swissmedic

Summary report on authorisation dated 29 August 2025

Lazcluze® (active substance: lazertinib)

Authorisation in Switzerland: 7 February 2025

Film-coated tablets in combination with amivantamab for the first-line treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations

About the medicinal product

Lazcluze is a cancer medicine containing the active substance lazertinib.

The medicinal product Lazcluze is used in combination with the active substance amivantamab as first-line treatment of adults with non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations that has advanced locally or spread to other parts of the body (metastasised).

Lazcluze in combination with amivantamab is used for treating patients in whom a specific change (mutation) is detectable in the epidermal growth factor receptor[1] (EGFR). These gene mutations are called exon 19 deletions or exon 21 L858R substitution mutations of the EGFR gene.

The treatment with the medicinal product Lazcluze in combination with amivantamab can slow or stop tumour growth and reduce the size of the tumour.

The medicinal product Lazcluze was authorised as part of "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. In addition to the FDA, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are currently represented in Project Orbis.

[1] A receptor is a protein or a protein complex located on the surface of, or inside, cells. When a specific substance binds to a receptor, a reaction is triggered in the cell.

Mode of action

The active substance lazertinib is what is known as an EGFR tyrosine kinase inhibitor.

The active substance lazertinib binds to the tyrosine kinase at the EGFR receptor in cancer cells. This receptor is often present and modified in non-small cell lung cancer. By blocking the activity of this receptor, the active substance lazertinib can stop the growth and replication of the cancer cells.

The medicinal product Lazcluze is used in combination with amivantamab to enhance the therapeutic effects and better control the progression of the cancer.

Administration

The medicinal product Lazcluze is a prescription-only medicine available as film-coated tablets at the dosage strengths of 80 mg and 240 mg.

The usual starting dose is 240 mg once daily in combination with amivantamab. The film-coated tablets are taken whole, unchewed with water. Lazcluze can be taken at any time prior to amivantamab when administered on the same day.

The doctor will adjust the treatment if required by the patient's state of health.

Efficacy

The efficacy of Lazcluze was investigated in the "MARIPOSA" study.

The study compared the efficacy of the combination of Lazcluze (lazertinib) and amivantamab with that of osimertinib monotherapy as first-line treatment.

A total of 858 patients with advanced or metastatic non-small-cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutations took part.

The study showed a significant improvement in progression-free survival (PFS)[2] in patients who had received Lazcluze in combination with amivantamab (23.7 months) compared with patients who had received osimertinib monotherapy (16.6 months).

In addition, overall survival (OS) was significantly improved in patients who had been treated with Lazcluze and amivantamab compared with patients who had been treated with osimertinib on its own.

Overall survival refers to the period between the start of treatment and the death of the patient

Precautions, undesirable effects, & risks

Lazcluze must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects are skin rashes (including acne), nail toxicity, gastrointestinal disorders, nausea, vomiting, decreased appetite, tingling of the skin, fatigue, muscle spasms and increased liver enzymes.

[2] PFS: progression-free survival. Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Rarely, interstitial lung disease (ILD)[3] - potentially serious in some cases - may occur.

The use of Lazcluze in combination with amivantamab increases the risk of serious, and potentially life-threatening, venous thromboembolic events (VTE)[4].

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

At present, limited drug treatment options are available for patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations.

The study described above showed a significant improvement in progression-free survival and overall survival for the treatment with Lazcluze in combination with amivantamab compared to existing options for the first-line treatment of patients with NSCLC and EGFR exon 19 deletions or exon 21 L858R substitution mutations, such as osimertinib combined with chemotherapy.

Taking all the risks and precautions into account, and based on the available data, the benefits of Lazcluze outweigh the risks. Swissmedic has therefore authorised the medicinal product Lazcluze, containing the active substance lazertinib, for use in Switzerland for the treatment of advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lazcluze®

Information for patients (package leaflet): Information for patients Lazcluze®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.

[3] Interstitial lung disease (ILD) is a group of lung diseases characterised by inflammation and scarring of the lung tissue that can cause respiratory symptoms and restricted oxygen absorption.

[4] Venous thromboembolic events (VTE) can be life-threatening and are associated with blood clots that form in the veins and may cause pulmonary embolism or deep vein thrombosis.