ASTRAZENECA PLC
Form 6-K
August 19, 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 August 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 __

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Yes __ No X

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ASTRAZENECA ANNOUNCES POSITIVE TOP-LINE RESULTS FROM THE PHASE III PROGRAMME OF CAZ-AVI IN PATIENTS WITH COMPLICATED INTRA-ABDOMINAL INFECTIONS (cIAI)

CAZ-AVI treated patients with cIAI as effectively as meropenem

CAZ-AVI also treated cIAI patients infected with ceftazidime-resistant bacteria as effectively as meropenem

AstraZeneca today announced positive top-line results from RECLAIM-1 and RECLAIM-2, the pivotal Phase III studies investigating the potential of the antibiotic ceftazidime-avibactam (CAZ-AVI) as a treatment for hospitalised adult patients with complicated intra-abdominal infections.

CAZ-AVI consists of a cephalosporin (ceftazidime), an established treatment for serious bacterial infections, and a next generation non-beta lactam beta-lactamase inhibitor (avibactam). CAZ-AVI is being developed to treat a broad range of Gram-negative bacterial infections which are becoming resistant to antibiotics and pose an increasing threat to public health. The addition of avibactam protects ceftazidime from being broken down by beta-lactamases that are produced by resistant bacteria.

The global RECLAIM-1 and RECLAIM-2 Phase III studies both evaluated the safety and efficacy of CAZ-AVI, administered intravenously as a two hour infusion (2000mg / 500mg) plus metronidazole, compared to meropenem, administered intravenously as a 30 minute infusion (1g), in hospitalised adult patients with complicated intra-abdominal infections. Data from the RECLAIM-1 and RECLAIM-2 studies were analysed as a single-pooled dataset with the agreement of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

In the RECLAIM-1 and RECLAIM-2 Phase III studies, CAZ-AVI met the objective of statistical non-inferiority compared to meropenem. The primary endpoint was a clinical cure rate 28 to 35 days after randomisation (the Test of Cure visit). CAZ-AVI also treated cIAI patients infected with ceftazidime-resistant bacteria as effectively as meropenem.

The adverse event rate for CAZ-AVI in combination with metronidazole was similar to meropenem. The most commonly reported adverse events for CAZ-AVI in combination with metronidazole were diarrhoea, nausea, vomiting and fever, which were not unexpected based on the known safety profiles of ceftazidime and metronidazole.

"We are very encouraged by these results which highlight the potential for CAZ-AVI to provide a much-needed new treatment option for serious and life-threatening intra-abdominal infections, especially where antibiotic resistance poses a threat to treatment," said Briggs Morrison, Executive Vice President, Global Medicines Development & Chief Medical Officer, AstraZeneca.

Studies are also underway for CAZ-AVI in complicated urinary tract infections (cUTI), nosocomial pneumonia and for the treatment of cIAI and cUTI patients with ceftazidime-resistant infections.

The RECLAIM-1 and RECLAIM-2 Phase III studies could form the basis of regulatory submissions seeking approval for a broader range of indications, in line with new EMA guidelines on the evaluation of medicines to treat bacterial infections. EU filing is anticipated in the first quarter of 2015, pending a full analysis of the data from the studies. The results will also be submitted to a scientific meeting in the first half of 2015.

CAZ-AVI is being jointly developed with Forest Laboratories, a wholly-owned subsidiary of Actavis. AstraZeneca holds the global rights to commercialise CAZ-AVI, with the exception of North America where the rights are held by Forest Laboratories.

About RECLAIM

RECLAIM-1 and RECLAIM-2 are Phase III, randomised, multi-centre, double-blind, double-dummy, parallel-group, comparative studies to determine the efficacy, safety, and tolerability of CAZ-AVI administered intravenously as a two hour infusion (2000mg / 500mg, every 8 hours), plus metronidazole, administered intravenously as a 60 minute infusion (0.5g every 8 hours), compared to meropenem, administered intravenously as a 30 minute infusion (1g every 8 hours). A total of 1,066 patients have been randomised to the RECLAIM-1 and RECLAIM-2 trials from 30 countries.

For the EMA, the co-primary analysis was conducted at the Test of Cure (TOC) in the Modified-Intent-to-Treat (MITT) and Clinically Evaluable (CE) patient populations. The non-inferiority margin was 12.5%; and the lower and upper bounds of the 95% confidence interval were -6.9% and 2.10% respectively for the MITT population and -4.61% and 2.89% for the CE population. For the FDA, the primary analysis was conducted at the TOC in the Microbiological Modified Intent-to-Treat (mMITT) population and the non-inferiority margin was 10%. The lower and upper bounds of the 95% confidence interval were -8.64% and 1.58% respectively.

The MITT population included all enrolled patients who received at least one dose of the study drug; the CE population are the patients who completed their course of treatment without deviation from the study protocol; and the mMITT population are those patients from the MITT group who were identified as carrying a pathogen at the start of treatment.

About CAZ-AVI
CAZ-AVI (ceftazidime-avibactam) is an investigational antibiotic being developed to treat serious Gram-negative bacterial infections. It consists of ceftazidime, a third-generation, antipseudomonal cephalosporin, that is an established treatment for serious Gram-negative bacterial infections, and avibactam, a next generation, non-beta lactam beta-lactamase inhibitor.

The addition of avibactam to ceftazidime protects ceftazidime from breakdown by serine-beta-lactamases. CAZ-AVI offers a differentiated profile versus existing treatment options in serious Gram-negative infections through its activity against a broad range of isolates of carbapenem-resistant Enterobacteriaceae and difficult to treat Pseudomonas aeruginosa combined with robust coverage of extended spectrum beta-lactamase-expressing pathogens.

About cIAI
Most intra-abdominal infections (IAI) are a result of processes involving inflammation and perforations of the gastrointestinal tract, such as appendicitis, peptic ulcer disease, and diverticulitis (a common digestive disease which involves the formation of pouches within the bowel wall). IAI is an important cause of morbidity and mortality and it is the second most commonly identified cause of severe sepsis in the intensive care unit.

From a clinical perspective, IAI are classified in two major categories: complicated and uncomplicated. Complicated intra-abdominal infections (cIAI) extend beyond the source organ into the peritoneal space (the space between the two membranes that separate the organs in the abdominal cavity from the abdominal wall). They cause peritoneal inflammation, and are associated with localised or diffuse peritonitis.

Antimicrobial therapy is an important part of the clinical management of IAI. The threat of antimicrobial resistance, however, is one of the major challenges associated with the antimicrobial management of cIAI.

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 August 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: 19 August 2014

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