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US FDA ADVISORY COMMITTEE RECOMMENDS NO CARDIOVASCULAR OUTCOMES TRIAL FOR PERIPHERALLY-ACTING MU-OPIOID RECEPTOR ANTAGONIST (PAMORA) CLASS INCLUDING MOVANTIK

SAN FRANCISCO, June 12, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) reported today that partner AstraZeneca announced that the majority of US Food and Drug Administration (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) members voted that the FDA should not require cardiovascular outcomes trials for the peripherally-acting mu-opioid receptor antagonist (PAMORA) class of drugs, which includes MOVANTIK™ (naloxegol oxalate), an investigational treatment for opioid-induced constipation (OIC) for patients with chronic non-cancer pain. Following a clarification of the vote, the majority of the Committee suggested continued post-approval data collection for cardiovascular safety.

The FDA convened a meeting of the AADPAC to review the class of peripherally acting opioid receptor antagonists on June 11-12, 2014. The meeting assessed the necessity, timing, design and size of cardiovascular outcomes trials to support approval of products in the class, for the proposed indication of OIC in patients taking opioids for chronic non-cancer pain. The FDA is not bound by the Advisory Committee's recommendation, but takes its advice into consideration when reviewing applications for investigational medicines. The Prescription Drug User Fee Act (PDUFA) date set by the FDA for MOVANTIK is September 16, 2014.

"We are exceptionally pleased that the Committee did not find it necessary to require a cardiovascular outcomes trial," said Howard W. Robin, President and CEO of Nektar Therapeutics. "We look forward to the FDA's continued review of the New Drug Application for MOVANTIK and the potential for MOVANTIK to become the first once-daily, oral PAMORA for the treatment of OIC for patients with chronic non-cancer pain."

MOVANTIK was designed using Nektar's proprietary oral, small molecule polymer conjugate technology. MOVANTIK is part of the exclusive worldwide licence agreement announced in September 2009 between AstraZeneca and Nektar.

Opioids play an important role in chronic pain relief by binding mu-receptors in the brain, but they also bind mu-receptors in the bowel. That is why patients taking opioids for chronic pain can develop OIC. In fact, the incidence of OIC can be as high as 81% in patients taking opioids. There is a significant unmet need for safe, effective treatment options for patients with OIC. An estimated 235 million prescriptions for opioids are written in the US each year, of which 20% are for chronic pain. For patients taking prescription opioids for chronic pain, constipation is one of the most common side effects and one not adequately relieved by laxatives.

In addition to the U.S., AstraZeneca has also submitted regulatory filings for MOVANTIK with health agencies in the European Union and Canada.

On June 4, 2014, the New England Journal of Medicine published data online from two pivotal Phase III studies of MOVANTIK, KODIAC-4 and KODIAC-5. Both studies met their primary endpoint, showing an improvement in treatment effect versus placebo. Results from these studies show that more OIC non-cancer pain patients treated with MOVANTIK at a 25 mg dose had a consistent response of increased spontaneous bowel movements through 12 weeks of treatment compared to placebo.

About MOVANTIK™ (naloxegol oxalate)

MOVANTIK is an investigational peripherally-acting mu-opioid receptor antagonist (PAMORA) specifically designed for the treatment of opioid-induced constipation (OIC) in patients with chronic non-cancer pain. In the Phase III clinical studies, MOVANTIK was administered as a once-daily tablet and is designed to block the binding of opioids to the opioid receptors in the gastrointestinal (GI) tract without impacting the opioid receptors in the brain.

About Opioid-Induced Constipation (OIC)

Opioids play an important role in chronic pain relief by binding mu-receptors in the brain. But they also bind mu-receptors in the bowel. That is why patients taking opioids for chronic pain can develop opioid-induced constipation (OIC). In fact, the incidence of OIC varies and has been reported as high as 81% in patients taking opioids.

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 the regulatory process and outcomes 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 voting and recommendations from the AADPAC areadvisory only and not binding on the FDA; (ii) upcoming 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; (iii) 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; (iv) 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; (v) 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; (vi) 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 (vii) 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.

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