ASTRAZENECA PLC
Form 6-K
June 13, 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 June 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-_____

US FDA ADVISORY COMMITTEE RECOMMENDS NO CARDIOVASCULAR OUTCOMES TRIAL FOR PERIPHERALLY-ACTING MU-OPIOID RECEPTOR ANTAGONIST (PAMORA) CLASS INCLUDING

MOVANTIK

AstraZeneca announced today that the majority of US Food and Drug Administration (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) members voted that the FDA should not require cardiovascular outcomes trials for the peripherally-acting mu-opioid receptor antagonist (PAMORA) class of drugs, which includes MOVANTIKTM (naloxegol oxalate), an investigational treatment for opioid-induced constipation (OIC) for patients with chronic non-cancer pain. Following a clarification of the vote, the majority of the Committee suggested continued post-approval data collection for cardiovascular safety.

The FDA convened a meeting of the AADPAC to review the class of peripherally acting opioid receptor antagonists on 11-12 June 2014. The meeting assessed the necessity, timing, design and size of cardiovascular outcomes trials to support approval of products in the class, for the proposed indication of OIC in patients taking opioids for chronic non-cancer pain. The FDA is not bound by the Advisory Committee's recommendation, but takes its advice into consideration when reviewing applications for investigational medicines. The Prescription Drug User Fee Act (PDUFA) date set by the FDA for MOVANTIK is 16 September 2014.

Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer said: "We are pleased that the Committee did not find it necessary to require a cardiovascular outcomes trial for the PAMORA class. We look forward to the outcome of the FDA's review of the New Drug Application for MOVANTIK and the potential to provide patients with chronic non-cancer pain affected by OIC with an additional treatment option."

Opioids play an important role in chronic pain relief by binding mu-receptors in the brain, but they also bind mu-receptors in the bowel. That is why patients taking opioids for chronic pain can develop OIC. In fact, the incidence of OIC can be as high as 81% in patients taking opioids. There is a significant unmet need for safe, effective treatment options for patients with OIC. An estimated 235 million prescriptions for opioids are written in the US each year, of which 20% are for chronic pain. For patients taking prescription opioids for chronic pain, constipation is one of the most common side effects and one not adequately relieved by laxatives.

If approved, MOVANTIK has the potential to be the first once-daily, oral PAMORA for the treatment of OIC for patients with chronic non-cancer pain. MOVANTIK is also under regulatory review with health agencies in the European Union and Canada.

On 4 June 2014 the New England Journal of Medicine published data online from two pivotal Phase III studies of MOVANTIK, KODIAC-4 and KODIAC-5. Both studies met their primary endpoint, showing an improvement in treatment effect versus placebo: more OIC non-cancer pain patients treated with MOVANTIK at a 25 mg dose had a consistent response of increased spontaneous bowel movements through 12 weeks of treatment compared to placebo.

About MOVANTIKTM (naloxegol oxalate)

MOVANTIK is an investigational peripherally-acting mu-opioid receptor antagonist (PAMORA) specifically designed for the treatment of opioid-induced constipation (OIC) in patients with chronic non-cancer pain. In the Phase III clinical studies, MOVANTIK was administered as a once-daily tablet and is designed to block the binding of opioids to the opioid receptors in the gastrointestinal (GI) tract without impacting the opioid receptors in the brain.

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 Opioid-Induced Constipation (OIC)

Opioids play an important role in chronic pain relief by binding mu-receptors in the brain. But they also bind mu-receptors in the bowel. That is why patients taking opioids for chronic pain can develop opioid-induced constipation (OIC). In fact, the incidence of OIC varies and has been reported as high as 81% in patients taking opioids.

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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13 June 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: 13 June 2014

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