Nektar Announces Expanded Phase 2 Clinical Development Plan For NKTR-102 (PEG-irinotecan)

Phase 2 Study for NKTR-102 Will Target Newly-Identified K-Ras Mutated Oncogene Population in Patients with Advanced Colorectal Cancer
New Phase 2 Clinical Trials Will Evaluate NKTR-102 in Advanced Breast and Ovarian Cancers

SAN CARLOS, Calif., June 2, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced an expanded Phase 2 development plan for NKTR-102 (PEG-irinotecan). The company will target newly-characterized colorectal cancer patients with K-Ras mutated gene status in its Phase 2 study in advanced colorectal cancer. In addition, NKTR-102 will be evaluated in Phase 2 trials in two new indications: platinum-refractory ovarian cancer and advanced breast cancer that is refractory to anthracycline and/or taxane-based therapies. These studies are expected to commence in the second half of 2008.

Recent data(2) presented at the 2008 American Society of Clinical Oncologists (ASCO) Annual Meeting shows colorectal cancer (CRC) patients with tumors that have K-Ras oncogene mutations (K-Ras mutant types) do not respond to EGFR-inhibitors, such as cetuximab. It is estimated that up to 45% of colorectal cancer cases have this mutated K-Ras gene. To target this newly- characterized K-Ras mutant patient population, Nektar will initiate a prospective study to evaluate the efficacy of NKTR-102 monotherapy in these patients. The primary endpoint of this randomized trial will be a clinically meaningful improvement in progression-free survival as compared to standard irinotecan monotherapy.

"With these recent clinical studies on K-Ras, there is no longer a clear standard of care for the second-line treatment of advanced colorectal cancer in patients with the K-Ras gene mutation," said Daniel Haller, M.D., Professor of Medicine at the Abramson Cancer Center at the University of Pennsylvania. "This novel oncolytic, NKTR-102, could offer an alternative and promising approach for tumors in this patient population."

The company also announced new trials for NKTR-102 in breast and ovarian cancer. These studies will be open-label, single-arm studies to evaluate the overall response rate (ORR) of NKTR-102 monotherapy in each tumor setting. The studies will implement a minimax design, known as the Simon design, which was first proposed by Dr. Richard Simon of the National Cancer Institute in 1989. The two-stage design is routinely used in the evaluation of oncolytics.(1)

"The promise of NKTR-102 and our small molecule PEGylation platform is capturing a great deal of attention among oncologists and clinical investigators," said Howard W. Robin, Nektar President and CEO. "We've seen significant and repeat anti-tumor activity in our Phase 1 study with NKTR-102. Our expanded Phase 2 clinical development plan will potentially accelerate our understanding and development of this novel therapy in multiple cancer types."

Details on the NKTR-102 Phase 2 clinical development plan will be discussed at an event on June 2, 2008 at 6:30 PM Central time. The event will be Webcast and can be accessed from the company's website at the following url: http://www.nektar.com/wt/page/asco.

About NKTR-102 (PEG-irinotecan)

Nektar is developing NKTR-102, a PEGylated form of irinotecan, which was invented by Nektar using its world-leading small molecule PEGylation technology platform. The product is currently in a Phase 2a study to evaluate NKTR-102 in combination with cetuximab.

Irinotecan is an important chemotherapeutic agent used for the treatment of solid tumors, including colorectal and lung cancers. By applying Nektar's small molecule PEGylation technology to irinotecan, NKTR-102 may prove to be a more powerful and tolerable anti-tumor agent. Preclinical studies show that treatment with NKTR-102 results in significant suppression of tumor growth in an irinotecan-resistant mouse colorectal tumor model and in similar models of breast and lung cancer. Administration of NKTR-102 in an animal model also results in a markedly improved time-concentration profile for SN38, the active metabolite of irinotecan, as compared to treatment with irinotecan.

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 can also be used to modify pharmaceutical agents to preferentially target certain systems within the body. 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 also used in eight additional approved partnered products in the U.S. or Europe today, including UCB's Cimzia(R) for Crohn's Disease, Roche's PEGASYS(R) for hepatitis C and Amgen's Neulasta(R) for neutropenia.

About Nektar

Nektar Therapeutics is a biopharmaceutical company that develops and enables differentiated therapeutics with its industry-leading PEGylation and pulmonary drug development technology platforms. Nektar PEGylation and pulmonary technology, expertise, manufacturing capabilities have enabled eight approved products for partners, which include the world's leading pharmaceutical and biotechnology companies. Nektar also develops its own products by applying its PEGylation and pulmonary 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 regarding the potential of NKTR-102 and the company's PEGylation technology platform. These forward-looking statements involve important risks and uncertainties, including but not limited to: (i) preclinical testing and clinical trials for NKTR-102 are long, expensive and uncertain processes, (ii) because the NKTR-102 product development programs are in the early phases of clinical development, the risk of failure is high and can occur at any stage of development, (iii) the company may fail to obtain regulatory approval of NKTR-102, (iv) the timing or success of the commencement or conclusion of NKTR-102 clinical trials is subject to a number of uncertainties including but not limited to clinical design, patient enrollment, regulatory requirements and clinical outcomes, (v) potential competition from existing approved products (branded or generic) or product candidates under development by other companies could negatively impact the commercial potential of NKTR-102 due to such common industry competitive factors as efficacy and safety profiles, pricing, and reimbursement by third party payers, and (vi) the company's patent applications for NKTR-102 may fail to issue; patents that have issued may not be enforceable; or unanticipated intellectual property licenses from third parties may 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 Quarterly Report on Form 10-Q filed with the SEC on May 9, 2008. 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. No information regarding or presented at the scientific meetings referred to above (or contained at the Internet links provided) is intended to be incorporated by reference in this press release.

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References and Glossary

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