

Summary report on authorisation dated 7 November 2025

Retsevmo[®] (active substance: selpercatinib)

Indication extension in Switzerland: 21 March 2025

Hard gelatin capsule for the treatment of cancers caused by changes in the RET gene

About the medicinal product

Retsevmo is a cancer treatment containing the active substance selpercatinib.

Swissmedic first authorised Retsevmo temporarily on 4 May 2021. The product was authorised for the treatment of certain cancers caused by abnormal changes in a gene called the "RET gene". These include:

- 1- A type of lung cancer called non-small cell lung cancer (NSCLC) in adults (known as RET fusion-positive NSCLC)
- 2- Thyroid cancer in adults (known as RET fusion-positive thyroid cancer)
- 3- A rare type of thyroid cancer called medullary thyroid cancer (MTC) in adults and adolescents aged 12 years and over (known as RET-mutation medullary thyroid cancer)

Retsevmo was authorised for these forms of cancers if they had progressed despite prior treatment with standard therapies and could not be surgically removed. In the meantime, the associated conditions of authorisation have been fulfilled and the temporary authorisation has been lifted.

The indication extensions dated 21 March 2025 mean that Retsevmo is now also temporarily authorised for the first-line treatment

of adults with NSCLC and authorised without special conditions for the first-line treatment of adults and adolescents aged 12 years and over who have advanced RET-mutation MTC.

Since the conditions in question are rare, life-threatening diseases, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

These indication extensions for Retsevmo were authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the indications are already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal products, and the extent to which the results can be accepted for Switzerland.

The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Retsevmo in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMEA/H/C/005375 /0011 and EMEA/H/C/0053175/II/0014/G and has only conducted a limited scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the reference authority: www.ema.europa.eu.

Mode of action

In patients whose cancer is characterised by a mutated RET gene, the gene mutation leads to the body producing a modified RET protein. This can lead to uncontrolled cell

growth and cancer. Retsevmo blocks the action of the modified RET protein and in this way is able to slow or stop the growth of the cancer. It can also help to reduce the size of the cancer.

Administration

Retsevmo, containing the active substance selpercatinib, is a prescription-only medicine and is available as hard gelatin capsules with dosage strengths of 40 mg or 80 mg. Retsevmo may only be used if a mutation of the RET gene has been identified using a molecular biological test suitable for the specific mutation.

The recommended dosage of Retsevmo is determined by the patient's body weight:

The dose is 120 mg for body weights of less than 50 kg and 160 mg for body weights of 50 kg or more. The corresponding dose is taken twice a day, at roughly 12-hour intervals. It should be taken at approximately the same time each day.

The capsules must be swallowed whole with a glass of water, either with or without food. The capsules must not be chewed, broken or opened before swallowing.

Efficacy

The efficacy of Retsevmo in the indication extensions was investigated in two pivotal trials, LIBRETTO-431 and LIBRETTO-531.

The aim of LIBRETTO-431 was to assess the efficacy of Retsevmo in adult patients with RET fusion-positive NSCLC who had not previously received systemic treatment¹ for metastatic disease (disease that has spread to another part of the body). Patients were randomised (assigned randomly) to either Retsevmo or a standard treatment. The primary endpoint was progression-free survival (PFS)². Retsevmo demonstrated superiority,

with a median PFS of 24.84 months, compared to 11.17 months for the control treatment. At the time of the last analysis, more deaths had been observed in the Retsevmo arm.

LIBRETTO-531 investigated the efficacy of Retsevmo in patients with RET-mutation MTC who had also not previously received systemic treatment. Participants received either Retsevmo or standard treatments (cabozantinib or vandetanib). This trial

¹ Systemic treatment: In contrast to local therapy (treatment at the site of the disorder), systemic treatment involves treatment of the entire body to eliminate a disorder.

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

showed that patients who received Retsevmo had better PFS than those who received the standard treatments.

Precautions, undesirable effects, & risks

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

Retsevmo may cause side effects, which must be reported to the doctor without delay, for example lung or breathing problems, liver problems, allergic reactions and high blood pressure.

The most common undesirable effects, experienced by more than 20% of all patients treated with Retsevmo, are oedema³, dry mouth, diarrhoea, high blood pressure, elevated aspartate aminotransferase (AST)⁴, el-

evated alanine aminotransferase (ALT)³, elevated blood creatinine⁵, rash, abdominal pain, nausea, vomiting, bleeding, fatigue or tiredness, headaches, reduced appetite and constipation.

Other relevant side effects also occurred during treatment with Retsevmo (e.g. QT interval prolongation⁶).

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

In trials, the medicinal product Retsevmo improved PFS in patients with RET fusion-positive NSCLC compared with standard treatment. Retsevmo also significantly improved PFS in RET-mutation MTC compared with existing treatments, while also displaying a lower rate of severe adverse reactions. Retsevmo covers a high medical need since it has been developed specifically for patients with tumours caused or driven by RET mutations.

Taking all the risks and precautions into account, and based on the available data, the benefits of the indication extensions outweigh the risks.

Swissmedic has therefore authorised the medicinal product Retsevmo containing the active substance selpercatinib in Switzerland

for the treatment of advanced RET-mutation MTC in adults and children aged 12 years and over.

Taking account of the current data on the efficacy and safety of selpercatinib compared with the control, the risk-benefit assessment was negative for authorisation without special conditions in the first-line treatment of NSCLC. In view of the large number of patients who changed from the control arm to selpercatinib, and given the lack of an alternative targeted treatment, Retsevmo was temporarily authorised for the first-line treatment of NSCLC (Art. 9a TPA).

The temporary authorisation is contingent on the timely submission of the data re-

³ Oedema: Fluid accumulation that can cause swelling of the hands or ankles

⁴ Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are enzymes produced mainly in the liver. Elevated levels of activity of these enzymes in the blood may indicate liver-related diseases.

⁵ Elevated levels of creatinine in the blood indicate that the kidneys are not working properly (renal impairment).

⁶ QT interval prolongation: The QT interval is one of the parameters measured when an electrocardiogram (ECG) is evaluated. QT prolongation is present if the heart rate is very low and the interval between the start of the Q wave and the end of the T wave is longer than 550 ms.

requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an

authorisation without special conditions in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Retsevmo®](#)

Information for patients (package leaflet): [Information for patients Retsevmo®](#)
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.