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Media and Public Relations

Press release

New medicine to help in the fight against antimicrobial resistance

Zavicefta is recommended for approval for patients with limited treatment options

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Zavicefta (ceftazidime/avibactam), a new treatment option against multi-drug resistant bacteria.

The lack of availability of medicines to treat patients with infections caused by resistant bacteria has become a major problem in recent years. It is estimated that at least 25,000 patients in the EU die each year from infections due to bacteria that are resistant to many medicines.

Zavicefta is a fixed combination of avibactam, a new beta-lactamase inhibitor, and ceftazidime, an antibiotic belonging to the class of third generation cephalosporins that is already approved for use in the EU. Resistance to cephalosporins and to another class of antibiotics, carbapenems, has been increasing lately, in particular in Gram-negative bacteria, and is of major concern. Beta-lactamases are enzymes involved in bacterial resistance to these antibiotics. By inhibiting the action of these enzymes, avibactam restores the activity of ceftazidime against ceftazidime-resistant pathogens. This antibacterial agent also has activity against many of the carbapenem-resistant *Enterobacteriaceae*, an area where there is currently an unmet medical need as patients have very few options available due to resistance to treatment.

The medicine is to be used in adult patients with intra-abdominal infection, urinary tract infection, as well as pneumonia acquired in a hospital setting. It is also indicated for the treatment of adult patients with infections caused by certain Gram-negative bacteria, for which there are only limited treatment options.

The efficacy of Zavicefta against certain Gram-negative bacteria has been demonstrated in the clinical trials that underpin the approval of the indications of intra-abdominal and urinary tract infections, and hospital-acquired pneumonia. The Committee for Medicinal Products for Human use (CHMP) considered that it is beneficial to make Zavicefta available for patients with infections caused by Gram-negative bacteria, when they have few or no therapeutic options to fight the disease, and recommended to include treatment of these patients in the product information on the basis of a limited set of data.



This is in line with EMA's guidance from November 2013 that allows for a flexible approach in the development of new antibiotics for human use, targeting multi-drug resistant pathogens in areas where treatments are needed.

EMA contributes to the European and global effort to tackle antimicrobial resistance. A major area of activity is to create an environment that stimulates and facilitates the development of new antimicrobials. The Agency's activities also include the monitoring and analysis of data on antimicrobials to guide policy and research, as well as the promotion of responsible use.

The opinion adopted by the CHMP at its April 2016 meeting is an intermediary step on Zavicefta's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Zavicefta is AstraZeneca AB.
3. The "Addendum to the guideline on the evaluation of medicinal products indicated for the treatment of bacterial infections in man", which outlines a new approach facilitating the development of antibacterial agents targeted against multidrug-resistant pathogens where patients have very limited or no remaining treatment options, is available [here](#).
4. More information on antimicrobial resistance is available on our website [here](#).
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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