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Retsevmo® (active substance: selpercatinib)

Temporary authorisation in Switzerland: 8 February 2021

Medicinal product (hard gelatin capsule) for the treatment of cancers caused by changes in a gene called RET

About the medicine

Retsevmo is a cancer treatment containing the active substance selpercatinib.

Therapy with Retsevmo is used if the cancer has spread in spite of treatment with current standard therapies and/or cannot be removed by surgery. Retsevmo was authorised for the treatment of the following cancers which are caused by certain abnormal changes in a gene called the "RET gene".

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 in adults and adolescents from 12 years of age (known as RET-mutation medullary thyroid cancer)

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.

Use

Retsevmo, with the active substance selpercatinib, is a prescription-only medicine and has been authorised as a hard gelatin capsule in the dosage strengths 40 mg and 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 bodyweight and is as follows:

- Below 50 kg: 120 mg Retsevmo

- 50 kg or above: 160 mg Retsevmo

The corresponding dose is taken twice a day, at roughly 12-hour intervals. It should be taken at approximately the same times of day each time.

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 was evaluated on the basis of the LIBRETTO-001 trial. The patients who took part in the trial showed disease progression when they were treated with the current standard therapy or did not tolerate the current standard therapy, or where no standard therapy was available.

1. RET fusion-positive NSCLC

The efficacy of Retsevmo was assessed on the basis of 218 patients with RET fusion-positive NSCLC who had previously received platinum-based chemotherapy.

Of the 218 patients in whom it was possible to evaluate efficacy[1], 56.9% responded to the treatment with a median[2] response duration of 17.5 months.

2. RET fusion-positive thyroid cancer

The efficacy of Retsevmo was assessed on the basis of 22 patients with RET fusion-positive thyroid cancer who had previously received systemic therapy.

Of the 22 patients in whom it was possible to evaluate efficacy[1], 77.3% responded to the treatment with a median[2] response duration of 18.4 months.

3. RET-mutation medullary thyroid cancer

The efficacy of Retsevmo was assessed on the basis of 143 patients with RET-mutation medullary thyroid cancer who had previously received treatment with cabozantinib and/or vandetanib.

Of the 143 patients in whom it was possible to evaluate efficacy[1], 69.2% responded to the treatment. It was not possible to determine the median[2] response duration.

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.
The most common undesirable effects experienced by patients treated with Retsevmo are dry mouth, diarrhoea, high blood pressure, elevated aspartate aminotransferase (AST)[3], elevated alanine aminotransferase (ALT)[2], fatigue or tiredness and constipation.

Other relevant side effects also occurred during treatment with Retsevmo (e.g. QT interval prolongation[4], high blood pressure,

[1] Evaluable efficacy: These patients underwent follow-up observation for at least 6 months.

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

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

[4] 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.

bleeding).

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 medicine has been authorised

When the temporary authorisation was granted, there were no specific therapies available in Switzerland for the treatment of cancer caused by a mutation in the RET gene. The current treatment consists of conventional standard therapies suitable for the type of tumour, irrespective of the RET gene mutation.

The efficacy data submitted for this temporary authorisation show convincing response rates for second-line therapy with Retsevmo in fusion-positive NSCLC, RET fusion-positive thyroid cancer and RET-mutation medullary thyroid cancer.

Based on all the available data, the benefits of Retsevmo outweigh the risks. Swissmedic has therefore granted a temporary authorisation for the medicine Retsevmo with the active substance selpercatinib for the treatment of adults with these cancers.

There is also an unmet medical need with respect to adolescents with medullary thyroid cancer. The temporary authorisation of Retsevmo as second-line therapy also for patients from the age of 12 with RET-mutation medullary thyroid cancer was therefore accepted on the basis of the biological similarity to adult patients and the provisional safety and efficacy data.

The medicinal product Retsevmo was authorised in Switzerland on a temporary basis (in accordance with Art. 9a of the Therapeutic Products Act) since not all clinical trials had been concluded at the time of authorisation.

The temporary authorisation is contingent on timely submission of the data requested by Swissmedic from ongoing clinical trials. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation.

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 (doctors, pharmacists and others) 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 Public Summary SwissPAR.
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