June 11, 2014

Nektar Therapeutics Stock Trading Halted Today; FDA Advisory Committee to Discuss Peripherally-Acting Opioid Receptor Antagonists

SAN FRANCISCO, June 11, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR), a biopharmaceutical company developing novel pain and cancer therapeutics, today announced that NASDAQ has halted trading of the company's common stock.

The U.S. Food and Drug Administration's (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) is meeting on June 11-12, 2014 to discuss potential cardiovascular risk associated with peripherally-acting opioid receptor antagonists which includes MOVANTIK™ (naloxegol oxalate), an investigational treatment for opioid-induced constipation (OIC). The AADPAC will consider the necessity, timing, design and size of cardiovascular outcomes trials to support approval of products in the class for the proposed indication of opioid-induced constipation in patients taking opioids for chronic pain.

The AADPAC meeting is scheduled for 8:00 a.m. ET. The briefing materials can be found on the FDA website at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm390304.htm.

MOVANTIK is being developed by Nektar partner AstraZeneca. The Prescription Drug User Fee Act (PDUFA) date set by the FDA for MOVANTIK is September 16, 2014. MOVANTIK is also under regulatory review with health agencies in the European Union and Canada.

The FDA is not required to follow the guidance of an advisory committee when rendering its final decisions on pending applications and other public health matters.

About Nektar

Nektar Therapeutics has a robust R&D pipeline of potentially high-value therapeutics in pain, oncology and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for MOVANTIK, 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 MOVANTIK 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-171, a new sodium channel blocker being developed as an oral therapy for the treatment of peripheral neuropathic 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, 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 late-stage development candidates that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a longer-acting PEGylated rFVIII therapeutic, which is in Phase 3 clinical development for patients with hemophilia A.

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 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," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding regulatory events for MOVANTIK™ (naloxegol oxalate) and the value and potential of our technology and research and development pipeline. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. 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) the outcome of the ADAAP advisory committee meeting and the subsequent FDA determinations made in the MOVANTIK™ new drug application review process will have a significant impact on the Company's financial position based on significant regulatory and launch milestone opportunities and a potential repayment obligation by the Company to AstraZeneca as described in our most recent Quarterly Report on Form 10-Q filed with the SEC on May 8, 2014 (the "Form 10-Q") and the Current Report on Form 8-K filed with the SEC on August 8, 2013, (ii) our drug candidates and those of our collaboration partners are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval for numerous reasons including safety and efficacy findings even after positive findings in previous preclinical and clinical studies; (iii) the timing of the commencement or end of clinical trials and the commercial launch of our drug candidates may be delayed or unsuccessful due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, 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) acceptance, review and approval decisions for new drug applications by health authorities is an uncertain and evolving process and health authorities retain significant discretion at all stages of the regulatory review and approval decision process; (v) 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 is therefore highly uncertain and unpredictable and one or more research and development programs could fail; and (vi) certain other important risks and uncertainties set forth in our Form 10-Q. 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.

Contact:
Nektar Therapeutics
Jennifer Ruddock
650-283-6253

SOURCE Nektar Therapeutics

News Provided by Acquire Media