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FDA Approves MOVANTIK™ (naloxegol) Tablets For The Treatment Of Opioid-Induced Constipation In Adult Patients With Chronic Non-Cancer Pain

SAN FRANCISCO, Sept. 16, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) reported today that partner AstraZeneca today announced that the US Food and Drug Administration (FDA) approved MOVANTIK™ (naloxegol) tablets as the first once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC), in adult patients with chronic, non-cancer pain.

Opioids play an important role in chronic pain relief and millions of patients are treated with them in the United States each year. They work by binding to mu-receptors in the central nervous system, but they also bind to mu-receptors in the gastrointestinal tract, which can result in patients suffering from OIC.

"As the first once-daily oral PAMORA approved in the U.S., MOVANTIK provides a new treatment option for a common and potentially debilitating side effect experienced by adult patients treated with opioids," said Howard W. Robin, President and CEO of Nektar Therapeutics. "Further, the approval of MOVANTIK represents a significant milestone in Nektar's evolution as it is the first oral small molecule medicine to be created with our proprietary polymer chemistry platform."

The FDA approval of MOVANTIK was based on data from the KODIAC clinical programme, which is comprised of four studies: KODIAC-4, -5, -7 and -8. KODIAC-4 and -5 were both placebo controlled, double-blind, 12 week studies assessing safety and efficacy, while KODIAC-7 was a 12 week safety extension to KODIAC-4, and KODIAC-8 was a 52 week open label, long-term safety study.

In line with the recommendation from the FDA Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) that took place in June 2014, AstraZeneca has agreed to conduct a post-marketing, observational epidemiologic cardiovascular safety study for MOVANTIK.

MOVANTIK is expected to be available to patients in the first half of 2015. MOVANTIK is currently a schedule II controlled substance because it is structurally related to noroxymorphone. During the review of the New Drug Application, the FDA evaluated the abuse potential of MOVANTIK and the approved labelling indicates that MOVANTIK has no risk of abuse or dependency. AstraZeneca submitted a petition for the descheduling of MOVANTIK to the US Drug Enforcement Administration (DEA) in March 2012, which was accepted for review and will be considered by the DEA as part of the process for addressing the descheduling request.

Results from KODIAC-4 and -5 were published in the *New England Journal of Medicine* on 19 June 2014. Naloxegol is also under regulatory review by the European Medicines Agency (EMA).

About MOVANTIK™ (naloxegol) tablets

MOVANTIK™ (naloxegol) is the first FDA approved once-daily peripherally-acting mu-opioid receptor antagonist (PAMORA) specifically designed for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. In the Phase III clinical studies, MOVANTIK was administered as a once-daily tablet and was designed to block the binding of opioids to opioid receptors in tissues such as the gastrointestinal (GI) tract.

MOVANTIK is part of the exclusive worldwide licence agreement announced on 21 September 2009 between AstraZeneca and Nektar Therapeutics. MOVANTIK was developed using Nektar's oral small molecule polymer conjugate technology.

About Nektar

Nektar Therapeutics has a robust R&D pipeline of potentially high-value therapeutics in pain, oncology, hemophilia and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for MOVANTIK. 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 nine 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 potential of 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 commercial launch of MOVANTIK™ is subject to the completion of the U.S. Drug Enforcement Agency's determination that MOVANTIK™ is an unscheduled drug under the Controlled Substances Act pursuant to a decontrol petition submitted by AstraZeneca in March 2012 and there is no prescribed timeframe for the DEA to complete its review of the decontrol; (ii) a marketing application for MOVANTIK™ remains under review by the European Medicines Agency, (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) patents may not issue from our patent applications for MOVANTIK™, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vii) the outcome of any existing or future intellectual property or other litigation related to our proprietary drug candidates or those of our collaboration partners including MOVANTIK™; and (viii) 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 1, 2014. 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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