Nektar Announces Dosing of First Patients in Phase 1 Clinical Study of NKTR-102 in Combination With 5-Fluorouracil/Leucovorin

SAN CARLOS, Calif., June 24, 2010 /PRNewswire via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) announced today that the first patients have been dosed in a new Phase 1 dose-escalation clinical study to evaluate NKTR-102, the company's lead oncology compound, in combination with 5-fluorouracil (5-FU)/leucovorin in refractory solid tumor cancers. The study is being conducted at University Hospitals Case Medical Center of the Case Comprehensive Cancer Center in Cleveland, Ohio.

"The dosing of the first patients in this combination study marks another important milestone in the strategic development of NKTR-102," said Lorianne Masuoka, M.D., Senior Vice President and Chief Medical Officer of Nektar. "The new Phase 1 study complements our continuing Phase 2 study in second-line colorectal cancer which is evaluating NKTR-102 as a single-agent as compared to irinotecan in patients possessing the KRAS gene mutation. Based upon the markedly enhanced activity of NKTR-102 over irinotecan in preclinical models of gastrointestinal cancer and its notable activity in Phase 2 clinical testing in breast and ovarian cancers, we believe NKTR-102 is a promising new anti-cancer agent that has the potential to provide an important treatment option for patients with the deadliest forms of colon and rectal 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. The Phase 1 study of NKTR-102 will assess the safety, pharmacokinetics and anti-tumor activity of this anti-cancer agent when given in combination with standard doses of 5-FU/leucovorin.

"The team at the Case Comprehensive Cancer Center is extremely excited to work with Nektar on the first clinical trial evaluating NKTR-102 in combination with 5-FU/leucovorin in cancer patients," said Neal Meropol, M.D., Chief, Division of Hematology and Oncology, University Hospitals Case Medical Center & Case Western Reserve University, and Associate Director for Clinical Research at the Case Comprehensive Cancer Center.

The chemotherapy agent 5-FU is currently used as a part of a combination treatment regimen for colorectal cancer in combination with irinotecan, which is also known as the FOLFIRI regimen. In preclinical models of colorectal tumors, NKTR-102 in combination with 5-FU demonstrates superior tumor growth inhibition when compared to standard irinotecan in combination with 5-FU. Data from these studies of NKTR-102 will be presented at the upcoming ESMO Conference: 12th World Congress on Gastrointestinal Cancer in Barcelona, Spain on July 3, 2010 (Abstract P-0025: "*Activity of NKTR-102 in nonclinical models of gastrointestinal cancers*.") .

About Metastatic Colorectal Cancer

Colorectal cancer is the third most commonly diagnosed cancer and the third leading cause of cancer death in both men and women in the U.S. (1) According to the American Cancer Society, nearly 150,000 new cases of colorectal cancer were diagnosed in the U.S. in 2009, and about 50,000 people will die annually of the disease. Worldwide, over 1.2 million people are diagnosed annually with colorectal cancer. (2) Most metastatic colorectal cancer patients have recurrence within two years and require retreatment with chemotherapy regimens. (3) The majority of metastatic colorectal cancer patients receive irinotecan-based regimens, primarily in combination with 5-FU/leucovorin. (4)

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 targets tumor tissue through the EPR effect resulting in enhanced intratumoral drug concentrations as 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. (5)

NKTR-102 is currently being studied in three separate tumor settings in Phase 2 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. 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 recently announced that it will be expanding 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 CNS.

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. 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 of the potential of the company's technology platform, the potential of NKTR-102 in the various cancer indications in which it is being studied, 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) 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; (ii) 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; (iii) the 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; (iv) 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; (v) 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; (vi) 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 (vii) 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, our 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 those risks and uncertainties set forth in the company's Current Reports on Form 8-K filed on June 7 and June 9, 2010, the Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 filed on May 6, 2010, and the Annual Report on Form 10-K for the year ended December 31, 2009, filed on March 3, 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) American Cancer Society, "*Colorectal Cancer Facts Figures 2008-2010*".

(2) GLOBOCAN, 2009.

(3) Decision Resources, 2009.

(4) Kantar Health, 2009.

(5) 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