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Rybrevant® (active substance: amivantamab)

Temporary authorisation in Switzerland: 20 January 2022

Medicinal product (concentrate for solution for infusion) for the treatment of non-small cell lung cancer (NSCLC) with activating Exon 20 gene mutations.

About the medicinal product

Rybrevant is a cancer medicine containing the active substance amivantamab and administered as an infusion into a vein.

Rybrevant is used to treat adults with non-small cell lung cancer (NSCLC) that has spread to other parts of the body (metastatic) or that cannot be removed surgically, and in whom the lung cancer has progressed during or after platinum-based chemotherapy.

The medicinal product Rybrevant is suitable for treating patients in whom a specific activating change (mutation) is detectable in the gene for the epidermal growth factor receptor[1] (EGFR).

This gene mutation is termed an Exon 20 insertion mutation of the gene for the EGFR.

Mode of action

The mutation of the EGFR in the cancer cell causes specific proteins to bind increasingly to receptors of the cancer cell and, as a result, trigger signals in the tumour cell that influence cell growth and cell division and can thereby initiate uncontrolled tumour growth.

The active substance amivantamab contained in the medicinal product Rybrevant is known as an EGFR-MET antibody. It attaches itself to the altered EGFR and to the MET receptor[2] of the cancer cell. This process blocks the receptors for the proteins that are responsible for signalling in the cancer cell relating to the growth and formation of further tumour cells. By blocking these receptors, Rybrevant is able to control the growth and spread of the cancer.

[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.

[2] MET receptor (mesenchymal-epithelial transition receptor) plays a role in cell differentiation.

Use

Rybrevant is a prescription-only medicine authorised as a concentrate for solution for infusion at the dosage strength of 350 mg / 7 ml.

A precondition for the use of Rybrevant is the detection of a specific EGFR Exon 20 change (insertion mutation).

The recommended dose depends on the patient's weight, i.e. 1,050 mg up to 80 kg and 1,400 mg above 80 kg body weight.

In weeks 1 to 4, the patients receive a dose once a week, followed by a dose every other week. The infusion solution of Rybrevant is administered intravenously by a healthcare professional.

Before treatment with Rybrevant, the patients receive appropriate medications for reducing side effects that may be associated with the administration of Rybrevant.

If infusion-related reactions occur, the doctor will provide appropriate medical support and, if necessary, adjust the infusion rate or discontinue the use of Rybrevant.

Efficacy

The efficacy of Rybrevant was investigated in a multi-centre open-label study (CHRYSALIS) in 81 subjects with insertion mutations in Exon 20 of the EGFR gene and whose disease had progressed during or after platinum-based chemotherapy. All study participants had lung cancer (NSCLC) at an advanced stage or with metastases.

The patients received Rybrevant until the disease progressed or serious side effects occurred.

The overall response rate (ORR) was measured. This shows the percentage of patients experiencing a reduction in tumour size. Overall survival 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 patients showed an overall response rate of 40%. The median[3] overall survival was 22.8 months.

Precautions, undesirable effects & risks

Rybrevant must not be used in those who are hypersensitive to the active substance amivantamab.

Rybrevant may cause side effects. The most common (affecting more than one in 10 users) serious adverse effects are skin rash, infusion-related reactions, nail toxicity, decreased blood protein (hypoalbuminaemia), fatigue, swelling due to the accumulation of fluid in the body (oedema), gastrointestinal symptoms and nausea. Suddenly occurring breathing problems may be symptoms of a serious interstitial[4] lung disease and must be investigated immediately by a doctor.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals for Rybrevant®.

[3] 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.

[4] Interstitial lung diseases refer to inflammatory conditions of lung tissue that can be caused, for example, by medicines.

Why the medicinal product has been authorised

Patients with metastatic or inoperable NSCLC have a poor prognosis.

Treatment with Rybrevant can help control the disease for a certain amount of time.

A clinically significant overall response rate was observed for Rybrevant in patients suffering from NSCLC with insertion mutations in Exon 20 of the EGFR gene.

Based on all the available data, the benefits of Rybrevant outweigh the risks. The medicinal product Rybrevant with the active substance amivantamab has been authorised temporarily in Switzerland for the treatment of adult patients with NSCLC and activating insertion mutations in Exon 20 of the EGFR gene (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 authorisation conditions have been satisfied, this temporary authorisation can be converted into an ordinary authorisation.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Rybrevant®

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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