21 November 2014
EMA/705109/2014
EMEA/H/C/002637

Questions and answers

Withdrawal of the marketing authorisation application for Egranli (balugrastim)

On 4 November 2014, Teva Pharma B.V. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Egranli, for reduction in the duration of neutropenia and the occurrence of febrile neutropenia in adult cancer patients.

What is Egranli?

Egranli is a medicine that contains the active substance balugrastim. It was to be available as a solution for injection in prefilled syringes.

What was Egranli expected to be used for?

Egranli was to be used to reduce the duration of neutropenia (abnormally low level of neutrophils, a type of white blood cell that fights infection) and the occurrence of febrile neutropenia (neutropenia with fever) in adult cancer patients receiving cytotoxic chemotherapy (medicines that treat cancer by killing cells).

How is Egranli expected to work?

The active substance in Egranli, balugrastim, is made up of 'granulocyte-colony-stimulating factor' (G-CSF), a naturally occurring protein in the body that promotes the production of white blood cells including neutrophils in the bone marrow. The G-CSF in Egranli is attached to another natural blood protein called albumin, which decreases the rate at which G-CSF is removed from the body and allows the medicine to have a longer duration of action and to be given less often.

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Balugrastim acts in the same way as naturally produced G-CSF, increasing the production of neutrophils and thereby helping to reduce the duration of neutropenia and to prevent febrile neutropenia (a sign of infection) in patients undergoing chemotherapy.

What did the company present to support its application?

Egranli was investigated in a main study in 304 breast cancer patients receiving chemotherapy, in which it was compared with another medicine containing a different long-acting G-CSF called pegfilgrastim. The main measure of effectiveness was the reduction in the duration of neutropenia and of the number of febrile neutropenia cases.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had given a positive opinion. The company withdrew before the European Commission had issued a decision on this opinion.

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 given a positive opinion, recommending that a marketing authorisation be granted for Egranli for the reduction of the duration of neutropenia and of the occurrence of febrile neutropenia.

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

In its letter notifying the Agency of the withdrawal of application, the company stated that it was withdrawing the application on the basis of its marketing strategy, and that it wished to focus on other projects. The withdrawal letter is available here.

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

The company informed the CHMP that there is no impact on patients as there are no ongoing clinical trials or compassionate use programmes using Egranli.