EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Withdrawal of the marketing authorisation application for Qinprezo (vosaroxin)

On 10 May 2017, Sunesis Europe Ltd officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for the cancer medicine Qinprezo, intended to be used in combination with cytarabine for the treatment of acute myeloid leukaemia (AML).

What is Qinprezo?

Qinprezo is a medicine that contains the active substance vosaroxin. It was to be available as a solution for injection into a vein.

What was Qinprezo expected to be used for?

Qinprezo was expected to be used, in combination with the cancer medicine cytarabine, to treat adult patients 60 years of age and older with AML, a type of cancer of the white blood cells. Qinprezo was for use in patients whose cancer had come back (relapsed) or had not responded to previous treatment (refractory).

How does Qinprezo work?

The active substance in Qinprezo, vosaroxin, works by blocking an enzyme called topoisomerase II. This enzyme is involved in making copies of DNA (a cell's genetic material) when the cell divides. By blocking the enzyme, vosaroxin prevents cancer cells from dividing, eventually killing them.

What did the company present to support its application?

The company presented data from one main study in a total of 711 patients aged 18 years and older with relapsed or refractory AML, in which Qinprezo given with cytarabine was compared with

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cytarabine on its own. The main measure of effectiveness was overall survival (how long patients lived).

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated lists of questions.

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 several concerns and was of the provisional opinion that Qinprezo could not have been approved for the treatment of patients 60 years of age and older with relapsed or refractory AML.

The CHMP was concerned that the data the company had provided, which were based on one main study only, did not provide compelling evidence of benefit. In addition, no beneficial effect was seen in overall survival in those patients 60 years of age and older whose cancer came back late and there were also concerns of an increased rate of infection in these patients.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Qinprezo 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 its decision to withdraw was based on the fact that the application was unlikely to receive approval in the EU, since data from the main study were not convincing enough, and the company had chosen to focus their resources on other priorities.

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 ongoing company-sponsored clinical trials with Qinprezo, although there are studies by academic investigators that are ongoing or planned. The company intends to make Qinprezo available to appropriate patients via a managed access programme.

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