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Nektar Therapeutics Announces MOVENTIG® (naloxegol) Receives Positive CHMP Opinion In EU For Treatment Of Adults With Opioid-Induced Constipation

SAN FRANCISCO, Sept. 26, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) reported today that partner AstraZeneca announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of MOVENTIG® (naloxegol) for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxatives. MOVENTIG is an investigational, peripherally-acting mu-opioid receptor antagonist (PAMORA).

OIC is a condition caused by prescription opioid pain medicines. Opioids 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.

The positive opinion was reached after a review of comprehensive data from the KODIAC clinical program, which was comprised of four studies assessing the safety and efficacy of MOVENTIG.

The CHMP's positive opinion on MOVENTIG will be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union. The final decision will be applicable to all 28 European Union member countries plus Iceland and Norway. Should the EC approve MOVENTIG, it will be the first once-daily, oral PAMORA available in these markets for the treatment of OIC in adult patients who have had an inadequate response to laxatives.

Today's announcement follows the approval on September 16, 2014, of MOVANTIK™ (naloxegol) tablets by the U.S. Food and Drug Administration (FDA) as the first once-daily PAMORA for the treatment of OIC in adult patients with chronic non-cancer pain.

About MOVENTIG® (naloxegol)
MOVENTIG is an investigational PAMORA specifically designed for the treatment of OIC in adult patients on prescription opioid pain medicines. In Phase III clinical studies, MOVENTIG 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.

The KODIAC clinical program was comprised of KODIAC-4, -5, -7 and -8. KODIAC-4 and -5 were identically-designed, placebo-controlled, double-blind, 12-week studies assessing safety and efficacy. KODIAC-7 was a 12-week safety extension to KODIAC-4, and KODIAC-8 was a 52-week long-term safety study.

MOVENTIG is part of the exclusive worldwide licence agreement announced on September 21, 2009, between AstraZeneca and Nektar Therapeutics. MOVENTIG 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™, the first FDA-approved 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. The AstraZeneca agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of MOVANTIK and an opioid. NKTR-181, a wholly-owned mu-opioid analgesic molecule for chronic pain conditions, has completed Phase 2 development. NKTR-171, a wholly-owned 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. In hemophilia, BAX 855, a longer-acting PEGylated Factor VIII therapeutic is in Phase 3 development conducted by partner Baxter. 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.

Nektar's technology has enabled nine approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including AstraZeneca's MOVANTIK, 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 MOVENTIG 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) although the CHMP has issued a positive opinion on MOVENTIG, the approval of MOVENTIG remains subject to the review and discretion of the European Commission; (ii) the commercial launch of MOVANTIK™ and MOVENTIG are subject to the completion of the U.S. Drug Enforcement Agency's (DEA) determination that MOVANTIK™ is an unscheduled drug under the United States 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; (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 and MOVENTIG, 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 MOVENTIG; 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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