NKTR-102 Receives Positive Opinion From EMA COMP for Orphan Medicinal Product Designation in Ovarian Cancer

SAN FRANCISCO, July 18, 2011 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that the European Medicines Agency Committee for Orphan Medicinal Products (COMP) has issued a positive opinion on its application for orphan medicinal product status for the company's lead oncology candidate, NKTR-102, for the treatment of women with ovarian cancer.

"There is a significant unmet need for additional treatments to address ovarian cancer," said Carlo DiFonzo, PhD, Vice President of Drug Development and Regulatory Affairs for Nektar. "We are pleased to have received a positive opinion from COMP for orphan medicinal product status in Europe to augment the U.S. Orphan Drug Designation recently received in April, as we continue the treatment of patients in our Phase 2 study of NKTR-102 in women with platinum-resistant ovarian cancer."

Nektar has a multi-national 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 yet approved by the FDA, the European Medicines Agency (EMA) or other Health Authorities. Following the issuance of a positive opinion from the EMA COMP, the opinion is forwarded to the European Commission for adoption of the decision and subsequent listing in the Community Register of Orphan Medicinal Products.

About Orphan Medicinal Product Designation in Europe

In the European Union, orphan medicinal product designation is designed to encourage the development of medicinal products for the diagnosis, treatment or prevention of life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union (EU). The designation provides incentives for sponsors to develop orphan medicinal products, including market exclusivity to a drug for a particular indication for a ten-year period after the drug is granted marketing approval. Additional incentives for the sponsor may include protocol assistance, filing fee reductions, and research grants.

About European Medicines Agency (EMA):

The EMA is a decentralized body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. Further information about EMA may be found at http://www.ema.europa.eu.

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) In the European Union, there are approximately 44,000 newly diagnosed cases of ovarian cancer each year and approximately 29,000 deaths result from ovarian cancer each year. (2) In the U.S., approximately 22,000 new cases of ovarian cancer will be diagnosed and 14,000 deaths are expected to be caused by ovarian cancer 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.(3)

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 for the treatment of second- and third-line 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.

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 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-Q filed with the Securities and Exchange Commission on April 29, 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.

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1 *American Cancer Society*, 2011.

2 *International Journal of Cancer*

3 Ovarian Cancer National Alliance

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