

# Positive CHMP Opinion for MOVENTIG (naloxegol)

## Moventig® (naloxegol) receives positive CHMP opinion in the EU for the treatment of adults with opioid-induced constipation

AstraZeneca today 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), an investigational, peripherally-acting mu-opioid receptor antagonist (PAMORA), for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s).

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 programme 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 laxative(s).

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 an investigational 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](http://www.astrazeneca.com)

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