ASTRAZENECA PLC
Form 6-K
November 13, 2012

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 2012

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-_____

ASTRAZENECA ANNOUNCES TOP-LINE PHASE III RESULTS FROM NALOXEGOL PIVOTAL TRIALS IN PATIENTS WITH OPIOID-INDUCED CONSTIPATION

12 November 2012

AstraZeneca today announced positive top-line results from two Phase III trials and one safety extension trial in patients with non-cancer related pain and opioid-induced constipation (OIC).
These Phase III KODIAC trials evaluated the safety and efficacy of naloxegol, an oral peripherally-acting, mu-opioid receptor antagonist for the treatment of OIC, a common side effect of prescription opioids.

KODIAC-04 and -05 are both multicenter, randomized, double-blind, placebo-controlled pivotal trials of 12 weeks duration evaluating 12.5 mg and 25 mg naloxegol administered once-daily. The primary endpoint in both trials was percentage of OIC responders versus placebo over 12 weeks of treatment where a responder was defined as having at least three Spontaneous Bowel Movements (SBM) per week, with at least one SBM per week increase over baseline, for at least nine out of 12 weeks, and at least three out of the last four weeks.
Under the design of both trials, statistical significance for the primary endpoint would be achieved if at least one of the two naloxegol doses had a p-value <0.025 compared with placebo.

Analysis of the data indicates that in KODIAC-04 both naloxegol doses (12.5 mg and 25 mg) demonstrated statistically significant results for the primary endpoint. P-values were 0.015 and 0.001 respectively.

In KODIAC-05,the 25 mg dose demonstrated a statistically significant result for the primary endpoint but the 12.5 mg dose did not. P-values were 0.202 for 12.5 mg and 0.021 for 25 mg.

The analyses also showed no clinically relevant imbalances in serious adverse events (SAEs), including externally adjudicated major cardiovascular events, across the three treatment arms in KODIAC-04, -05 and -07. The most common adverse events (AEs) in the naloxegol treatment arms in both trials were abdominal pain, diarrhea and nausea.InKODIAC-07, (the safety extension ofKODIAC-04) the occurrence of AEs and SAEs was lower than in KODIAC-04 and -05. Among non serious adverse events, arthralgia was the most common and was reported only in patients in the naloxegol 25 mg arm. All other common AEs were distributed similarly across the three treatment arms. In KODIAC-04 and -05 for either naloxegol dose, compared to placebo, there were no significant differences in change from baseline in mean daily pain scores or mean total daily opioid dose. A full assessment of the safety and tolerability findings of all three studies is ongoing.

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

"Opioid-induced constipation is a burdensome condition which is often overlooked, inadequately managed and can negatively impact a patient's quality of life," said Martin Mackay, President of Research and Development, AstraZeneca. "The top-line results of the pivotal KODIAC
studies provide important new information on the safety and efficacy of naloxegol as a potential treatment for opioid-induced constipation and we are looking forward to advancing this programme."

The core Phase III KODIAC programme for naloxegol is comprised of four clinical trials which are designed to investigate the safety and efficacy of naloxegol for the treatment of OIC in patients with non-cancer related pain. The full data from these trials will be submitted for presentation at future medical meetings.

The three trials reporting top-line results today include KODIAC-04, -05, and -07. KODIAC-04 and -05 are replicate pivotal 12-week efficacy and safety trials, while KODIAC-07 is a 12-week safety extension of KODIAC-04.
After initial locking of the database for KODIAC-05, data associated with one patient that was previously assessed as non-retrievable was found to be retrievable. These data were added to the database and the database was again locked and underwent a final analysis.
All three trials were conducted in patients with non-cancer pain and documented OIC, who require daily opioid therapy.

Enrolment is complete for the open-label, randomized, 52-week long-term safety trial (KODIAC-08) and the trial is expected to be completed by Q1 2013.

Naloxegol is currently considered a Schedule II controlled substance by the US Drug Enforcement Administration (DEA) based on structural relatedness to noroxymorphone. AstraZeneca has conducted the studies necessary to evaluate the abuse potential and dependence-producing properties of naloxegol in support of obtaining decontrol. A petition for the decontrol of naloxegol was submitted to the DEA in March 2012 and subsequently accepted for review. Commercialisation and launch in the US will be subject to both FDA approval and DEA schedule determination.

- ENDS -

NOTES TO EDITORS

About Naloxegol
Naloxegol is a peripherally-acting mu-opioid receptor antagonist being investigated for the treatment of constipation (opioid-induced constipation or OIC) as a side effect of prescription opioid pain medicines.

Top-line results of the Phase II study of naloxegol (formerly NKTR-118) were previously presented at the American College of Gastroenterology Annual Clinical Meeting and the American Academy of Pain Management Annual Meeting. Naloxegol was developed using Nektar's oral small molecule polymer conjugate technology.

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

Globally, approximately 40-50% (28-35 million) patients taking opioids for long-term pain develop constipation. 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 clinical-stage biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugate technology platforms. Nektar has a robust R&D pipeline of therapeutic candidates in oncology, pain and other areas. The company is headquartered in San Francisco, California, with additional R&D operations in Huntsville, Alabama and Hyderabad, India. Further information about Nektar and its drug development programs and capabilities may be found online at

www.nektar.com

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. 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 UK
Esra Erkal-Paler +44 20 76048030
Vanessa Rhodes +44 20 7604 8037

Media Enquiries Sweden
Ann-Leena Mikiver +46 8 553 260 20

Investor Enquiries
James Ward-Lilley +44 20 7604 8122 mob: +44 7785 432613
Karl Hård +44 20 7604 8123 mob: +44 7789 654364
Nicklas Westerholm +44 20 7604 8124 mob: +44 7585 404950
Ed Seage +1 302 886 4065 mob: +1 302 373 1361

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: 12 November 2012 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary