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Questions and answers

Withdrawal of the marketing authorisation application for Rasival (aliskiren / valsartan)

On 15 September 2010, Novartis Europharm Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Rasival, for the treatment of essential hypertension in adults whose blood pressure is already adequately controlled with a combination of aliskiren and valsartan taken separately.

What is Rasival?

Rasival is a medicine that contains the active substances aliskiren and valsartan. It was to be available as film-coated tablets.

What was Rasival expected to be used for?

Rasival was expected to be used to treat essential hypertension (high blood pressure) in adults whose blood pressure is already adequately controlled with a combination of aliskiren and valsartan taken separately. 'Essential' means that the hypertension has no obvious cause.

How is Rasival expected to work?

The two active substances in Rasival are anti-hypertensive medicines that are already in use in the European Union (EU).

Aliskiren reduces the production of the angiotensin II (a hormone that narrows blood vessels), while valsartan blocks the receptors to which angiotensin II normally attaches. By blocking the activity of angiotensin II, Rasival acts to widen blood vessels and so lower blood pressure.

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What did the company present to support its application?

The effects of Rasival were first tested in experimental models before being studied in humans.

The company presented results of studies designed to show that the tablet containing the two substances is absorbed in the body in the same way as the separate tablets. In addition, one main study was carried out in around 1,200 patients with essential hypertension. Patients received either Rasival or a medicine containing only one of the active substances, aliskiren or valsartan, for eight weeks. The main measure of effectiveness was the average change in the blood pressure.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn at 'day 180'. This means that the CHMP had evaluated the documentation provided by the company and formulated a list of questions. The company had not yet responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP list of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Rasival could not have been approved for the treatment of essential hypertension.

The CHMP wanted further studies to be carried out on how Rasival behaved in the body, specifically after a patient has eaten food. In addition, the CHMP was not convinced that the company had demonstrated that the combination of aliskiren and valsartan is widely used in clinical practice.

Therefore, at the time of the withdrawal, the CHMP was of the opinion the company had not provided enough scientific data to support the application for Rasival.

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 in clinical trials or compassionate use programmes, as there are no ongoing trials with Rasival.