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Questions and answers

Withdrawal of the marketing authorisation application for Zafiride (NGR-human tumour necrosis factor alpha)

On 1 June 2017, MolMed S.p.A. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Zafiride for the treatment of advanced malignant pleural mesothelioma.

What is Zafiride?

Zafiride is a medicine containing the active substance NGR-human tumour necrosis factor alpha. It was to be available as a solution for infusion (drip) into a vein.

What was Zafiride expected to be used for?

Zafiride was expected to be used for treating adults with advanced malignant pleural mesothelioma, a cancer of the lining of the lungs usually caused by exposure to asbestos.

The medicine was intended for those patients whose cancer has worsened within 6 months of treatment with cancer medicines including pemetrexed.

Zafiride was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 3 June 2008 for malignant mesothelioma. Further information on the orphan designation can be found here.

How does Zafiride work?

The active substance in Zafiride is thought to work by attaching to targets called CD13 and TNF receptors, found on new blood vessels forming around tumours. Once attached to these receptors, it damages the walls of the blood vessels supplying the tumours, thereby helping to slow down the growth of the cancer.

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What did the company present to support its application?

The company's application included results from a main study in 400 patients which looked at how long patients lived when treated with Zafiride in combination with other cancer medicines. Zafiride was compared with placebo (a dummy treatment), and all patients in the study had previously been treated with pemetrexed-based chemotherapy.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

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 concerns and was of the provisional opinion that Zafiride could not be approved for the second-line treatment of advanced malignant pleural mesothelioma in patients whose disease had worsened within 6 months of treatment with pemetrexed.

The CHMP noted there was inadequate information in several areas of the application, including on the manufacture of the medicine, its testing in humans and animals and its safety. With regard to the medicine's effectiveness, the main study did not show convincingly that Zafiride was better than placebo at prolonging lives in the intended patients. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Zafiride did not outweigh its risks.

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

In its letter notifying the Agency of the withdrawal of the application, the company stated that it would be unable to provide requested data on the medicine's manufacture within the required time frame. 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 are no consequences for patients currently included in clinical trials or compassionate use programmes using Zafiride.

If you are in a clinical trial or compassionate use programme and need more information about your treatment, contact the doctor who is giving it to you.