EUROPEAN MEDICINES AGENCY
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Press Office

Press release

European Medicines Agency recommends approval of a new medicine for multidrug-resistant tuberculosis

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a conditional marketing authorisation for Sirturo (bedaquiline) for use as part of a combination therapy for pulmonary multidrug-resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

Tuberculosis is an infection caused by *Mycobacterium tuberculosis* that primarily affects the lungs. In the European Union, tuberculosis is an orphan indication and was estimated in 2011 to occur in 2.3 out of 10,000 people. Multidrug-resistant tuberculosis is defined as tuberculosis that is resistant to at least isoniazid and rifampicin, which are two major 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 recent years, the burden of tuberculosis resistant to first-line therapy has increased rapidly in the absence of new treatment options. Multidrug-resistant tuberculosis is associated with a 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.

Sirturo is the first representative of a new class of medicines against mycobacteria. The Committee considered that Sirturo could contribute to responding to the high unmet medical need for new treatment options for pulmonary multidrug-resistant tuberculosis. It recommended granting conditional marketing authorisation because, although the data supplied by the applicant show that the medicine's benefits outweigh its risks, the data are not yet comprehensive. Therefore, additional studies on the use of Sirturo should be conducted.

Sirturo is the third positive opinion recently granted by the CHMP for a medicine to be used in the treatment of multidrug-resistant tuberculosis, after the November 2013 recommendations for Deltyba (also for a conditional approval) and Para-aminosalicylic acid Lucane. This highlights the Agency's ongoing efforts to tackle the growing public-health challenge of antibacterial resistance.

The CHMP opinion on Sirturo will now be sent to the European Commission for the adoption of a marketing-authorisation decision.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Sirturo is Janssen-Cilag International N.V.
3. Sirturo has been designated as an orphan medicinal product.
4. More information on the positive opinions granted by the CHMP in November 2013 for the approval of Deltyba and Para-aminosalicylic acid Lucane can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/11/WC500155472.pdf.
5. Conditional approval allows the marketing authorisation of medicines that target areas of unmet medical need before comprehensive data sets are available, to speed up patient access to much needed new medicines.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu