKTR-102 was well tolerated as a monotherapy and when administered in combination with 5-FU in all of the studies.

These data were presented in a poster titled "*Activity of NKTR-102 in nonclinical models of gastrointestinal cancers*" (Abstract P-0025) at the ESMO Conference: 12th World Congress on Gastrointestinal Cancer in Barcelona, Spain on July 3-5, 2010. The poster can be found on Nektar's website at http://www.nektar.com/product_pipeline/oncology_nktr-102.html.

About NKTR-102

NKTR-102, a novel topoisomerase I inhibitor-polymer conjugate compound, was invented by Nektar using its advanced polymer conjugate technology platform. NKTR-102 is designed to optimize the pharmacokinetic and pharmacodynamic profile of irinotecan by reducing peak concentrations of the active metabolite and extending drug half-life. In addition, the unique macromolecular structure of NKTR-102 takes advantage of the enhanced permeation and retention (EPR) effect in tumor tissue to achieve enhanced drug concentrations in tumors compared to normal tissues. Tumor exposure was increased four-fold with NKTR-102 in nonclinical tumor models as compared to irinotecan and was also associated with increased anti-tumor activity. (1)

NKTR-102 is currently being tested in three separate tumor settings in clinical development. In colorectal cancer, a 174-patient randomized Phase 2/3 study is currently enrolling to evaluate single-agent NKTR-102 compared to single-agent irinotecan in patients with second-line colorectal cancer with the KRAS gene mutation. A Phase 1 study of NKTR-102 is ongoing to assess the safety, pharmacokinetics and anti-tumor activity of this anti-cancer agent when given in a combination with standard doses of 5-FU/leucovorin. In breast cancer, a 70-patient Phase 2 study of single-agent NKTR-102 in women with metastatic breast cancer has completed enrollment and is ongoing with a significant number of women still on treatment. In ovarian cancer, the company has expanded its existing 71-patient study to evaluate single-agent NKTR-102 in an additional 50 women with platinum-resistant/refractory ovarian cancer. Phase 3 development planning for NKTR-102 is also underway in ovarian cancer.

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 and only company to create permanent small molecule-polymer conjugates with enhanced oral bioavailability and restricted entry into the central nervous system.

Nektar is currently conducting clinical and preclinical programs in oncology, pain and other therapeutic areas. In September 2009, Nektar 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. In addition to the ongoing clinical trials for NKTR-102, the company's second oncology compound, NKTR-105, is being tested in a Phase 1 clinical study in cancer patients with refractory solid tumors.

Nektar is headquartered in San Carlos, California, with additional R&D and manufacturing 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 the company's current views as to the potential superiority of NKTR-102 as compared to irinotecan, the potential of NKTR-102 in the various cancer indications in which it is being studied, the potential of the company's polymer conjugate technology platform, and the potential for certain of the company's other drug candidates. These forward-looking statements involve substantial risks and uncertainties including but not limited to one or more of the following: (i) the superiority of NKTR-102 as compared to irinotecan in preclinical tumor models of gastrointestinal cancer is not necessarily predictive of future success in clinical trials; (ii) 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) prior to receiving regulatory approval due to efficacy, safety or other factors; (iii) 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; (iv) the clinical study data previously announced by the company from clinical studies of NKTR-102 in any particular cancer indication are not necessarily predictive of the outcomes for other cancer indications for which NKTR-102 is being studied; (v) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of the company's technology platform to potential new drug candidates is therefore very uncertain and unpredictable and one or more research and development programs could fail; (vi) the company's patent applications for its proprietary or partner drug candidates may not issue, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; (vii) the outcome of any existing or future intellectual property or other litigation related to the company's proprietary drug candidates including without limitation NKTR-102; and (viii) if the company is unable to establish and maintain collaboration partnerships or appropriate transaction structures relating to its drug candidates (e.g. NKTR-102) on attractive commercial terms, the company's business, results of operations and financial condition could suffer. Other important risks and uncertainties are detailed in the company's reports and other filings with the Securities and Exchange Commission, including without limitation, those risks and uncertainties set forth in the company's Form 10-Q for the quarter ended March 31, 2010 filed on May 6, 2010. The company undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.


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(1) Eldon et. al. "*NKTR-102, a novel PEGylated irinotecan conjugate, results in sustained tumor growth inhibition in mouse models of human colorectal and lung tumors that is associated with increased and sustained SN38 exposure*." AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, October 2007.

SOURCE Nektar Therapeutics