EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/CHMP/257409/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Arikayce liposomal

amikacin

On 23 July 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Arikayce liposomal,[2] intended for the treatment of non-tuberculous mycobacterial (NTM) lung infections caused by *Mycobacterium avium* Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis. The applicant for this medicinal product is Insmed Netherlands B.V.

Arikayce liposomal will be available as a 590-mg nebuliser dispersion[3]. The active substance of Arikayce liposomal is amikacin, a well-established aminoglycoside antibacterial (ATC code: J01GB06), the mode of action of which is disruption of production of vital bacterial proteins.

The benefits with Arikayce liposomal are its ability to treat the above-mentioned infections effectively. The most common side effects are nephrotoxicity, ototoxicity and effects on neuromuscular conditions that may be due to chronic exposure to amikacin.

The full indication is:

> Arikayce liposomal is indicated for the treatment of non-tuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium Complex (MAC) in adults with limited treatment options who do not have cystic fibrosis (see sections 4.2, 4.4 and 5.1).
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> 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
[2] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained
[3] Correction from suspension to dispersion.

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