Nektar Therapeutics Announces Positive Topline Results for NKTR-102 From First Stage of Phase 2 Study in Platinum-Resistant Ovarian Cancer

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SAN CARLOS, Calif., Jan 12, 2010 /PRNewswire via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced preliminary results from the first stage of a two-stage Phase 2 clinical study evaluating NKTR-102 in women with platinum-resistant ovarian cancer. In the first stage of the study, 39 patients enrolled with platinum-resistant disease were evaluable 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(1). The first stage of the NKTR-102 Phase 2 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 each dose schedule, respectively. The Phase 2 study has now completed enrollment with a total of 71 patients. Approximately one-third of the patients in the study remain on NKTR-102 treatment, including a number of patients in the first stage of the study.

"The early and dramatic reductions in CA-125 in many of the patients with platinum-resistant and refractory ovarian cancer indicate that NKTR-102 has great therapeutic potential," said Prof. Dr. Ignace Vergote, Head of the Department of Obstetrics and Gynaecology and Gynaecologic Oncology at the Catholic University of Leuven, European Union and Lead Investigator of the NKTR-102 study. "NKTR-102 is one of the most promising agents for platinum-resistant ovarian cancer I have seen in 25 years, as evidenced by the number of women in the study with tumor response and rapid biochemical response. This drug warrants further definitive Phase 3 testing as quickly as possible. The investigators look forward to presenting the final data at an upcoming scientific meeting."

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%).

"This population of heavily pre-treated patients, which includes a high proportion of women with platinum-refractory disease, is among the most challenging to treat in oncology," said Lorianne Masuoka, M.D., Senior Vice President and Chief Medical Officer. "Almost half of the patients in the first stage of our study had platinum-refractory disease, having progressed within three weeks of their last platinum regimen. We are highly encouraged by the compelling efficacy seen to-date in the patients from the first stage of our study. This efficacy is accompanied by a favorable safety profile with regard to both GI side effects and neutropenia."

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. 44% of the patients in the first stage were platinum-refractory, having progressed within three weeks of their last platinum therapy. 77% of the patients in the first stage had a platinum-free interval of less than three months (progression within three months of last platinum therapy). 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(2). Agents currently approved by the U.S. Food & Drug Administration to treat women with platinum-resistant ovarian cancer have modest overall response rates of between 6.5 to 13.8%(3,4).

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 underway 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.

The company also announced today that it has opened the second stage of its Phase 2 study of NKTR-102 in women with metastatic breast cancer evaluating two dose regimens (q14 and q21 day dose schedules). Enrollment of the first stage of this two-stage study is complete for both regimens (20 patients per regimen).

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. In addition to the releasable polymer technology, Nektar is the first company to create a permanent small molecule-polymer conjugate with enhanced oral bioavailability and restricted entry into the CNS. Nektar is currently conducting clinical and preclinical programs in oncology, pain and other therapeutic areas. 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-102 is being evaluated in Phase 2 clinical studies for the treatment of ovarian, breast and colorectal cancers. NKTR-105 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, preliminary results from stage 1 of a Phase 2 study for NKTR-102 in ovarian cancer, and an update on the status of a two stage Phase 2 study of NKTR-102 in breast 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 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; (vii) 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; and (vii) 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 Quarterly Report on Form 10-Q and Annual Report on Form 10-K. Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.


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(2) *American Cancer Society*, 2009.

(3) Gordon et al., *Journal of Clinical Oncology* 2001, 19: 3312-3322

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