EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2018
EMA/CHMP/447907/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xerava

eravacycline

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xerava, intended for the treatment of complicated intra-abdominal infections in adults. The applicant for this medicinal product is Tetraphase Pharmaceuticals Ireland Limited.

Xerava will be available as a 50-mg powder for concentrate for solution for infusion. The active substance of Xerava is eravacycline, a fluorocycline belonging to the tetracycline group of antibiotics (ATC code: J01AA13). Eravacycline inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit, thus preventing the incorporation of amino acid residues into elongating peptide chains.

The benefits with Xerava are its ability to effectively treat complicated intra-abdominal infections. The most common side effects are nausea, vomiting and infusion site phlebitis.

The full indication is:

> "Xerava is indicated for the treatment of complicated intra-abdominal infections (cIAI) in adults (see sections 4.4 and 5.1).
>
> Consideration should be given to official guidance on the appropriate use of antibacterial agents."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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