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Withdrawal of application for the marketing authorisation of Sitoiganap (allogeneic and autologous haptenised and irradiated cells and cell lysates derived from glioma)

Epitopoietic Research Corporation-Belgium (E.R.C.) withdrew its application for a marketing authorisation of Sitoiganap to treat adults with a type of brain cancer called malignant glioma, that is progressive (continues to grow) or recurrent (has come back) after treatment.

The company withdrew the application on 2 May 2022.

What is Sitoiganap and what was it intended to be used for?

Sitoiganap was intended for use in adults to treat progressive or recurrent malignant glioma, a very aggressive type of brain cancer that affects the 'glial' cells (the cells that surround and support the nerve cells).

The medicine is prepared from the patient's own cancer cells (autologous cells) and cancer cells from other patients (allogeneic cells), which are modified in the laboratory (haptenised and irradiated).

Sitoiganap was to be given as an injection into the skin.

Sitoiganap was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 January 2014 for the treatment of glioma. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu3131211.

How does Sitoiganap work?

Sitoiganap is expected to work by activating the patient's immune system (the body's natural defences) so that it attacks and kills the cancer cells. When the modified cells are injected into the patient, it is expected that the allogeneic cancer cells will help the immune system recognise the patient's own cancer cells as 'foreign' and stimulate an immune response against them, helping to slow down or stop the progression of the disease.

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What did the company present to support its application?

The company presented the results of one main study involving 26 patients with malignant glioma, where Sitoiganap was compared with placebo (a dummy treatment), both taken with bevacizumab (another cancer medicine). Patients who received Sitoiganap plus bevacizumab were also given GM-CSF and cyclophosphamide (two medicines to stimulate the immune response). The main measures of effectiveness were how long the patients lived and how long the patients lived without their disease getting worse.

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

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still unresolved issues.

What did the Agency recommend at that time?

Based on the review of the available information, at the time of the withdrawal, the Agency had concerns and its provisional opinion was that Sitoiganap could not have been authorised for the treatment of glioma.

The Agency had concerns about the way the medicine was produced and the documentation describing the manufacturing process, leading to uncertainties about the quality of the medicine. The Agency also considered that the non-clinical studies did not demonstrate how the medicine is supposed to work in patients with glioma. Adding to these concerns, the results of the main study were not robust enough to show that Sitoiganap was effective at treating patients with glioma, and the safety profile of the medicine could not be established.

Therefore, at the time of the withdrawal, the Agency was not able to draw conclusions on the effectiveness of Sitoiganap in treating glioma and its opinion was that the benefits of Sitoiganap in this use 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 the decision was based on the need to collect further data to address EMA's concerns.

Does this refusal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Sitoiganap.

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