FDA Grants Orphan Drug Designation for Nektar's Investigational Drug, NKTR-102, for Treatment of Women with Ovarian Cancer

SAN FRANCISCO, April 21, 2011 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that the company's oncology drug candidate, NKTR-102, has been granted orphan drug status for the treatment of women with ovarian cancer by the U.S. Food and Drug Administration (FDA).

"This designation is an important step in the overall development program for NKTR-102 and underscores our commitment to treating women with ovarian cancer," said Dr. Lorianne Masuoka, Senior Vice President and Chief Medical Officer of Nektar Therapeutics.

Nektar has a Phase 2 study ongoing for NKTR-102 that is enrolling approximately 125 patients with platinum-resistant ovarian cancer whose disease has progressed following treatment with pegylated liposomal doxorubicin (PLD) therapy. In addition, Phase 3 planning is also underway for NKTR-102 in ovarian cancer. For more information about clinical trials for NKTR-102, please visit the Nektar Therapeutics website at www.nektar.com or www.clinicaltrials.gov.

NKTR-102 is an investigational agent and is not approved by the FDA, the European Medicines Agency (EMA) or other Health Authorities.

About Orphan Drug Designation in the U.S.

In the United States, the Orphan Drugs Act (ODA) provides for the orphan drug designation which aims to encourage the development of drugs involved in the diagnosis, prevention or treatment of a medical condition affecting fewer than 200,000 people in the country. The designation grants U.S. market exclusivity to a drug for a particular indication for a seven-year period if the sponsor complies with certain FDA specifications. Additional incentives for the sponsor include tax credits related to clinical trial expenses and a possible exemption from the FDA-user fee. The designation does not shorten the duration of the regulatory review and approval process.

About Ovarian Cancer

Ovarian cancer is the fifth leading cause of cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. (1) Approximately 22,000 new cases of ovarian cancer will be diagnosed and 14,000 deaths are expected to be caused by ovarian cancer in the United States this year. (1) Treatment options following relapse are limited and overall long-term survival among ovarian cancer patients has not changed significantly in nearly 40 years. (2)

About NKTR-102

Nektar is developing NKTR-102, a next-generation topoisomerase I inhibitor, with reduced peak concentrations and a continuous concentration profile. NKTR-102 was invented by Nektar using its advanced polymer conjugate technology platform, and is the first oncology product candidate to leverage Nektar's releasable polymer technology platform. NKTR-102 has been evaluated in two separate Phase 2 studies for the treatment of platinum-refractory/resistant ovarian cancer and metastatic breast cancer patients. In addition, NKTR-102 is also being tested as a single agent in a Phase 2 clinical trial in patients with second-line colorectal cancer and a Phase 1 clinical trial evaluating NKTR-102 in combination with 5-FU therapy.

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 areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for NKTR-118, an investigational drug candidate, being evaluated in Phase 3 clinical studies as a once-daily, oral tablet for the treatment of opioid-induced constipation. The agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of NKTR-118 and an opioid. NKTR-181, a novel mu-opioid analgesic molecule, is being evaluated in Phase 1 clinical studies. In oncology, NKTR-102, a novel topoisomerase I-inhibitor, is being evaluated in Phase 2 clinical studies for the treatment of breast, ovarian and colorectal cancers. NKTR-105, a novel anti-mitotic agent, is in a Phase 1 clinical study in cancer patients with refractory solid tumors.

Nektar's technology has enabled seven approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia.

Nektar is headquartered in San Francisco, California, with additional R&D 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.

Forward-Looking Statements

This press release contains forward-looking statements that reflect management's current views regarding NKTR-102 and certain other drug candidates in Nektar's pipeline. These forward-looking statements involve numerous risks and uncertainties, including but not limited to: (i) Nektar's product candidates and those of its collaboration partners are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval for numerous reasons including safety and efficacy findings even after positive findings in preclinical and clinical studies; (ii) 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; (iii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of Nektar's technology platform to potential new drug candidates is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (iv) Nektar's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required in the future; (v) the outcome of any future intellectual property or other litigation related to Nektar's proprietary product candidates or complex commercial agreements; and (vi) certain other important risks and uncertainties set forth in Nektar's Annual Report on Form 10-K and Current Report on Form 8-K filed with the Securities and Exchange Commission on March 1, 2011. Actual results could differ materially from the forward-looking statements contained in this press release. Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.

Nektar Investor Inquiries:	
Jennifer Ruddock/Nektar Therapeutics	(650) 631-4954
Susan Noonan/SA Noonan Communications, LLC	(212) 966-3650
Nektar Media Inquiries:	
Karen Bergman/BCC Partners	(650) 575-1509
Michelle Corral/BCC Partners	(415) 794-8662

(1) *American Cancer Society*, 2011.

(2) Ovarian Cancer National Alliance

SOURCE Nektar Therapeutics