22 July 2022
EMA/641196/2022
EMEA/H/C/005893

Withdrawal of application for the marketing authorisation of Parsaclisib Incyte Biosciences Distribution B.V. (parsaclisib)

Incyte Biosciences Distribution B.V. withdrew the application for a marketing authorisation of its medicine, Parsaclisib Incyte Biosciences Distribution B.V., for the treatment of marginal zone lymphoma, a cancer of the white blood cells.

The company withdrew the application on 27 June 2022.

What is Parsaclisib Incyte Biosciences Distribution B.V. and what was it intended to be used for?

Parsaclisib Incyte Biosciences Distribution B.V. was developed as a medicine to treat adults with marginal zone lymphoma (MZL), a cancer of a type of white blood cell called B lymphocytes or B cells. In this disease, abnormal B lymphocytes multiply too quickly and live for too long. The medicine was intended to be used on its own in patients whose cancer had returned or not responded to at least one previous cancer treatment.

Parsaclisib Incyte Biosciences Distribution B.V. contains the active substance parsaclisib and was to be available as tablets.

Parsaclisib Incyte Biosciences Distribution B.V. was designated an 'orphan medicine' (a medicine used in rare diseases) on 25 July 2019 for the treatment of MZL. Further information on the orphan designation can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3192185

How does Parsaclisib Incyte Biosciences Distribution B.V. work?

Parsaclisib blocks the effects of an enzyme called phosphatidylinositol-3-kinase which plays a role in the growth and survival of white blood cells. This enzyme is overactive in patients with MZL. By blocking it, parsaclisib was expected to cause the death of the cancer cells, thereby delaying, or stopping disease progression.

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What did the company present to support its application?

The company provided results from a main study which evaluated the effect of the medicine on its own in 100 patients with MZL that had returned after, or not responded to, at least one previous cancer treatment. In this study, the medicine was not compared with any other treatment and the main measure of effectiveness was the proportion of patients who showed a response to treatment (partial or complete response).

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had some concerns, and its provisional opinion was that Parsaclisib Incyte Biosciences Distribution B.V. could not have been authorised.

The Agency had some concerns, including the fact that there was no comparator in the main study, some data on how the body processes the medicine were missing, and there was not enough justification for the dosing regimen. As the company had applied for a conditional marketing authorisation, the Agency also noted that the company had not shown that its medicine has advantages over existing treatments. Finally, there were some questions about the manufacturing process and quality of the medicine.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Parsaclisib Incyte Biosciences Distribution B.V. 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 was not able to satisfactorily address the Agency's concerns, namely regarding the study design and the feasibility of conducting further studies.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Parsaclisib Incyte Biosciences Distribution B.V.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.