February 5, 2013

Nektar Announces Initiation of Investigator-Initiated Trial Evaluating Etirinotecan Pegol (NKTR-102) as a Third-Line Treatment in Patients with Metastatic and Recurrent Non-Small Cell Lung Cancer (NSCLC)

SAN FRANCISCO, Feb. 5, 2013 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) announced today the start of a Phase 2 investigator-initiated study of etirinotecan pegol in patients with metastatic and recurrent NSCLC. The study is being conducted at the Abramson Cancer Center of the University of Pennsylvania under the direction of Charu Aggarwal, M.D., M.P.H., Assistant Professor of Oncology and Corey Langer, M.D., Professor of Oncology.

"Patients with metastatic or recurrent non-small cell lung cancer currently have no standard treatment options after failure of second-line treatment," said Dr. Aggarwal. "In Phase 1 studies, etirinotecan pegol demonstrated encouraging anti-tumor activity in a broad range of solid tumors including non-small cell lung cancer. We are highly interested in evaluating etirinotecan pegol as a potential treatment option for this patient population."

The primary endpoint of the Phase 2 study is overall response rate (ORR). Secondary endpoints include progression free survival (PFS), overall survival (OS), median duration of response (DoR) and the safety profile of etirinotecan pegol in patients with NSCLC after failure of second-line therapy. The open label, single-arm trial is expected to enroll approximately 37 patients who will receive etirinotecan pegol once every three weeks as monotherapy.

"We are very pleased that Dr. Aggarwal and Dr. Langer have identified and proposed this study of single-agent etirinotecan pegol in patients with this difficult to treat cancer," said Robert Medve, M.D., Senior Vice President and Chief Medical Officer of Nektar Therapeutics. "We are pleased that there has been so much interest in etirinotecan pegol from the oncology community. The results of these studies will provide us with a greater understanding of the potential of etirinotecan pegol to benefit patients in need of new treatment options."

About NSCLC

Lung cancer is the leading cause of cancer-related mortality in the US with NSCLC accounting for approximately 85% of all lung cancer diagnoses [1]. Most NSCLC patients present with loco-regionally advanced or metastatic disease. Platinum-based chemotherapy is the mainstay of treatment for NSCLC in the first-line setting for metastatic disease. Even after response to first-line therapy, patients eventually develop progressive disease and require additional treatment. Currently, pemetrexed, docetaxel, and erlotinib are the only FDA approved agents in the second line setting. Erlotinib is the only agent approved for use in the third-line setting, however, progression-free survival and overall survival remain suboptimal and there are no cytotoxics formally approved to treat patients in the third-line setting. Consequently, there is a need for new therapies that are safe and effective, which may 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 anti-tumor 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 and glioma 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 is being evaluated in Phase 3 clinical studies 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, is in Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-

opioid analgesic 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 Phase 2 studies for the treatment of ovarian and colorectal cancers.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including Affymax's OMONTYS® for anemia, 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.

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1. Siegel, R., D. Naishadham, and A. Jemal, Cancer statistics, 2012. CA Cancer J Clin, 2012. 62(1): p. 10-29.

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