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Press Office

Press release

Lux Biosciences GmbH withdraws its marketing authorisation application for Luveniq (voclosporin)

The European Medicines Agency has been formally notified by Lux Biosciences GmbH of its decision to withdraw its application for a centralised marketing authorisation for the medicine Luveniq (voclosporin), 10 mg soft capsules.

Luveniq was intended to be used for the treatment of patients with chronic non-infectious uveitis involving the posterior or intermediate segments of the eyes as characterised by a high degree of inflammation and in whom corticosteroids are inappropriate, do not provide adequate control, or cannot be tapered below 10mg/day. Voclosporin was designated an orphan medicinal product on 14 September 2007.

The application for the marketing authorisation for Luveniq was initially submitted to the Agency on 10 February 2010 and the medicine received a negative opinion by the Committee for Medicinal Products for Human Use (CHMP) on 23 June 2011. The company submitted a re-examination request for Luveniq on 8 July 2011. At the time of the withdrawal it was under review by the CHMP.

In its official letter, the company stated that they were unable to demonstrate to the satisfaction of the CHMP an overwhelming effect showing that the benefits of Luveniq outweigh its risks, and thus would qualify for a recommendation for authorisation with one pivotal study only.

More information about Luveniq and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company will be published on the Agency's website after the CHMP meeting on 17-20 October 2011.

Notes

1. This press release is available on the Agency's website.
2. The CHMP Assessment Report will be published on the Agency's website at later stage.

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3. The questions and answers document on the refusal of the marketing authorisation for Luveniq can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/002069/WC500109123.pdf

4. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.

5. The company informed the CHMP that withdrawal does not have any consequences on any ongoing clinical trials or compassionate use program.

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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