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New antibiotic to fight infections caused by multidrug-resistant bacteria

22 March 2024

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Infections due to Gram-negative bacteria that are resistant to many currently available antibiotics are a serious public health problem since patients have limited or sometimes no treatment options. Infections due to multidrug-resistant bacteria are estimated to cause 35,000 deaths in the EU every year.

Emblaveo is a fixed-dose combination of two active

substances, aztreonam and avibactam. Aztreonam is already authorised for use in the EU on its own and avibactam is authorised for use in combination with another antibiotic (ceftazidime). Aztreonam is an antibiotic that belongs to the group 'beta-lactams'. It works by attaching to proteins on the surface of the bacteria. This prevents the bacteria from building their cell walls, which kills them.

Avibactam blocks the action of many of the bacterial enzymes called beta-lactamases. These enzymes enable bacteria to break down beta-lactam antibiotics, such as aztreonam, making them resistant to the antibiotic's action. By blocking these enzymes, avibactam restores the activity of aztreonam against aztreonam-resistant bacteria.

Emblaveo will be available to be given by infusion into a vein.

EMA's human medicines committee (CHMP) considered that the benefits of Emblaveo outweigh its risks for patients with infections caused by Gram-negative bacteria when they have few or no therapeutic options to fight the disease. Aztreonam has been shown to be effective at treating a range of serious infections. Microbiology data indicate that aztreonam in combination with avibactam will be effective in infections caused by many multidrug-resistant aerobic Gram-negative pathogens and the combination could therefore address an unmet medical need.

Emblaveo was evaluated under EMA's accelerated assessment mechanism because it is considered to be of major public health interest.

EMA's recommendation is based on the safety and efficacy data already available for each active substance and the results of two phase III randomised studies submitted by the applicant. The studies were not designed to demonstrate efficacy but do provide safety and complementary data for the combination. This is in line with [EMA's guideline](#) that allows for a flexible approach in the development of new antibiotics for human use targeting multidrug-resistant pathogens for which new treatments are needed.

The most frequent side effects in patients treated with Emblaveo were a decrease in the number of red blood cells,

elevated levels of liver transaminase and diarrhoea. This is in line with the documented safety information available for each individual substance.

The opinion adopted by the CHMP is an intermediary step on Emblaveo'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 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 or use of this medicine in the context of the national health system of that country.

Notes:

- The applicant for Emblaveo is Pfizer Europe Ma EEIG.
- Avibactam, in combination with ceftazidime, is authorised for use in the EU as [Zavicefta](#).
- Aztreonam is authorised for use in the EU as [Cayston](#).

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