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Exkivity® (active substance: mobocertinib)

Temporary authorisation in Switzerland: 1 June 2022

Medicinal product (gelatin hard capsules) for the treatment of non-small cell lung cancer (NSCLC) with exon 20 gene mutation of the epidermal growth factor receptor (EGFR).

About the medicinal product

Exkivity is a cancer medicine containing the active substance mobocertinib and administered orally as a capsule.

Exkivity 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 Exkivity is suitable for treating patients in whom a specific change (mutation) is detectable in the epidermal growth factor receptor[1] (EGFR). This gene mutation is termed an exon 20 insertion mutation of the EGFR.

Exkivity was authorised in connection with "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. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic) and the United Kingdom (MHRA) are represented in Project Orbis.

Mode of action

The mutation of the EGFR triggers signals in the tumour cell that influence cell growth and cell division and can thereby initiate uncontrolled tumour growth.

The active substance mobocertinib contained in the medicinal product Exkivity is known as a tyrosine kinase inhibitor and acts against EGFR mutations, including exon 20

[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.

insertion mutations. Mobocertinib can inhibit the specific gene mutations of the EGFR and bind to the mutated growth factor receptors. This mechanism of action enables Exkivity to control the growth and spread of the cancer.

Use

Exkivity is a prescription-only medicine authorised as gelatin hard capsules for oral administration at the dosage strength of 40 mg.

A precondition for the use of Exkivity is the detection of a specific EGFR exon 20 insertion mutation.

The recommended dosage is 160 mg (4 capsules) once daily. Exkivity can be taken independently of meals (i.e. with or without food).

The treatment with Exkivity is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments.

If required for reasons of tolerability and safety, the doctor will adapt the dosage to the individual patient's state of health.

Efficacy

The efficacy of Exkivity was investigated in a multi-centre, single-arm, open-label study (AP32788-15-101) in 114 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 non-small cell lung cancer (NSCLC) at an advanced stage or with metastases.

The patients received Exkivity at the dosage of 160 mg/day until the disease progressed or serious side effects occurred.

The overall response rate 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.

For the patients treated with Exkivity, this study showed an overall response rate of 28% and a median[2] overall survival of 20.2 months.

Precautions, undesirable effects & risks

Exkivity must not be used in those who are hypersensitive to the active substance mobocertinib.

Exkivity may cause side effects. The most common serious adverse effects are diarrhoea, nausea, vomiting, dehydration, renal impairment, rash, decreased appetite, cardiac failure and interstitial lung disease[3]. Exkivity can trigger potentially fatal cardiac arrhythmias.

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

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

Why the medicinal product has been authorised

Patients with metastatic or inoperable NSCLC have a poor prognosis. Treatment with Exkivity can help control the disease for a certain amount of time.

A clinically significant overall response rate was observed for Exkivity in patients suffering from NSCLC with an exon 20 insertion mutation of the epidermal growth factor receptor.

Based on all the available data, the benefits of Exkivity outweigh the risks. The medicinal product Exkivity with the active substance mobocertinib has been authorised temporarily in Switzerland for the treatment of adult NSCLC patients with exon 20 insertion mutation of the EGFR (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 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 Exkivity®

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

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 Public Summary SwissPAR.

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