EMA/31583/2025
EMEA/H/C/006074

Lazcluze (*lazertinib*)

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

What is Lazcluze and what is it used for?

Lazcluze is a cancer medicine used to treat adults with advanced non-small cell lung cancer (NSCLC) who have not been treated before. It is used in people whose cancer cells have certain mutations (changes) in the epidermal growth factor receptor (EGFR) gene: exon 19 deletion or exon 21 L858R substitution mutation. Lazcluze is used in combination with another cancer medicine, amivantamab.

Lazcluze contains the active substance lazertinib.

How is Lazcluze used?

The medicine can only be obtained with a prescription. Treatment with Lazcluze should be started by a doctor who is experienced in using cancer medicines. Before starting treatment, patients must be tested to confirm that the tumour cells have certain changes to the EGFR gene.

Lazcluze is available as tablets to be taken by mouth once a day. Treatment should continue until the disease gets worse or unacceptable side effects occur.

At the initiation of treatment, patients should be given anticoagulants (substances that prevent the blood from clotting) to reduce risks of venous thromboembolic events (VTE, problems due to the formation of blood clots in veins).

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

How does Lazcluze work?

The active substance in Lazcluze, lazertinib, is a type of cancer medicine called a tyrosine kinase inhibitor. It blocks the activity of EGFR, a protein which normally controls the growth and division of cells. In lung cancer cells, EGFR is often overactive, causing uncontrolled growth of cancer cells. By blocking EGFR, lazertinib helps to reduce the growth and spread of the cancer. Lazertinib primarily targets the mutated EGFR and has less effect on normal EGFR, therefore minimising undesirable effects caused by blocking normal EGFR.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Lazcluze have been shown in studies?

Lazcluze was investigated in a main study involving 1,074 patients with advanced NSCLC with EGFR gene exon 19 deletion or exon 21 L858R substitution mutation who had not been treated before.

Patients in the study either took Lazcluze plus amivantamab, Lazcluze alone or osimertinib (another medicine targeting mutated EGFR) alone. Those given Lazcluze plus amivantamab lived 23.7 months without their disease getting worse compared with 16.6 months for patients given osimertinib alone.

What are the risks associated with Lazcluze?

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

The most common side effects with Lazcluze combined with amivantamab (which may affect more than 1 in 10 people) include rash, nail toxicities (nail abnormalities with pain or discomfort), infusion-related reaction, hypoalbuminaemia (low blood levels of the protein albumin), hepatotoxicity (liver damage), oedema (swelling), stomatitis (inflammation of the lining of the mouth), venous thromboembolism, paraesthesia (sensations like numbness, tingling, pins and needles), tiredness, constipation, diarrhoea, dry skin, decreased appetite, itching, hypocalcaemia (low blood calcium levels), eye problems and nausea (feeling sick).

The most common serious side effects with Lazcluze combined with amivantamab (which may affect more than 1 in 10 people) is venous thromboembolism. Other serious side effects (which may affect up to 1 in 10 people) include pneumonia (infection of the lungs), rash, interstitial lung disease (disorders causing scarring in the lungs), pneumonitis (inflammation of the lungs), COVID-19, hepatotoxicity, pleural effusion (fluid around the lungs), infusion-related reaction, respiratory failure (inability of the lungs to work properly), tiredness, oedema, hypoalbuminaemia and hyponatraemia (low blood sodium levels).

Why is Lazcluze authorised in the EU?

Treatment with Lazcluze and amivantamab was shown to prolong the time patients with NSCLC with EGFR gene mutations live without their disease getting worse. To confirm the effectiveness of the combination treatment, the company marketing Lazcluze will submit further results of the main study, including the time patients lived overall.

Regarding safety, there is a risk of venous thromboembolism with Lazcluze and amivantamab which should be minimised by giving anticoagulants to patients. Other side effects were considered acceptable for a cancer treatment.

The European Medicines Agency therefore decided that Lazcluze’s benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Lazcluze

Lazcluze received a marketing authorisation valid throughout the EU on 20 January 2025.

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

This overview was last updated in 01-2025.