



## **NKTR-102 Demonstrates Synergistic Anti-Tumor Activity in Combination with Pegylated Liposomal Doxorubicin in Platinum-Resistant Ovarian Cancer**

### **New Preclinical Studies for NKTR-102 Presented at 2011 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer**

SAN FRANCISCO, Nov. 15, 2011 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) today presented positive preclinical data for NKTR-102, a next-generation topoisomerase I inhibitor, at the 2011 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer being held in San Francisco, California. The preclinical data demonstrates that NKTR-102 administered in combination with pegylated liposomal doxorubicin (PLD) *in vivo* has strong synergistic anti-cancer properties exhibiting a 100% complete response rate with no tumor re-growth in over 90% of animals. In addition, the study showed that there was no additive toxicity when combining NKTR-102 with PLD in a preclinical model of ovarian cancer.

"Results from these nonclinical studies of NKTR-102 combined with PLD and as a single agent are highly compelling," said Robert Medve, M.D., Chief Medical Officer of Nektar Therapeutics. "In the models of platinum-resistant ovarian cancer, NKTR-102 showed synergistic anti-tumor activity with PLD. These preclinical data support the future exploration of NKTR-102 in combination with PLD in platinum-resistant ovarian cancer."

The data presented at the 2011 AACR-NCI-EORTC meeting show that in an *in vivo* model of platinum-resistant human ovarian cancer, a single-dose of single-agent NKTR-102 resulted in a 100 percent complete response rate and a delay in tumor growth of up to 38 days at the highest dose. In the same model, multiple doses of single-agent PLD achieved only one partial response and a delay in tumor growth of up to only 24 days at its highest dose. NKTR-102 administered in combination with PLD showed synergistic anti-tumor activity with a 100 percent complete response rate and no tumor re-growth for 93% of the animals within a 69-day observation period.

#### **NKTR-102 and PLD Nonclinical Data**

These data were presented today at the 2011 AACR-NCI-EORTC meeting during the Topoisomerase Inhibitors session (Abstract C209) entitled "*Strong synergistic activity of NKTR-102 - Pegylated Liposomal Doxorubicin (PLD) Combination Therapy in a Nonclinical Model of Platinum-Resistant A2780 Human Ovarian Cancer.*" The poster presentation is also available at [http://www.nektar.com/product\\_pipeline/oncology\\_nktr-102.html](http://www.nektar.com/product_pipeline/oncology_nktr-102.html).

#### **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 is being evaluated in multiple clinical studies. In ovarian cancer, a 71-patient Phase 2 clinical trial of NKTR-102 has been completed in patients with platinum-refractory/resistant ovarian cancer. In June 2010, the ovarian cancer Phase 2 study was expanded to evaluate single-agent NKTR-102 in women who progressed while on Doxil therapy, and this study is ongoing. In metastatic breast cancer, a 70-patient study of NKTR-102 in second- and third-line metastatic breast cancer is completed. A Phase 3 clinical trial of NKTR-102 in patients with metastatic breast cancer, the BEACON study (BrEAst Cancer Outcomes with NKTR-102) study, is planned to start in December 2011. NKTR-102 is also being tested in second-line colorectal cancer as both a single-agent and in combination with 5-fluoracil/leukovorin.

#### **About Ovarian Cancer**

Nearly all ovarian cancers will become resistant or refractory to platinum-based therapy over time. 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 15,000 deaths are expected to be caused by ovarian cancer in the United States this year.(2) Initial response rates to treatment with platinum-based agents can be as high as 80 percent, but most patients recur. Treatment options following relapse are limited and overall long-term survival among ovarian cancer patients has not changed significantly in nearly 40 years.(3) 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 percent.(4,5)

## 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 therapeutic 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 wholly-owned by Nektar, is being evaluated in Phase 1 clinical studies. In oncology, NKTR-102, a novel proprietary 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. Additional development stage products that leverage Nektar's proprietary technology platform include peginesatide, for which Affymax and partner Takeda submitted an NDA to the FDA in May 2011, and Baxter's BAX 855, a long-acting PEGylated rFVIII program planned to enter Phase 1 clinical development in 2011.

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>.

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This press release contains forward-looking statements that reflect Nektar's current views as to the therapeutic potential of NKTR-102 in combination with PLD based on observations from preclinical data, the potential of Nektar's polymer conjugate technology platform, and the potential for certain of Nektar's other drug candidates and those of its collaboration partners.

These forward-looking statements involve substantial risks and uncertainties including but not limited to one or more of the following: (i) the preclinical data for NKTR-102 in combination with PLD described in this press release and presented at the 2011 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer may not be predictive of future success in clinical trials; (ii) there is currently a significant shortage of PLD drug supply and there is substantial uncertainty as to when this supply shortage will subside—as a result, future clinical trials of NKTR-102 in combination with PLD (if any) could be substantially delayed; (iii) the size, scope and timing of our investment in any future clinical studies in ovarian cancer will depend upon a number of important variables, including our evaluation of the expanded Phase 2 clinical study results for NKTR-102 in platinum resistant/refractory ovarian cancer, discussions with health authorities and key opinion leaders, evolving regulatory standards and requirements, the estimated cost and time required for additional clinical studies, and prioritization of Nektar's research and development opportunities; (iv) 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 such as NKTR-102 in combination with PLD is therefore very uncertain and unpredictable and one or more research and development programs could unexpectedly fail; (v) Nektar's patent applications for its proprietary or partner drug candidates may not issue, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vi) the outcome of any existing or future intellectual property or other litigation related to Nektar's proprietary drug candidates including without limitation NKTR-102. Other important risks and uncertainties are detailed in Nektar's filings with the Securities and Exchange Commission, including without limitation, those risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 filed with the SEC on November 4, 2011.

Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise

### *References:*

- (1) JCO Vol 29, No 15\_suppl, 2011: 5047.
- (2) American Cancer Society, 2011.
- (3) Ovarian Cancer National Alliance
- (4) Gordon et al., *Journal of Clinical Oncology*, 2001, 19: 3312-3322
- (5) Doxil US Package Insert, 2008. <http://www.doxil.com/>

