



Nektar and Roswell Park Cancer Institute Announce Initiation of Investigator-Sponsored Trial Evaluating Etirinotecan Pegol (NKTR-102) as a Second-Line Treatment in Patients with Relapsed or Refractory Small Cell Lung Cancer (SCLC)

SAN FRANCISCO, CA and BUFFALO, NY, October 24, 2013 -- Nektar Therapeutics (NASDAQ:NKTR) and Roswell Park Cancer Institute (RPCI) announced today that the first patients have been dosed in a phase II investigator-sponsored study of etirinotecan pegol in patients with relapsed or refractory Small-Cell Lung Cancer (SCLC). The study is being conducted at Roswell Park under the direction of Alex Adjei, M.D., Ph.D., F.A.C.P., Senior Vice President for Clinical Research and Chair of the Department of Medicine at RPCI.

Etirinotecan pegol is the first long-acting topoisomerase-I inhibitor that concentrates in tumor tissue and provides sustained tumor suppression throughout the entire chemotherapy cycle.

“For patients with relapsed small-cell lung cancer, prognosis is poor with second-line therapy,” said Dr. Adjei. “Approved topoisomerase-I inhibitors have demonstrated anti-tumor activity in small-cell lung cancer, but their use is often hampered by significant toxicity and pharmacokinetics. Given this background, we are very interested in evaluating etirinotecan pegol as a potential treatment option for this patient population.”

The primary endpoint of the phase II study is the 18-week progression-free survival (PFS) rate. Secondary endpoints include objective response rate (ORR), overall survival (OS), median duration of response (DoR) and the safety profile of etirinotecan pegol in patients with relapsed SCLC. This single-stage study will evaluate etirinotecan pegol in two patient cohorts: chemo-resistant (those progressing within three months after completing first-line therapy) and chemo-sensitive (those progressing at three months or later after completing first-line therapy). The study is expected to enroll approximately 38 patients who will receive etirinotecan pegol once every three weeks as monotherapy.

“We are very pleased that Dr. Adjei has identified and proposed this study of single-agent etirinotecan pegol in this difficult to treat patient population,” said Robert Medve, M.D., Senior Vice President and Chief Medical Officer of Nektar Therapeutics. “This is the third phase II investigator-sponsored trial evaluating etirinotecan pegol and demonstrates our continued commitment to fully understanding etirinotecan pegol’s potential in resistant or refractory cancers where there are limited treatment options.”

About SCLC

Small-cell lung cancer (SCLC) is one of the most aggressive and lethal cancers in humans. It accounts for 15-20% of all lung cancer. Although standard combination cytotoxic chemotherapy

agents have shown antitumor activity with initial responses of 70%–90% for both limited and extensive stages of SCLC, long-term survival is low and most patients eventually develop progressive disease within the first 2 years.¹⁻³ Consequently, there is a need for new therapies that are safe and effective, which also improve overall survival and quality of life.

About Etirinotecan Pegol

Etirinotecan pegol is a unique, targeted topoisomerase-I inhibitor designed for prolonged tumor cell exposure. Etirinotecan pegol 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 antitumor activity. The BEACON study is a Phase 3 clinical study currently evaluating etirinotecan pegol for the treatment of locally recurrent or metastatic breast cancer. In addition to metastatic breast cancer, etirinotecan pegol is also being evaluated for the treatment of ovarian, colorectal, high-grade glioma and non-small-cell lung cancers.

About Roswell Park Cancer Institute

The mission of Roswell Park Cancer Institute (RPCI) is to understand, prevent and cure cancer. Founded in 1898, RPCI is one of the first cancer centers in the country to be named a National Cancer Institute-designated comprehensive cancer center and remains the only facility with this designation in Upstate New York. The Institute is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading cancer centers; maintains affiliate sites; and is a partner in national and international collaborative programs. For more information, visit www.roswellpark.org, call 1-877-ASK-RPCI (1-877-275-7724) or email askrpci@roswellpark.org. Follow Roswell Park on Facebook and Twitter.

About Nektar

Nektar Therapeutics (NASDAQ: NKTR) 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 completed Phase 3 development as a once-daily, oral tablet for the treatment of opioid-induced constipation. For naloxegol, an MAA has been accepted for filing in Europe, and an NDA has been submitted for filing in the U.S. 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 molecule for chronic pain conditions, has completed Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-opioid analgesic molecule in development to treat acute pain is in Phase 1 clinical development. 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 a number of Phase 2 studies. In anti-infectives, Amikacin Inhale is in Phase 3 studies conducted by Bayer Healthcare to treat patients with Gram-negative pneumonia.

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. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a long-acting PEGylated rFVIII program, which is in Phase 3 clinical development.

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 <http://www.nektar.com>.

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 etirinotecan pegol as a potential new therapy for cancer patients; the value of our advanced polymer conjugate technology platform; and the potential of certain of our other drug candidates and those of our collaboration partners. 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 forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking 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 Phase 3 clinical study; (ii) the statements regarding the therapeutic potential of etirinotecan pegol are based on preclinical data and data from completed Phase 2 clinical studies and future clinical study results may not confirm these earlier 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 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; (vi) the outcome of any existing or future intellectual property or other litigation related to our proprietary drug candidates; and (vii) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2013. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. 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.

Nektar Investor Inquiries:

Jennifer Ruddock/Nektar Therapeutics (415) 482-5585

Susan Noonan/SA Noonan Communications, LLC (212) 966-3650

Roswell Park Media Inquiries: (716) 845-5747

Tara Yates, Director of Public Affairs tara.yates@roswellpark.org

Nektar Media Inquiries:

Marisa Borgasano/MSL

(781) 684-0770

Brianne Cannon /MSL

(415) 817-2545

nektar@schwartzmsl.com

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