ASTRAZENECA PLC
Form 6-K
June 28, 2016

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 2016

Commission File Number: 001-11960

AstraZeneca PLC

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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 ANTIBIOTIC ZAVICEFTA APPROVED IN THE EUROPEAN UNION FOR PATIENTS WITH SERIOUS BACTERIAL INFECTIONS

28 June 2016

AstraZeneca today announced that the European Commission (EC) has granted marketing authorisation for Zavicefta (ceftazidime-avibactam, previously known as CAZ AVI), a new combination antibiotic for the treatment of patients with serious Gram-negative bacterial infections requiring hospitalisation.

The approval includes intravenous use of Zavicefta for the treatment of adult patients suffering from complicated intra-abdominal infections (cIAI); Complicated urinary tract infections (cUTI), including pyelonephritis; hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP); and, the treatment of aerobic Gram-negative infections in adult patients who have limited treatment options.

Zavicefta has been developed in response to the urgent need for new antibiotics to treat serious infections that are becoming increasingly resistant, such as multi-drug resistant P. aeruginosa, carbapenem-resistant Gram-negative pathogens, and ESBL-producing Enterobacteriaceae.

Hans Sijbesma, Managing Director, AstraZeneca Antibiotics Business Unit, said: "Zavicefta is an important addition to the arsenal of antibiotics in the global fight against antimicrobial resistance. Effective treatment options are rapidly running out for serious Gram-negative infections. Zavicefta helps bridge that gap and allows a broad population of patients across Europe to benefit from this new medicine."

The approval is based on data from an extensive clinical trial programme demonstrating the safety and efficacy of Zavicefta. The data include results from three Phase III studies in cIAI; Phase II and III studies in cUTI; and data from a Phase I study for HAP/VAP. An additional Phase III study evaluating the efficacy of Zavicefta in ceftazidime-resistant cUTI and cIAI, compared to the best available therapy, was also included in the submission.

The EC marketing authorisation applies to all 28 EU member countries plus Iceland, Norway and Liechtenstein.

About Zavicefta
Zavicefta (ceftazidime-avibactam) is a combination antibiotic that has been developed to treat serious Gram-negative bacterial infections. It consists of a combination of avibactam and ceftazidime - a third generation antipseudomonal cephalosporin with a well-established efficacy and safety profile. Avibactam is a first-in-class broad-spectrum -lactamase inhibitor, which protects ceftazidime against degradation by Class A, C and some D, -lactamases.

The addition of avibactam to ceftazidime protects ceftazidime from breakdown by -lactamases. Zavicefta offers a differentiated profile versus existing treatment options in serious Gram-negative infections through its coverage of a broad range of species of Enterobacteriaceae including those that produce ESBL and KPC, together with activity against difficult-to-treat P. aeruginosa.

Ceftazidime-avibactam is being jointly developed by AstraZeneca and Allergan. AstraZeneca holds the global rights to commercialise Zavicefta, with the exception of North America, where the rights are held by Allergan.

About Antimicrobial Resistance
The increasing resistance to antibiotics is a growing public health concern because of the limited treatment options available for these serious infections. In Europe, antimicrobial resistance causes approximately 25,000 deaths every year, and two-thirds of these deaths are estimated to be due to resistant Gram-negative bacteria1. The clinical burden

associated with antimicrobial resistance is estimated to cost Europe approximately €1.5 billion per year1. At present, 700,000 deaths are estimated to be attributed to antimicrobial resistance globally.2

About Complicated Intra-abdominal Infection (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. In fact, it is the second most commonly identified cause of severe sepsis in the intensive care unit (ICU).

About Complicated Urinary Tract Infection (cUTI)
Complicated urinary tract infections (cUTI) are defined as a clinical syndrome characterised by pyuria and a documented microbial pathogen on culture of urine or blood. Patients usually present with symptoms including fever, chills, malaise, flank pain, back pain, and/or costo-vertebral angle pain or tenderness, that occur in the presence of a functional or anatomical abnormality of the urinary tract or in the presence of catheterisation.

About Hospital-Acquired Pneumonia (HAP) including Ventilator Associated Pneumonia (VAP)
Hospital-acquired pneumonia (HAP) refers to the development of lung infections after a patient has been hospitalised for a minimum of 48 hours. If, after 48 hours, the infection develops during the use of intubation and mechanical ventilation, the condition is then called ventilator associated pneumonia (VAP).

VAP is generally a severe illness, with patients requiring treatment in the intensive care unit (ICU). Some non-intubated patients with HAP can have either mild or more severe pneumonia.

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

References

1. European Centre for Disease Prevention and Control (ECDC). Technical Report: the bacterial challenge: time to react. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500008770.pdf Accessed April 2016.
2. Review on AMR, Antimicrobial resistance: Tackling a crisis for the health and wealth of nations, 2014.

28 June 2016

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: 28 June 2016

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