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Questions and answers

Refusal of the marketing authorisation for Adlumiz (anamorelin hydrochloride)

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Adlumiz, intended for the treatment of anorexia, cachexia or unintended weight loss in patients with non-small cell lung cancer.

The company that applied for authorisation is Helsinn Birex Pharmaceuticals Ltd. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Adlumiz?

Adlumiz is a medicine that contains the active substance anamorelin hydrochloride. It was to be available as 100 mg tablets to be taken by mouth.

What was Adlumiz expected to be used for?

Adlumiz was expected to be used to treat anorexia (loss of appetite), cachexia (a form of muscle wasting with significant weight loss) or unintended weight loss in patients with a type of lung cancer called non-small cell lung cancer.

How does Adlumiz work?

Adlumiz attaches to and activates a target on cells called a ghrelin receptor. Activation of the receptor causes release of substances in the body which are expected to act in the brain to increase appetite and prevent weight loss.

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What did the company present to support its application?

The company presented results of two main studies involving a total of around 1,000 non-small cell lung cancer patients with cachexia. Patients were given either Adlumiz or placebo (a dummy treatment) and the main measures of effectiveness were changes in lean body mass (body weight excluding fat) and hand grip strength.

What were the CHMP's main concerns that led to the refusal?

The CHMP concluded that the studies show a marginal effect of Adlumiz on lean body mass and no proven effect on hand grip strength or patients' quality of life. In addition, following an inspection at clinical study sites, CHMP considered that the safety data on the medicine had not been recorded adequately. This meant that a thorough evaluation of potential risks with Adlumiz was not possible.

Therefore the CHMP was of the opinion that the benefits of Adlumiz did not outweigh its risks and recommended that it be refused marketing authorisation.

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

The company informed the CHMP that there are no ongoing clinical trials or compassionate use programmes in Europe with Adlumiz.