

January 18, 2014

# Nektar Presents Positive Clinical Data from a Phase 1 Study of Etirinotecan Pegol (NKTR-102) in Combination with 5-Fluorouracil/Leucovorin at the 2014 Gastrointestinal Cancers Symposium

SAN FRANCISCO, Jan. 18, 2014 /PRNewswire/ -- Nektar Therapeutics' (Nasdaq: NKTR) presented favorable data today from a Phase 1 study of etirinotecan pegol (EP, NKTR-102) in combination with 5-fluorouracil (5-FU)/Leucovorin (LV) in patients with advanced cancer. NKTR-102 is the first long-acting topoisomerase I-inhibitor designed to concentrate in tumor tissue, provide sustained tumor suppression throughout the entire chemotherapy cycle, and to reduce the peak exposures that are associated with toxicities of other cytotoxics. These new data were presented at the 2014 Gastrointestinal Cancers Symposium in San Francisco, California.

"Topoisomerase I inhibition combined with 5-fluorouracil (5-FU) and leucovorin (LV) remains one of the most active combinations used today in advanced colorectal cancer. NKTR-102, a long-acting topoisomerase I-inhibitor, was safely combined with 5-FU/LV, and showed signs of clinical benefit including both objective responses and tumor marker reductions," said Ramesh K. Ramanathan, M.D., Virginia G. Piper Cancer Center, Scottsdale and Clinical Professor of Medicine, College of Medicine- Phoenix Campus, University Arizona and a principal investigator of the trial. "Continued development using this promising long-acting topoisomerase combination therapy is warranted, especially in clinical trials for advanced gastrointestinal malignancies."

The phase 1 study assessed the safety, pharmacokinetics and anti-tumor activity of NKTR-102 when given in combination with standard doses of 5-FU/leucovorin. Data was presented from 26 patients enrolled in 5 cohorts in a standard dose escalation design.

The study established a recommended dose of 75 mg/m<sup>2</sup> NKTR-102 in combination with standard doses of 5-FU/LV given every two weeks. Promising clinical activity, including objective response (2 patients), clinical benefit (stable disease > =6 months; 10 patients) and clinically significant declines in tumor markers were observed (including a patient with pancreatic cancer whose disease had progressed on prior irinotecan). Toxicities of diarrhea and reversible neutropenia were generally manageable with dose delays and reductions.

#### 2014 Gastrointestinal Cancers Symposium Presentation Details

**Poster C55:** "A phase I study of etirinotecan pegol in combination with 5-fluorouracil and leucovorin in patients with advanced cancer."

- Session Title: Cancers of the Colon and Rectum-Prevention, Screening, and Diagnosis
- Date/Time/Location: January 18, 2014 7:00-7:55 a.m. and 12:00-2:00pm Pacific Time, Level 1 West Hall

#### **About Etirinotecan Pegol (NKTR-102)**

NKTR-102 is a new potential therapeutic option in development for advanced breast cancer. It is the first long-acting topoisomerase I-inhibitor with a non-overlapping mechanism of action with other agents used to treat breast cancer, which may mitigate potential cancer cross-resistance and reduce overlapping toxicities. In November 2012, NKTR-102 was designated a Fast Track development program by the U.S. FDA for the treatment of patients with locally recurrent or metastatic breast cancer progressing after treatment with ATC.

NKTR-102 is believed to penetrate the vasculature of the tumor environment more readily than normal vasculature, increasing the concentration of active drug within tumor tissue to enhance anti-tumor activity. The unique PK profile of NKTR-102 provides continuous exposure of active drug throughout the entire chemotherapy cycle, with reduced peak exposures that can be associated with toxicities. In addition to metastatic breast cancer, NKTR-102 is also being evaluated for the treatment of ovarian, colorectal, glioma and lung cancers.

## **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 naloxegol (NKTR-118), an investigational drug candidate, which has been filed for regulatory approvals in the U.S., Europe and Canada as a once-daily, oral tablet for the treatment of opioid-induced constipation. This agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of naloxegol and an opioid. NKTR-181, a novel mu-opioid analgesic candidate for chronic pain conditions, which has completed Phase 2 development in osteoarthritis patients with chronic knee pain. In oncology, etirinotecan pegol (NKTR-102) is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer and is also in Phase 2 studies for the treatment of ovarian, colorectal, lung and brain cancers. In anti-infectives, Amikacin Inhale is in Phase 3 studies conducted by Bayer Healthcare as an adjunctive treatment for intubated and mechanically ventilated patients with Gram-negative pneumonia. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a longer-acting PEGylated rFVIII program, which is in Phase 3 clinical development.

Nektar's technology has enabled eight 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 operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at <a href="http://www.nektar.com">http://www.nektar.com</a>.

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "could," "potential," "may" and similar references to future periods. Examples of forward-looking statements include our current views regarding the therapeutic potential of etirinotecan pegol in combination with 5-FU/LV in patients with advanced cancer; the potential of certain of our other drug candidates and those of our collaboration partners; and certain other statements regarding our business. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, observations and assumptions regarding the potential of our drug candidates and our technology. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forwardlooking statements. Important factors that could cause our actual results to differ materially from those indicated in the forwardlooking statements include, among others: (i) etirinotecan pegol is still in clinical development and the risk of failure is high and can unexpectedly occur at any time prior to regulatory approval for numerous reasons including safety and efficacy findings from the ongoing BEACON clinical study; (ii) statements regarding the therapeutic potential of etirinotecan pegol in combination with 5-FU/LV are based on preclinical data and Phase 1 clinical data and future clinical results may not confirm these findings; (iii) the timing of the commencement or end of clinical trials, target timeframe for the availability of clinical results, and the successful commercial launch of our drug candidates may be delayed or unsuccessful due to 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; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of our technology platform to potential new drug candidates such as etirinotecan pegol (either alone or in combination with other therapies) is therefore very uncertain and unpredictable and could unexpectedly fail at any time; (v) patents may not issue from our patent applications for etirinotecan pegol, 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 our proprietary drug candidates. Other important risks and uncertainties are detailed in our reports and other filings with the Securities and Exchange Commission ("SEC"), including without limitation, those risks and uncertainties set forth in our quarterly report on Form 10-Q for the quarter ended September 30, 2013, filed with the SEC on November 7, 2013. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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