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MOVENTIG® Approved In The European Union For Opioid-Induced Constipation

First-in-class treatment approved for adult patients with opioid-induced constipation who have had an inadequate response to laxatives

SAN FRANCISCO, Dec. 9, 2014 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) reported partner AstraZeneca today announced that MOVENTIG® (naloxegol) has been granted Marketing Authorisation by the European Commission (EC) for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s). MOVENTIG is the first once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) to be approved in the European Union (EU).

Opioids play an important role in chronic pain relief and 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.

Briggs Morrison, Executive Vice President, Global Medicines Development & Chief Medical Officer, AstraZeneca, said: "Constipation is one of the most common side effects for those using opioid pain medication. We're very pleased to have received marketing authorisation for MOVENTIG, as it allows us to offer a new treatment option for the millions of patients across Europe who suffer from opioid-induced constipation and haven't responded to laxatives."

The approval of MOVENTIG was based on data from the KODIAC clinical programme, which was 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.

The EC marketing authorisation applies to all member states of the EU, Iceland, Norway and Lichtenstein. Today's announcement follows the approval on 16 September 2014 of MOVANTIK™ (naloxegol) tablets by the US Food and Drug Administration, as the first once-daily PAMORA for the treatment of OIC in adult patients with chronic non-cancer pain.

About MOVENTIG® (naloxegol)
MOVENTIG is a peripherally-acting mu-opioid receptor antagonist (PAMORA) specifically designed for the treatment of opioid-induced constipation (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 programme was comprised of four studies: KODIAC-4, -5, -7 and -8. KODIAC-4 and -5 were identically designed, 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 long-term safety study.

MOVENTIG is part of the exclusive worldwide licence agreement announced on 21 September 2009 between AstraZeneca and Nektar Therapeutics. MOVENTIG 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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