FDA Approves MOVANTIK (naloxegol) Tablets

FDA APPROVES MOVANTIK™ (naloxegol) TABLETS C-II FOR THE TREATMENT OF OPIOID-INDUCED CONSTIPATION IN ADULT PATIENTS WITH CHRONIC NON-CANCER PAIN

AstraZeneca today announced that the US Food and Drug Administration (FDA) approved MOVANTIK™ (naloxegol) tablets C-II 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.

“The FDA approval of MOVANTIK provides a new treatment option for adult patients with chronic non-cancer pain suffering from opioid-induced constipation, a common side effect of opioid therapy,” said Dr. Briggs Morrison, Executive Vice President, Global Medicines Development & Chief Medical Officer, AstraZeneca. “We are pleased to provide physicians and their patients with a once-daily oral treatment supported by a robust clinical programme.”

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.

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-4and -5were 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 C-II

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 AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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