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Media and Public Relations

Press release

New medicine to treat infections in adults

Vabomere, a combination of an antibiotic and new beta-lactamase inhibitor, addresses bacterial resistance

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Vabomere (meropenem trihydrate/vaborbactam), a new treatment option against the following infections in adults:

- Complicated urinary tract infection, including pyelonephritis, a sudden and severe infection causing the kidneys to swell and which may permanently damage them;
- Complicated intra-abdominal infection;
- Hospital-acquired pneumonia, including ventilator associated pneumonia;
- Bacteria in the blood associated with any of the infections listed above;
- Infections due to aerobic Gram-negative organisms in adults with limited treatment options.

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 European Union (EU) die each year from infections due to bacteria that are resistant to many medicines.

Vabomere is a fixed combination of vaborbactam, a new beta-lactamase inhibitor and meropenem, a broad-spectrum antibiotic belonging to the class of carbapenems that is already approved for use in the EU. It is a powder for concentrate for solution for infusion (drip into a vein).

Resistance to 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 beta-lactamases, vaborbactam protects meropenem from being inactivated and restores its activity against many, but not all, carbapenem-resistant pathogens.

In the clinical development program, the exposure to vaborbactam at the recommended dose was shown to be sufficient to protect the activity of meropenem against carbapenem-resistant Enterobacteriaceae. The CHMP also agreed that the studies did not indicate any major concerns regarding the safety profile of meropenem-vaborbactam.

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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 their responsible use.

The opinion adopted by the CHMP is an intermediary step on Vabomere's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once the marketing authorisations 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 is Rempex London Ltd.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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