EMA/357238/2019
EMEA/H/C/004844

Libtayo (*cemiplimab*)

An overview of Libtayo and why it is authorised in the EU

What is Libtayo and what is it used for?

Libtayo is a cancer medicine used on its own to treat adults with a type of skin cancer called cutaneous squamous cell carcinoma when the cancer is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body). It is used in patients who cannot have surgery or treatment with radiation to cure their disease.

Libtayo contains the active substance cemiplimab.

How is Libtayo used?

Treatment with Libtayo must be started and supervised by a doctor experienced in treating cancer. The medicine can only be obtained with a prescription.

Libtayo is given as an infusion (drip) into a vein lasting 30 minutes. The recommended dose is 350 mg once every 3 weeks. Treatment can continue for as long as the disease remains stable and the patient does not experience unacceptable side effects. The doctor may need to delay doses if certain side effects occur, or stop treatment altogether if side effects are severe.

For more information about using Libtayo, see the package leaflet or contact your doctor or pharmacist.

How does Libtayo work?

The active substance in Libtayo, cemiplimab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a receptor (target) called PD-1 found on certain cells of the immune system called T cells. Cancer cells can make proteins (PD-L1 and PD-L2) that attach to this receptor and switch off the activity of the T cells, preventing them from attacking the cancer. By attaching to the receptor, cemiplimab prevents PD-L1 and PD-L2 from switching off the T cells, thereby increasing the ability of the immune system to kill cancer cells.

What benefits of Libtayo have been shown in studies?

Libtayo is effective at treating cutaneous squamous cell carcinoma in many patients. In a main study involving a total of 193 patients, the cancer shrank in around 39% of patients with metastatic disease

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who received 350 mg Libtayo every 3 weeks for around one year. Among patients with locally advanced disease who received Libtayo every 2 weeks (at a dose of 3 mg/kg bodyweight) for around 2 years, 44% of patients showed shrinkage of their cancer.

What are the risks associated with Libtayo?

Libtayo is associated with side effects related to the activity of the immune system, which can be serious, although most side effects go away with appropriate treatment or on stopping Libtayo. The most common immune-related effects (which may affect up to 1 in 10 people) were hypothyroidism (an underactive thyroid gland with tiredness, weight gain, and skin and hair changes), pneumonitis (inflammation in the lungs causing shortness of breath and cough), skin reactions, hyperthyroidism (an overactive thyroid gland which can cause hyperactivity, sweating, weight loss and thirst) and hepatitis (inflammation of the liver).

Severe reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis (life-threatening reactions with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals) have been reported with Libtayo.

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

Why is Libtayo authorised in the EU?

Libtayo is effective at treating cutaneous squamous cell carcinoma, a cancer with few treatment options once it has spread. However, the study involved a small number of patients and additional data are required. As for the medicine's safety, its side effects are manageable and similar to those seen in other cancer treatments of this type. The European Medicines Agency therefore decided that Libtayo's benefits are greater than its risks and it can be authorised for use in the EU.

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

What information is still awaited for Libtayo?

Since Libtayo has been given conditional authorisation, the company that markets Libtayo will provide data from an ongoing study on the effectiveness and safety of the medicine for cutaneous squamous cell carcinoma. The company will also investigate whether the medicine works differently depending on the levels of PD-L1 produced by the cancer cells.

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

The company that markets Libtayo will provide a guide and an alert card for patients with information on the signs and symptoms of immune-related side effects of the medicine, as well as instructions on contacting their doctor if they experience symptoms.

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

As for all medicines, data on the use of Libtayo are continuously monitored. Side effects reported with Libtayo are carefully evaluated and any necessary action taken to protect patients.

Other information about Libtayo

Libtayo received a conditional marketing authorisation valid throughout the EU on 28 June 2019.

Further information on Libtayo can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/libtayo.

This overview was last updated in 06-2019.