AstraZeneca

POSITIVE CHMP OPINION FOR CAZ AVI

POSITIVE CHMP OPINION FOR CAZ AVI IN THE EU FOR SERIOUS BACTERIAL INFECTIONS

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion, recommending the approval of a new antibiotic, CAZ AVI 2g/0.5g powder.

CAZ AVI is being developed to treat a broad range of Gram-negative bacterial infections that are increasingly resistant to antibiotics, including multi-drug resistant *P. aeruginosa*, carbapenem-resistant Gram-negative pathogens, and ESBL-producing *Enterobacteriaceae*. Increasing antibiotic resistance in Gram-negative bacteria is a growing public health concern because of the limited new treatment options for these serious infections. In Europe, Gram-negative bacteria are responsible for two thirds of the annually reported 25,000 deaths resulting from antimicrobial resistance.1

The recommendation is for intravenous use in the treatment of adult patients with complicated intra-abdominal infection (cIAI), complicated urinary tract infection (cUTI) including pyelonephritis, and hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP). The CHMP also recommended that CAZ AVI be indicated for the treatment of infections caused by aerobic Gram-negative organisms in adult patients who have limited treatment options.

The CHMP's positive opinion is based on a review of data from an extensive clinical trial programme demonstrating the safety and efficacy of CAZ AVI. The submission included data 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, which evaluated the efficacy of CAZ AVI in ceftazidime-resistant cUTI and cIAI compared to the best available therapy, was also included for consideration.

The CHMP's positive opinion on CAZ AVI will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). The final decision by the EC is expected in the coming months and will be applicable to all 28 EU member countries plus Iceland, Norway and Liechtenstein.

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

About CAZ AVI CAZ AVI is an investigational antibiotic being 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 β-lactamase inhibitor, which protects ceftazidime against degradation by Class A, C and some D, β-lactamases.

The addition of avibactam to ceftazidime protects ceftazidime from breakdown by β-lactamases. CAZ AVI 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*.

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 characterized 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 catheterization.

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 despite 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

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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.

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