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Lumykras® (active substance: sotorasib)

Temporary authorisation in Switzerland: 16 December 2021

Film-coated tablets for the second-line treatment of KRAS G12C-mutated, non-squamous, non-small cell lung cancer (NSCLC)

About the medicine

Lumykras is a cancer treatment containing the active substance sotorasib. It is used to treat adults with a specific type of lung cancer, known as non-squamous, non-small cell lung cancer (NSCLC). Lumykras is used when the KRAS gene in the lung cancer cells displays a particular change. This is known as the KRAS G12C mutation. The lung cancer to be treated is either advanced and/or has already spread to other sites in the body (metastasised).

Lumykras is a second-line treatment. This means it is prescribed for patients whose lung cancer has already been treated with other medicines that were not sufficiently effective.

Mode of action

The modified KRAS G12C gene triggers the formation of a protein. This KRAS G12C protein is involved in the growth and proliferation of the cancer cells. Sotorasib, the active substance in Lumykras, appears to block the modified KRAS protein.
Lumykras inhibits this protein by binding to it. This slows or stops the growth of the cancer.

Use

Lumykras is a prescription-only medicine authorised as a film-coated tablet at the dosage strength of 120 mg.
Lumykras can only be used in patients who have been proven to have a specific mutation of the KRAS gene, known as the KRAS G12C mutation.

The recommended dosage is 960 mg (eight 120 mg tablets). The film-coated tablets are swallowed once a day. They should be taken at the same time every day, with or without food.

Efficacy

Lumykras exhibited clinically relevant efficacy in the single-arm[1] study CodeBreaK 100 in 126 patients with a KRAS G12C mutation and advanced and/or metastatic NSCLC that had been previously treated with other lung cancer medicines, but which had continued to progress despite this treatment. The proportion of patients with an objective tumour reduction (objective response rate, ORR) was 37%. Median[2] survival (overall survival, OS) was 12.5 months.

Precautions, undesirable effects & risks

Treatment with Lumykras brings with it the risk of medicinal product-induced liver damage that could lead to hepatitis. Depending on the severity of this undesirable effect, it may be necessary to pause treatment, reduce the dosage or discontinue Lumykras completely.

While undergoing treatment with Lumykras, patients are at risk of a lung disease (interstitial lung disease, ILD) that can be potentially fatal. They will therefore be monitored for respiratory symptoms.

The very common undesirable effects following administration of Lumykras include diarrhoea, nausea, fatigue, vomiting, constipation, stomach pain, fever, joint and back pain, shortness of breath, cough, low red blood cell count (anaemia), headache and fluid accumulation in the body (oedema).

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

Why the medicine has been authorised

Patients with advanced NSCLC involving a KRAS G12C mutation have a poor chance of survival and cannot be satisfactorily treated with the cancer treatments currently in use. The number of people in Switzerland who develop this form of lung cancer each year is estimated at around 300. Since this is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to important medicinal products for rare diseases. The CodeBreaK 100 study demonstrated convincing efficacy in reducing tumour size and extending survival. Further studies of dosage, tolerability and efficacy are still in progress.

Based on all the available data, the benefits of Lumykras outweigh the risks. The medicinal product Lumykras has been authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials 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 in the event of a positive benefit-risk assessment of the results.

[1] Single-arm = the study is performed without a comparator group (e.g. a group receiving another medicinal product or placebo).

[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.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lumykras®

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

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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