ASTRAZENECA PLC
Form 6-K
December 09, 2014

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of December 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

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

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 MOVANTIKTM (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

CONTACTS

Media Enquiries
Esra Erkal-Paler +44 20 7604 8030 (UK/Global)
Vanessa Rhodes +44 20 7604 8037 (UK/Global)
Ayesha Bharmal +44 20 7604 8034 (UK/Global)
Jacob Lund +46 8 553 260 20 (Sweden)

Investor Enquiries
Thomas Kudsk Larsen +44 20 7604 8199 mob: +44 7818 524185
Karl Hård +44 20 7604 8123 mob: +44 7789 654364
Eugenia Litz +44 20 7604 8233 mob: +44 7884 735627
Christer Gruvris +44 20 7604 8126 mob: +44 7827 836825

9 December 2014

-ENDS-

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 09 December 2014

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary