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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 in adults to treat:

- a type of skin cancer called cutaneous squamous cell carcinoma. It is used on its own in adults who cannot have surgery or treatment with radiation to cure their disease when the cancer is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body). It is also used on its own as adjuvant treatment (given after surgery or radiation to prevent the cancer from coming back) following surgery and radiation in adults with cutaneous squamous cell carcinoma that has a high risk of coming back;
- a type of skin cancer called basal cell carcinoma (BCC) when the cancer is locally advanced or metastatic. It is used in adults who cannot tolerate treatment with a type of medicine called a 'hedgehog pathway inhibitor (HHI)' or whose disease has worsened after such treatment;
- a type of lung cancer called non-small cell lung cancer (NSCLC) when the cancer is locally advanced and cannot be treated with chemotherapy (medicines to treat cancer) and radiation therapy, or when the cancer is metastatic. It is used either alone in adults whose tumours have a protein called PD-L1 in more than 50% of cells and no mutations in the genes *EGFR, ALK* and *ROS1* involved in the development of NSCLC, or together with platinum-based chemotherapy in patients whose tumours have PD-L1 in at least 1% of the cells and no mutations in the *EGFR, ALK* and *ROS1* genes.
- cervical cancer that has come back (recurrent) or is metastatic. It is used in adults whose disease has progressed during or after treatment with platinum-based chemotherapy.

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 once every 3 weeks. When used as adjuvant treatment for cutaneous squamous cell carcinoma, Libtayo is given either once every 3 weeks or once every 3 weeks for the first 12 weeks and then once every 6 weeks at a double dose. Treatment can continue

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for as long as the disease remains stable and the patient does not experience unacceptable side effects. When used as adjuvant treatment, Libtayo can be given up to a maximum of 48 weeks.

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?

Cutaneous squamous cell carcinoma

A main study involving 193 adults showed that Libtayo was effective at treating cutaneous squamous cell carcinoma. In the study, the cancer shrank in around 39% of patients with metastatic disease who received Libtayo every 3 weeks for around one year. Among patients with locally advanced disease who received Libtayo every 2 weeks for around 2 years, 44% of patients showed shrinkage of their cancer.

Another main study showed that when used as an adjuvant treatment, Libtayo was more effective than placebo (a dummy treatment) at reducing the risk of the cancer returning. The study involved 415 adults who had completed treatment with surgery and radiation for cutaneous squamous cell carcinoma that had a high risk of coming back. The main measure of effectiveness was disease-free survival (the time patients lived without their cancer coming back). Based on the data available, after 24 months of treatment, around 87% of those given Libtayo were alive without any signs or symptoms of their cancer compared with around 64% for those given placebo.

Basal cell carcinoma

Treatment with Libtayo showed benefits in adults with locally advanced and metastatic BCC. In a study involving adults who were given Libtayo for around one year, the cancer shrank in 32% (27 out of 84) of those with locally advanced disease and 29% (10 out of 35) of those with metastatic disease. Libtayo was not compared with another treatment in this study.

Non-small cell lung cancer

In a study involving 710 adults with advanced or metastatic *EGFR*/*ALK*/*ROS1*-negative NSCLC with high levels of PD-L1 (in more than 50% of tumour cells), those treated with Libtayo lived longer (about 22 months on average) than those treated with platinum-based chemotherapy (about 14 months). Those treated with Libtayo lived for 6.2 months on average without their disease getting worse, compared with 5.6 months for those given chemotherapy.

A second study involving 466 adults with advanced or metastatic *EGFR*/*ALK*/*ROS1*-negative NSCLC found that in those whose tumours produce PD-L1 in at least 1% of cells, Libtayo given with platinum-based chemotherapy increased the time that they lived. Of the 327 adults with PD-L1 in at least 1% of tumour cells, those treated with Libtayo plus platinum-based chemotherapy lived for an average of 22 months compared with 13 months for those treated with platinum-based chemotherapy alone. In

addition, those treated with Libtayo plus chemotherapy lived for about 9 months without their disease getting worse, compared with 6 months for those given chemotherapy alone.

Cervical cancer

In a main study in 608 adults with recurrent or metastatic cervical cancer previously treated with platinum-based chemotherapy, those given Libtayo lived for about 12 months, compared with 8.5 months for those given chemotherapy. On average, those treated with Libtayo lived for 2.8 months without their disease getting worse, compared with 2.9 months for those given chemotherapy.

What are the risks associated with Libtayo?

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

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 the medicine.

When Libtayo is used alone, the most common immune-related effects (which may affect up to 1 in 10 people) include hypothyroidism (an underactive thyroid gland with tiredness, weight gain, and skin and hair changes), hyperthyroidism (an overactive thyroid gland which can cause weight loss, nervousness, rapid heartbeat and tiredness), pneumonitis (inflammation in the lungs causing shortness of breath and cough), hepatitis (inflammation of the liver), colitis (inflammation of the large bowel) and skin reactions.

When Libtayo is used with platinum-based chemotherapy, the most common immune-related effects (which may affect up to 1 in 10 people) include hypothyroidism, hyperthyroidism, increased or decreased levels of thyroid-stimulating hormone in the blood (which could be signs of an underactive or overactive thyroid gland), skin reactions and pneumonitis.

Severe skin 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.

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, and basal cell carcinoma, for which no other options were available for second-line treatment (treatment given when first treatment is not sufficiently effective or stops working) at the time of authorisation. When used as an adjuvant treatment for cutaneous squamous cell carcinoma, Libtayo was also effective at reducing the risk of the cancer coming back. Libtayo also showed promising effectiveness in the treatment of NSCLC with high PD-L1 levels and in the treatment of cervical cancer after progression during or after treatment with platinum-based chemotherapy. Libtayo used in combination with platinum-based chemotherapy is also effective at treating NSCLC where at least 1% of tumour cells produce PD-L1.

As for the medicine’s safety, Libtayo’s side effects are considered manageable and similar to those seen with other monoclonal antibody cancer treatments.

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 was originally given ‘conditional authorisation’. The authorisation was then switched to standard authorisation as the company provided additional data requested by the Agency.

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

The company that markets Libtayo will provide 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 what to do 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.

The conditional marketing authorisation was switched to a standard marketing authorisation on 1 July 2022.

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 11-2025.