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Press Office

**Press release**

# European Medicines Agency recommends two new treatment options for tuberculosis

## Both medicines target multidrug-resistant forms of the disease

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the authorisation of Deltyba (delamanid) and Para-aminosalicylic acid Lucane (para-aminosalicylic acid), two treatment options for use in combination with other medicines against multidrug-resistant tuberculosis.

Multidrug-resistant tuberculosis is defined as tuberculosis caused by *Mycobacterium tuberculosis* that is resistant to at least isoniazid and rifampicin, which are two anti-tuberculosis medicines used in standard treatment. Approximately 450,000 cases of multidrug-resistant tuberculosis occur globally every year, which corresponds to approximately 5% of the world's annual burden of tuberculosis. In the European Union, tuberculosis is an orphan indication. It was estimated in 2011 to occur in 2.3 out of 10,000 people.

Multidrug-resistant tuberculosis is associated with a very high mortality rate and poses a significant public-health threat as individuals infected with drug-resistant strains are unable to receive adequate treatment and can potentially spread their infection.

**Conditional marketing authorisation recommended for Deltyba**

The CHMP recommended granting a conditional marketing authorisation for Deltyba (delamanid), for the treatment of adult patients with pulmonary infections due to multidrug-resistant tuberculosis when an effective treatment regimen cannot otherwise be devised for reasons of resistance or tolerability.

The Committee considered that Deltyba responds to the high unmet need for new treatment options for pulmonary multidrug-resistant tuberculosis. The data supplied by the applicant show that the medicine's benefits outweigh its risks but are not yet comprehensive, therefore the CHMP concluded that additional studies on the long-term effectiveness of Deltyba should be conducted.

This is the outcome of a re-examination of the CHMP's previous recommendation to refuse granting of a marketing authorisation for Deltyba adopted on 25 July 2013.

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**Marketing authorisation recommended for Para-aminosalicylic acid Lucane**

The Committee also recommended granting a marketing authorisation for Para-aminosalicylic acid Lucane against multidrug-resistant tuberculosis in adults and paediatric patients when an effective treatment regimen cannot otherwise be devised for reasons of resistance or tolerability.

Para-aminosalicylic acid, of which Para-aminosalicylic acid Lucane is a new formulation, was the second medicine to be introduced for the treatment of tuberculosis, in 1946, and was part of standard-of-care treatment until the 1970s. Its use resumed in the 1990s with the emergence of multidrug-resistant tuberculosis. Para-aminosalicylic acid Lucane is currently available in France in a compassionate-use programme.

The approval of these two medicines highlights the Agency's ongoing efforts to tackle the growing public-health challenge of antibacterial resistance.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Deltyba is Otsuka Novel Products GmbH.
3. The applicant for Para-aminosalicylic acid Lucane is Lucane Pharma SAS.
4. Deltyba and Para-aminosalicylic acid Lucane have both been designated as orphan medicinal products.
5. A question-and-answer document on the outcome of the re-examination of Deltyba is available here: http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/human/002552/WC500155462.pdf
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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