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Nektar Initiates Phase 1 Clinical Program Evaluating NKTR-102 (PEG-irinotecan) for Potential to Treat Patients with Refractory Solid Tumors

In Preclinical Studies, NKTR-102 Significantly Reduced Tumor Growth and Minimized Side Effects

SAN CARLOS, Calif., Mar 13, 2007 (BUSINESS WIRE) -- Nektar Therapeutics (Nasdaq:NKTR) has initiated a Phase 1 clinical trial program, evaluating the safety, tolerability and pharmacokinetics of NKTR-102 (PEG-irinotecan), an innovative new oncology therapy with the potential to treat patients with refractory solid tumors, the company announced today.

NKTR-102 is a PEGylated small molecule invented by Nektar using its leading PEGylation technology. It is a PEGylated form of irinotecan, a chemotherapeutic agent used for the treatment of solid tumors. The Phase 1 trial is a multicenter, open-label, dose escalation study that will enroll up to 30 patients at multiple cancer research sites in the U.S.

"In preclinical studies in tumor-bearing mice, NKTR-102 resulted in significantly higher reduction in tumor growth than irinotecan in colon, lung and breast tumors," said David Johnston, Ph.D., senior vice president of research and development. "Furthermore, preclinical studies revealed that NKTR-102 was well-tolerated with significant reduction of neutropenia and diarrahea, two debilitating side effects of non-PEGylated irinotecan."

About Nektar Advanced PEGylation Technology

Nektar PEGylation technology can enhance the properties of therapeutic agents by increasing drug circulation time in the bloodstream, decreasing immunogenicity and dosing frequency, increasing bioavailability and improving drug solubility and stability. It is a technique in which non-toxic polyethylene glycol (PEG) polymers are attached to therapeutic agents, and it is applicable to most major drug classes, including proteins, peptides, antibody fragments, small molecules, and other drugs. Nektar PEGylation technology is used in eight approved products in the U.S. and/or Europe today, including Roche's PEGASYS(R) for hepatitis C and Amgen's Neulasta(R) for neutropenia. Two other products using Nektar PEGylation technology have been filed for approval by Nektar partners in both the U.S. and the European Union, including UCB's Cimzia (TM) for Crohn's Disease.

About NKTR-102

NKTR-102 is synthesized by conjugating a Nektar PEG to irinotecan. Irinotecan is a cytotoxic anti-cancer agent widely used to treat colorectal, lung, esophageal, and other solid tumors. In the United States it is indicated as a component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum. It is also indicated for patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy. Based on preclinical studies and experience with PEG technology, Nektar believes that following intravenous administration of NKTR-102, irinotecan will be slowly released from NKTR-102, resulting in prolonged systemic exposure of irinotecan.

Almost one million patients with solid tumors are treated with chemotherapy annually in the U.S. The three largest patient groups are colorectal (14%), lung (17%), and breast (26%). Despite the number of treatments available, cancer is a high unmet medical need. More than 500,000 people each year die of cancer in the U.S.

-- Colorectal cancer is the third most common cancer among men and women and the second leading cause of cancer deaths. An estimated 106,680 new cases of colon and 41,930 new cases of rectal cancer were expected in 2006.

-- Lung cancer is the most common cancer-related death in both men and women. An estimated 174,470 new cases of lung cancer were expected in 2006.

-- Breast cancer ranks second among cancer deaths in women; more than 40,000 women die each year from breast cancer. An estimated 212,920 women will have been diagnosed with invasive breast cancer in the U.S. during 2006.

About Nektar

Nektar Therapeutics is a biopharmaceutical company with a mission to develop and enable differentiated therapeutics with its industry-leading pulmonary and PEGylation technology platforms. Nektar pulmonary and PEGylation technology, expertise, manufacturing capabilities and know-how have enabled nine approved products for partners, which include the world's leading pharmaceutical and biotechnology companies. Nektar also develops its own products by applying its pulmonary and PEGylation technology platforms to existing medicines with the objective to enhance performance, such as improving efficacy, safety and compliance.

This press release contains forward-looking statements and other information that reflect the company's current views and expectations as to the company's PEGylation Technology and NKTR-102 (PEG-irinotecan) development program. These forward-looking statements involve risks and uncertainties, including but not limited to: (i) preclinical testing and clinical trials are long, expensive and uncertain processes, (ii) because the NKTR-102 program is in the early phases of clinical development, the risk of failure is high and can occur at any stage of development, (iii) the company's ability to obtain regulatory approval of the NKTR-102 product candidate and (iv) there can be no assurance that the company's patent applications for NKTR-102 will issue, patents that have issued will be enforceable, or that intellectual property licenses from third parties may not be required in the future. Other important risks and uncertainties are detailed in the company's reports and other filings with the SEC, including its most recent Annual Report on Form 10-K. Actual results could differ materially from the forward-looking statements contained in this press release. The company undertakes no obligation to update forward-looking statements, whether as a result of new information, future events, or otherwise.

Sources: Cancer Facts and Figures, 2006 (American Cancer Society); CancerMetrics, 2006 (The Mattson Jack Group).

PEGASYS is a registered trademark of Roche.

Neulasta is a registered trademark of Amgen.

SOURCE: Nektar Therapeutics

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