ASTRAZENECA PLC
Form 6-K
November 19, 2013

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 November 2013

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-_____

NEW DRUG APPLICATION FOR NALOXEGOL ACCEPTED BY UNITED STATES FOOD AND DRUG ADMINISTRATION

AstraZeneca today announced that the United States Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for naloxegol, an investigational peripherally-acting mu-opioid receptor antagonist (PAMORA), which has been studied in opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, the most common side effect caused by chronic administration of prescription opioid pain medicines.

The NDA filing was based on comprehensive data from the core Phase III KODIAC programme, which is comprised of four clinical trials designed to investigate the safety and efficacy of naloxegol for the treatment of OIC. Two pivotal Phase III studies, KODIAC-04 (n=652) and KODIAC-05 (n=700), both 12-week, multicentre, randomized, double blind, placebo-controlled pivotal trials evaluated 12.5 mg and 25 mg doses of naloxegol, administered once-daily. KODIAC-07, a 12-week safety extension of KODIAC-04, and KODIAC-08 (n= 534) was an open-label controlled, randomised, 52-week, long-term safety trial.

Naloxegol has the potential to be the first once-daily oral PAMORA for patients with OIC in the United States. Naloxegol was developed using Nektar's oral small molecule polymer conjugate technology.

Naloxegol is part of the exclusive worldwide license agreement announced on 21 September 2009, between AstraZeneca and Nektar Therapeutics. Under the terms of the amended license agreement, AstraZeneca will make a $70 million milestone payment to Nektar within five business days of acceptance of the NDA by the FDA.

About Naloxegol
Naloxegol is an investigational peripherally-acting mu-opioid receptor antagonist (PAMORA), which has been specifically designed for the treatment of opioid-induced constipation (OIC), a condition caused by prescription opioid pain medicines. Naloxegol is a once-daily tablet designed to block the binding of opioids to the opioid receptors in the gastrointestinal (GI) tract without impacting the opioid receptors in the brain.

Naloxegol is part of the exclusive worldwide license agreement announced on 21 September 2009, between AstraZeneca and Nektar Therapeutics (NASDAQ:NKTR). Naloxegol was developed using Nektar’s oral small molecule polymer conjugate technology.

About Opioid-Induced Constipation
Opioids bind to specific proteins called opioid receptors. When the opioids bind to certain opioid receptors in the gastrointestinal (GI) tract, constipation may occur. Opioid-induced constipation (OIC) is a result of increased fluid absorption and lower GI motility due to opioid receptor binding in the GI tract.

Globally, approximately 40-50% (28-35 million) of patients taking opioids for long-term pain develop OIC. About 40-50% (11-18 million) of those OIC sufferers achieve the desired treatment outcomes with current options that include over-the-counter and prescription laxatives.

About Nektar
Nektar Therapeutics (NASDAQ: NKTR) is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar has a robust R&D pipeline of potentially high-value therapeutics in oncology, pain and other therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for naloxegol (NKTR-118), an investigational drug candidate, which has completed Phase 3 development as a once- daily, oral tablet for the treatment of opioid-induced constipation. This

agreement also includes NKTR-119, an earlier stage development programme that is a co-formulation of naloxegol and an opioid. NKTR-181, a novel mu-opioid analgesic candidate for chronic pain conditions, is in Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-opioid analgesic in development to treat acute pain is in Phase 1 clinical development. In oncology, etirinotecan pegol (NKTR-102) is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer and is also in Phase 2 studies for the treatment of ovarian and colorectal cancers. In anti-infectives, Amikacin Inhale is in Phase 3 studies conducted by Bayer Healthcare to treat patients with Gram-negative pneumonia.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a long-acting PEGylated rFVIII programme, which is in Phase 3 clinical development.

Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programmes and capabilities may be found online at http://www.nektar.com

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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19 November 2013

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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: 19 November 2013 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary