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Questions and answers

Withdrawal of the marketing authorisation application for Luveniq (voclosporin)

On 13 October 2011, Lux Biosciences GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Luveniq, for the treatment of chronic active non-infectious uveitis involving the intermediate or posterior segments of the eye.

What is Luveniq?

Luveniq is a medicine that contains the active substance voclosporin. It was to be available as capsules to be taken by mouth.

What was Luveniq expected to be used for?

Luveniq was expected to be used to treat chronic active non-infectious uveitis involving the intermediate or posterior segments of the eye. Uveitis is inflammation of the uvea (the middle layer of the eye) which can lead to loss of vision. It is called 'non-infectious' when it is caused by the body's own immune system (the body's natural defences) attacking the uvea.

Luveniq was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 14 September 2007 for the treatment of chronic non-infectious uveitis.

How is Luveniq expected to work?

Luveniq is an immunosuppressive agent, which means that it reduces the activity of the immune system. It belongs to the class of calcineurin inhibitors. It targets T-cells, a type of white blood cell in the immune system that is particularly active in inflammation. It was expected to decrease the inflammation seen in uveitis by blocking an enzyme called calcineurin which is involved in activating T-cells.

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What did the company present to support its application?

The effects of Luveniq were first tested in experimental models before being studied in humans. The application was supported by one main study involving 218 patients with non-infectious uveitis which compared Luveniq with placebo. The patients were treated for at least 24 weeks. The main measure of effectiveness was how the inflammation of the eye improved after 16 weeks and 24 weeks of treatment, measured by looking at the change in the amount of vitreous haze (clouding of the vitreous humour, the clear gel between the lens and the retina of the eyeball).

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had given a negative opinion. The company had requested a re-examination of the negative opinion, but this re-examination had not yet finished when the company withdrew the application.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had previously given a negative opinion in June 2011 recommending that the marketing authorisation be refused for Luveniq for the treatment of chronic active non-infectious uveitis involving the intermediate or posterior segments of the eye.

At the time of the negative opinion, the CHMP was not convinced that the benefits of Luveniq had been shown to outweigh the risks as a treatment for chronic non-infectious uveitis. Only one main study supported the application and the results did not show in a robust way that Luveniq was more effective than placebo at reducing eye inflammation, while no difference was seen in the patients' eyesight compared with placebo. Luveniq also caused side effects which are known to occur with this type of immunosuppressive medicine, including hypertension (high blood pressure). Therefore, the CHMP was of the opinion that the benefits of Luveniq had not been shown to outweigh its risks and recommended that it be refused marketing authorisation.

What were the reasons given by the company for withdrawing the application?

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no consequences for patients included in ongoing clinical trials. If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

The summary of the opinion of the Committee for Orphan Medicinal Products for Luveniq can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.