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Tepmetko® (active substance: tepotinib)

Temporary authorisation in Switzerland: 22.06.2021

Medicinal product (film-coated tablets) for the treatment of non-small cell lung cancer (NSCLC) with MET exon 14 skipping mutations.

About the medicinal product

Tepmetko is a cancer treatment containing the active substance tepotinib.

Tepmetko is used to treat adults with non-small cell lung cancer (NSCLC).

The treatment is given to patients whose lung cancer has spread to other parts of the body (metastatic) and who possess a change (mutation) in a gene that makes an enzyme called MET receptor tyrosine kinase. The genetic mutation in these patients is known as a MET exon 14 skipping mutation.

Since this is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements.

Mode of action

Tepmetko inhibits the formation of the enzyme MET receptor tyrosine kinase, whose production is increased in this type of cancer. By blocking this protein (enzyme), Tepmetko can curb the growth and spread of the cancer.

Use

Tepmetko is a prescription-only medicine authorised as a film-coated tablet at the dosage strength of 225 mg tepotinib. Tepmetko may only be used if a specific mutation of the MET gene is detected: MET exon 14 skipping mutation.

The recommended dose is 450 mg (2 film-coated tablets) once daily. The film-coated tablets should be swallowed whole with food or shortly after a meal. They may not be broken, chewed or crushed.

Treatment with Tepmetko has not been investigated in children or adolescents.

Efficacy

The efficacy of Tepmetko was investigated in an open-label study (VISION) with 83 subjects who had already received previous treatment for this cancer and patients (69 subjects) who had not received any previous treatment, all of whom possessed a MET exon 14 skipping mutation. All study participants had lung cancer (NSCLC) at an advanced stage or with metastases.

The patients received 450 mg tepotinib once daily. The objective response rate (ORR) was measured. This shows the percentage of patients experiencing a reduction in tumour size. Overall survival while taking Tepmetko was another outcome recorded in the study. The overall survival refers to the period between the start of treatment and the death of the patient.

The previously untreated patients and the previously treated group both showed an ORR of 45%. The median[1] overall survival was 17.6 months in the previously untreated group and 19.7 months in the previously treated group.

Precautions, undesirable effects & risks

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

Tepmetko may cause side effects. The most common (affecting more than one in 10 users) serious side effects in patients treated with Tepmetko are swelling due to the accumulation of fluid in the body (oedema), nausea, diarrhoea, tiredness, loss of appetite, vomiting, increased blood creatinine, shortness of breath, increased liver enzyme levels, accumulation of fluid in the chest with trouble breathing, cough and/or pain, reduced blood protein level. Suddenly occurring breathing problems, with coughing or fever, may be symptoms of a serious lung disease (interstitial lung disease) and must be investigated immediately by a doctor.

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

The disease of metastatic NSCLC has a fatal outcome in all cases. Specific treatment with Tepmetko, the MET tyrosine kinase inhibitor tepotinib, can control the disease for a certain period.

In the VISION study described above, a clinically significant overall response rate was observed during the treatment with Tepmetko in MET exon 14 skipping mutation-positive NSCLC.

Based on all the available data, the benefits of Tepmetko outweigh the risks. The medicinal product Tepmetko with the active substance tepotinib has been authorised temporarily in Switzerland for the treatment of adult patients with MET exon 14 skipping NSCLC (Art. 9a TPA) since not all clinical studies had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these

[1] 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.

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 Tepmetko®

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

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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