Nektar Announces Positive Phase 2 Clinical Data from First Stage of NKTR-102 Study in Women with Platinum-Resistant Ovarian Cancer

SAN CARLOS, Calif., March 8, 2010 /PRNewswire via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced preliminary progression-free survival data from the first stage of a two-stage Phase 2 clinical study evaluating single-agent treatment with NKTR-102 in women with platinum-resistant ovarian cancer. In the first stage of the study, 39 patients were enrolled with platinum-resistant disease and were evaluable for the secondary endpoint of progression-free survival (PFS).

The study showed that women who received NKTR-102 once every 21 days (q21 day) had a median PFS of 21.0 weeks. In the second arm of the study, women who received NKTR-102 once every 14 days (q14 day) had a median PFS of 12.2 weeks. Progression-free survival is a measure of how long patients live without their disease advancing. Current agents approved by the U.S. Food & Drug Administration to treat women with platinum-resistant ovarian cancer have median PFS of between 9.1 and 13.6 weeks.(1)

"NKTR-102 has demonstrated a progression-free survival time of nearly five months, which is remarkable for a largely refractory population that is expected to have a PFS of less than three months," said Lorianne Masuoka, M.D., Senior Vice President and Chief Medical Officer. "With a confirmed objective GCIG response rate of 35 percent also in the every three week dose schedule and a favorable toxicity profile, NKTR-102 appears to offer great promise to women with chemo-resistant ovarian cancer. We look forward to sharing additional data when all patients have concluded both stages of the study."

77% of the 39 women in the first stage of the NKTR-102 Phase 2 study had progressed within three months of their last platinum dose and 44% of patients in the first stage had actually progressed within three weeks of their last platinum regimen. There are patients in the first stage of the study still receiving treatment with NKTR-102.

In January, Nektar reported initial data from the first stage of the Phase 2 study for the primary endpoint of overall response rate using Gynecologic Cancer InterGroup (GCIG) criteria, i.e., a combination of response by tumor imaging (RECIST) and/or ovarian cancer biomarker (CA-125) criteria.(2) Women in the first stage of the study showed an overall GCIG response rate of 32% (6/19) in the once every 14 days (q14 day) dose schedule and 35% (7/20) for the once every 21 days (q21 day) dose schedule. Confirmed objective response rates using RECIST were 21% (4/19) and 22% (4/18) for the q14 day and q21 day dose schedules, respectively. CA-125 response rates were 31% (5/16) and 38% (6/16), for the q14 day and q21 day dose schedules, respectively.

The most commonly observed grade 3 or grade 4 side effects in the study to date (every 14 day/every 21 day dose schedule) were diarrhea (29%/10%) and neutropenia (14%/10%).

The Phase 2 study has now completed enrollment with a total of 71 patients treated. The study is ongoing. Full data are expected to be presented at a major scientific conference in 2010.

About the Study

The Phase 2 study is evaluating two dose regimens (q14 day and q21 day) of single-agent NKTR-102 in women with platinum-resistant ovarian cancer. The study employs a two-stage design, with 41 patients in the first stage and 30 patients in the second stage. Two patients in the q14 day dose regimen in the first stage had platinum-sensitive disease and were not evaluable for the primary outcome measure. The primary endpoint for the study is overall response rate using Gynecologic Cancer InterGroup (GCIG) criteria, a combination of response by tumor imaging (RECIST) and/or ovarian cancer biomarker (CA-125) criteria. Secondary endpoints of the Phase 2 study include progression-free survival and safety.

CA-125 is a biochemical marker that is found in the blood of ovarian cancer patients and is measured to assess disease progression and recurrence. RECIST classifies response based upon tumor reduction measured by imaging methods.

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.(3) Agents currently approved by the U.S. Food & Drug Administration to treat women with platinum-resistant ovarian cancer also have modest overall response rates of between 6.5 to 13.8%.(1), (4)

About NKTR-102

Nektar is developing NKTR-102, a topoisomerase I inhibitor-polymer conjugate 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.

In addition to the fully-enrolled Phase 2 study currently ongoing in platinum-resistant ovarian cancer, NKTR-102 is also being tested in two separate Phase 2 clinical trials in patients with metastatic breast cancer and second-line colorectal 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. Nektar is currently conducting clinical and preclinical programs in oncology, pain and other therapeutic areas. In addition to the releasable polymer technology used in NKTR-102, Nektar is the first company to create a permanent small molecule-polymer conjugate with enhanced oral bioavailability and restricted entry into the CNS. Nektar recently 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. NKTR-105, Nektar's second oncology program developed using its proprietary small molecule advanced polymer conjugate technology, is in a Phase 1 clinical study in cancer patients with refractory solid tumors.

Nektar is headquartered in San Carlos, 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.

This press release contains forward-looking statements that reflect the company's current views regarding the potential of the company's technology platforms, the potential of NKTR-102 as a drug candidate, preliminary results from stage 1 of a Phase 2 clinical study for NKTR-102 in ovarian cancer.. 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 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 preliminary Phase 2 results for NKTR-102 in ovarian cancer patients in stage 1 described in this press release is preliminary data only and remains subject to final data gathering and analysis review procedures; (iv) the preliminary results from stage 1 of the NKTR-102 clinical study for ovarian cancer is not necessarily indicative or predictive of the future results from stage 2 of this clinical study and therefore the outcome of the final clinical study results for NKTR-102 in ovarian cancer remains uncertain; (v) the company's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may not be enforceable, or intellectual property licenses from third parties may be required in the future; (vi) the data from clinical studies in Nektar-102 from any particular cancer indication is not necessarily predictive of the outcomes for other cancer indications for which NKTR-102 is being studied by the company (i.e. breast and colorectal cancers); (vii) if Nektar is unable to establish and maintain collaboration partnerships (such as for NKTR-102) on attractive commercial terms or at all, the company's business, results of operations and financial condition could suffer; and (viii) the outcome of any existing or future intellectual property or other litigation related to the company's proprietary product candidates including without limitation NKTR-102. Other important risks and uncertainties are detailed in the company's reports and other filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K filed with the SEC on March 3, 2010. 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)Gordon et al., *Journal of Clinical Oncology* 2001, 19: 3312-3322

(2)2008 International Gynecologic Cancer Society. Gynecological Cancer Intergroup, http://www.gcig.igcs.org/CA-125.html

(3)*American Cancer Society*, 2009.

(4)Doxil US Package Insert, 2008. http://www.doxil.com/

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