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Cejemly (*sugemalimab*)

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

What is Cejemly and what is it used for?

Cejemly is a cancer medicine used in adults to treat a lung cancer called non-small cell lung cancer (NSCLC) that has spread to other parts of the body (metastatic). It is used together with platinum-based chemotherapy (other cancer medicines).

Cejemly is not used when the cancer cells have certain changes affecting genes called *EGFR*, *ALK*, *ROS1* or *RET*, as these changes may reduce the medicine's effectiveness.

Cejemly contains the active substance sugemalimab.

How is Cejemly used?

Treatment with Cejemly should be started and supervised by a doctor experienced in the use of cancer medicines. The medicine can only be obtained with a prescription.

Cejemly is given as an infusion (drip) into a vein over 60 minutes every 3 weeks.

Treatment with Cejemly should continue until it stops working. The doctor may interrupt treatment if certain side effects occur or stop it altogether for certain severe side effects.

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

How does Cejemly work?

The active substance in Cejemly, sugemalimab, is a monoclonal antibody (a type of protein) designed to attach to a protein called PD-L1 found on some cancer cells. Cancer cells use this PD-L1 protein to bind to certain receptors on the surface of T cells (cells of the immune system). This blocks the activity of T cells and prevents them from attacking the cancer. By attaching to the PD-L1 protein on the cancer cells, sugemalimab stops them from blocking the T cell activity. This increases the ability of the immune system to kill the cancer cells.

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What benefits of Cejemly have been shown in studies?

A main study found that Cejemly increased the time people with metastatic non-small cell lung cancer lived without their disease getting worse.

The study involved 479 people with metastatic NSCLC with no changes affecting the *EGFR*, *ALK*, *ROS1* or *RET* genes. They received either Cejemly or placebo (a dummy treatment), each given together with platinum-based chemotherapy. The study found that people who received Cejemly lived for an average of 9 months before their cancer got worse compared with 5 months for people who received placebo. Overall, people who received Cejemly with chemotherapy lived for around 25 months, while those who received placebo with chemotherapy lived for around 17 months.

What are the risks associated with Cejemly?

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

The most common side effects with Cejemly (which may affect more than 1 in 10 people) include anaemia (low red blood cells), increased levels of aminotransferases (liver enzymes), rash, hyperlipidaemia (high blood fat levels), hyperglycaemia (high blood glucose levels), hyponatraemia (low blood levels of sodium), hypokalaemia (low blood levels of potassium), proteinuria (protein in urine), abdominal (belly) pain, tiredness, arthralgia (joint pain), hypoaesthesia (reduced sensation to touch, pain and temperature), hypothyroidism (underactive thyroid gland) and hypocalcaemia (low blood levels of calcium).

Cejemly is also commonly associated with side effects related to the activity of the immune system on body organs. Most will go away with appropriate treatment or after suspending or stopping Cejemly.

Why is Cejemly authorised in the EU?

A main study has shown that, when used together with platinum-based chemotherapy, Cejemly increases the time people with metastatic non-small cell lung cancer live without their disease getting worse, as well as the time they live overall. The side effects of Cejemly are similar to those seen with other medicines that act on PD-L1 and are used together with chemotherapy. The European Medicines Agency therefore decided that Cejemly's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Cejemly will provide a patient card about side effects affecting the immune system and when to seek help if these occur. This card will also inform healthcare professionals that the patient is being treated with Cejemly.

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

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

Other information about Cejemly

Cejemly received a marketing authorisation valid throughout the EU on 24 July 2024.

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

This overview was last updated in 08-2024.