EMA/478271/2017
EMEA/H/C/004338

EPAR summary for the public

Bavencio

avelumab

This is a summary of the European public assessment report (EPAR) for Bavencio. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Bavencio.

For practical information about using Bavencio, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bavencio and what is it used for?

Bavencio is a cancer medicine used to treat adults with Merkel cell carcinoma (MCC), a type of skin cancer, when the cancer has spread to other parts of the body.

Because the number of patients with MCC is low, the disease is considered 'rare', and Bavencio was designated an 'orphan medicine' (a medicine used in rare diseases) on 14 December 2015.

Bavencio contains the active substance avelumab.

How is Bavencio used?

Bavencio can only be obtained with a prescription, and treatment should be started and monitored by a doctor experienced in the treatment of cancer.

Bavencio is given as an infusion (drip) into a vein lasting around 1 hour, once every 2 weeks. The dose depends on body weight. Treatment should continue as long as the patient benefits from it or side effects become unacceptable.

Before the first 4 infusions of Bavencio, the patient receives an antihistamine and paracetamol to help prevent infusion-related reactions, such as reddening of the skin, chills, fever, back or abdominal

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(belly) pain, allergic reactions and difficulty breathing. If no reactions have occurred by the fourth infusion, the treating doctor may decide to stop giving these medicines before subsequent infusions.

How does Bavencio work?

The active substance in Bavencio, avelumab, is a monoclonal antibody, a type of protein designed to recognise and attach to a protein called 'programmed death-ligand-1' (PD-L1), which is present on the surface of many cancer cells. PD-L1 usually attaches to cells of the immune (defence) system called T cells, preventing the T cells from attacking the cancer cells. By attaching to PD-L1, Bavencio prevents the cancer cells from switching off the T cells, thereby increasing the ability of the T cells to kill the cancer cells.

What benefits of Bavencio have been shown in studies?

Bavencio can reduce tumour size in some patients, leading to either partial responses or complete response (when no signs of the cancer remain).

In a main study involving 88 patients with metastatic MCC who had received previous treatment with chemotherapy (cancer medicines), around 33% of patients (29 out of 88) were considered to have had a complete or partial response to the medicine; in most of these patients, the response lasted for at least 6 months.

Early results from an ongoing study looking at the effects of Bavencio in patients with metastatic MCC who had not received previous chemotherapy showed that the complete or partial response rate at the time of analysis was 62% (18 out of 29 patients).

What are the risks associated with Bavencio?

The most common side effects with Bavencio (which may affect more than 1 in 10 people) include tiredness, nausea (feeling sick), diarrhoea, decreased appetite, constipation, infusion-related reactions, weight loss and vomiting. Serious side effects include immune-related and infusion-related reactions, anaemia (low red blood cell counts), difficulty breathing and abdominal pain.

For the full list of all side effects and restrictions with Bavencio, see the package leaflet.

Why is Bavencio approved?

Patients with MCC that has spread and come back after initial treatment with chemotherapy have very limited treatment options. Although the response rates to Bavencio are not outstanding, the duration of the response (at least 6 months) is important for these patients, since the responses seen with chemotherapy medicines are of shorter duration. In addition, early data from an ongoing study indicate that the majority of patients who have not had previous chemotherapy also respond to treatment with Bavencio, with a similar duration of response. The safety of Bavencio is considered acceptable and side effects manageable with the additional measures put in place.

The European Medicines Agency therefore decided that Bavencio's benefits are greater than its risks and recommended that it be approved for use in the EU.

Bavencio has been given 'conditional approval'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Bavencio?

Since Bavencio has been granted a conditional approval, the company that markets the medicine will provide further data from the ongoing study of patients who did not receive chemotherapy before starting treatment with Bavencio.

What measures are being taken to ensure the safe and effective use of Bavencio?

The company that markets Bavencio will issue educational materials for healthcare professionals and patients containing important information about possible side effects of Bavencio, particularly immune-related reactions, and how to manage them.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Bavencio have also been included in the summary of product characteristics and the package leaflet.

Other information about Bavencio

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Bavencio on 18 September 2017.

The full EPAR for Bavencio can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Bavencio, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Bavencio can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 09-2017.