Significant Anti-Tumor Activity of NKTR-102 in Patients With Refractory Solid Tumors; Interim Data Published in ASCO 2008 Proceedings

Nektar's Technology Enables First-Ever PEGylation of a Small Molecule with Demonstrated Therapeutic Activity

SAN CARLOS, Calif., May 16, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) announced initial results today from a Phase 1 study of NKTR- 102, PEGylated irinotecan. The data shows significant anti-tumor activity in patients with refractory solid tumors. The study also demonstrates that Nektar's small molecule PEGylation technology produced an increase in SN38 exposure that was up to six-fold higher than the exposure previously reported with irinotecan at equivalent doses. SN38, a topoisomerase I inhibitor, is the active metabolite of irinotecan.

The ASCO abstract reports interim data on 27 of 32 patients in the first of three dose schedules from the Phase 1 trial.(1) Results for the first schedule (weekly x3 q4 weeks) found anti-tumor activity in 7 out of the total 32 patients evaluable for efficacy. Partial responses were confirmed in three patients, or 10% (greater than 30% tumor regression per RECIST), and other evidence of anti-tumor activity was confirmed in four patients, or 12% (tumor regression by more than 15% but less than 30% per RECIST, or significant biomarker evidence).

"This significant anti-tumor activity in a number of patients whose tumors have progressed on prior therapies makes NKTR-102 one of the most promising cancer drugs I have ever studied," said Daniel D. Von Hoff, M.D., lead Phase 1 investigator for NKTR-102, Physician-in-Chief at the Translational Genomics Research Institute and Chief Medical Officer for the Scottsdale Clinical Research Institute at Scottsdale Healthcare.

Nektar's proprietary PEGylation technology can enhance the properties of therapeutic agents by increasing drug circulation time, improving pharmacokinetics, decreasing immunogenicity and dosing frequency, increasing bioavailability and improving drug solubility and stability.

"The impressive Phase 1 results with NKTR-102 represent a major advancement for our small molecule PEGylation platform," said Howard W. Robin, President and CEO of Nektar. "Using our proprietary technology, Nektar is the first company to create a PEGylated small molecule with a unique pharmacokinetic profile that has demonstrated therapeutic activity in patients. This pioneering success with NKTR-102 validates our platform and opens the door to a wide range of potential small molecule opportunities. "

Clinical Trial Summary

In the Phase 1 dose-escalation trial, the safety, pharmacokinetics and anti-tumor activity of NKTR-102 monotherapy was evaluated in patients with refractory solid tumors. Patients received 90-minute infusions of NKTR-102 (PEGylated irinotecan) repeated as follows: weekly for three weeks with the fourth week off; every two weeks; or every three weeks. Tumor responses are being evaluated according to RECIST (Response Evaluation Criteria in Solid Tumors) criteria.

In the first dose schedule (weekly x3 q4 weeks), NKTR-102 was administered to a total of 32 patients with advanced solid tumors who had failed prior treatments or had no standard treatment available to them. Doses ranged from 58 mg/m2 to 230 mg/m2. Tumor regression, anti-tumor activity or prolonged disease stabilization was observed in a number of cancer types, including non- small cell lung cancer, ovarian, small cell lung cancer, cervical, adrenocortical, esophageal, and Hodgkin's lymphoma.

Results from the second and third dose schedules of this Phase 1 trial will be presented by featured speaker, Dr. Daniel D. Von Hoff, at an investor event on June 2, 2008. The Webcast event will begin at 6 pm Central time and will occur during the American Society of Clinical Oncology (ASCO) 2008 Annual Meeting in Chicago, Illinois. Nektar will also present its Phase 2 clinical development plan for NKTR-102.

Side effects in the first dose schedule were diarrhea and neutropenia and were identified as manageable toxicities, with diarrhea being the dose- limiting toxicity associated with administration of NKTR-102. The recommended Phase 2 dose (RP2D) was 115 mg/m2. No Grade 4 or Grade 5 toxicities were observed with administration of NKTR-102.

The Phase 1 trial, sponsored by Nektar Therapeutics, includes clinical sites at Translational Generational Clinical Research Services at Scottsdale Healthcare and the Louisville Oncology Clinical Research Program. The company also expects to present results from this trial at additional scientific forums later this year.

The NKTR-102 abstract entitled "Phase 1 dose finding and pharmacokinetic study of NKTR-102 (PEGylated irinotecan): early evidence of anti-tumor activity" (Abstract No. 13518, published in the ASCO proceedings) can also be found on Nektar's website at http://www.nektar.com/wt/page/nktr102media.

About NKTR-102

Nektar is developing NKTR-102, a PEGylated form of irinotecan, which was invented by Nektar using its world-leading small molecule PEGylation technology platform. The product is currently in Phase 2 clinical development to evaluate its efficacy and safety in combination with cetuximab. Irinotecan is an important chemotherapeutic agent used for the treatment of solid tumors, including colorectal and lung cancers. By applying Nektar's small molecule PEGylation technology to irinotecan, NKTR-102 may prove to be a more powerful and tolerable anti-tumor agent.

Nektar PEGylation technology is used in eight additional approved partnered products in the U.S. or Europe today, including UCB's Cimzia(R), Roche's PEGASYS(R) for hepatitis C and Amgen's Neulasta(R) for neutropenia.

About Nektar

Nektar Therapeutics is a biopharmaceutical company that develops and enables differentiated therapeutics with its industry-leading PEGylation and pulmonary drug development technology platforms. Nektar PEGylation and pulmonary technology, expertise, manufacturing capabilities have enabled eight approved products for partners, which include the world's leading pharmaceutical and biotechnology companies. Nektar also develops its own products by applying its PEGylation and pulmonary technology platforms to existing medicines with the objective to enhance performance, such as improving efficacy, safety and compliance.

This press release contains forward-looking statements regarding the potential of NKTR-102 and Nektar's PEGylation technology platform. These forward-looking statements involve important risks and uncertainties, including but not limited to: (i) clinical trials for NKTR-102 are long, expensive and uncertain processes; (ii) because NKTR-102 is in the early phases of clinical development, the risk of failure is high and can occur at any stage of development regardless of promising data from one or more prior preclinical or clinical studies, (iii) the timing or success of the commencement or end of clinical trials may be delayed or unsuccessful due to slower than anticipated patient enrollment, drug manufacturing challenges, changing standards of care, clinical trial design, and/or clinical outcomes; (iv) Nektar may fail to obtain regulatory approval of NKTR-102; (v) potential competition from existing approved products (branded or generic) or product candidates under development by other companies could negatively impact the commercial potential of NKTR-102 due to such common industry competitive factors as efficacy and safety profiles, pricing, and reimbursement by third party payers; and (vi) Nektar's patent applications for NKTR-102 may fail to issue; patents that have issued may not be enforceable; or unanticipated intellectual property licenses from third parties may be required in the future. Other important risks and uncertainties are detailed in Nektar's reports and other filings with the SEC including its most recent Quarterly Report on Form 10-Q filed with the SEC on May 9, 2008. 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. No information regarding or presented at the scientific meetings referred to above (or contained at the Internet links provided) is intended to be incorporated by reference in this press release.

Contacts:
Tim Warner (650) 283-4915 or twarner@nektar.com
Stephan Herrera (415) 488-7699 or sherrera@nektar.com
Jennifer Ruddock (650) 631-4954 or jruddock@nektar.com

References and Glossary

(1) Borad, M.J., Hamm, J.T., Rosen, L.S., Jameson, G., Utz, J., Mulay, M., Eldon, M., Dhar, S., Acosta, L., Von Hoff, D.D., "Phase 1 Dose-finding and pharmacokinetic study of NKTR-102 (Pegylated irinotecan): early evidence of anti-tumor activity"; ASCO 2008 Annual Meeting Proceedings, May 15, 2008.

SOURCE Nektar Therapeutics

http://www.nektar.com/