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Alunbrig® (active substance: brigatinib)

First authorisation in Switzerland: 4 May 2021

Medicinal product (tablet) for the treatment of cancers related to changes in a gene called ALK

About the medicinal product

Alunbrig is a cancer treatment containing the active substance brigatinib.

Alunbrig is used to treat adults with a type of lung cancer called "non-small cell lung cancer" (NSCLC).

The treatment is given to patients whose lung cancer is related to a defective form of a specific gene called anaplastic lymphoma kinase (ALK) (ALK-positive NSCLC). The cancer is also locally advanced in the patients or has spread to other parts of the body (metastasised).

Alunbrig is used as first-line treatment, i.e. if no treatment with another drug with the same mode of action (ALK inhibitor[1]) has been administered. Alunbrig is also used in patients who have previously been treated with crizotinib (an active substance in medicines that are already authorised for the treatment of ALK-positive NSCLC) and whose disease has continued to progress during the treatment with crizotinib.

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

In patients with ALK-positive NSCLC, the defective ALK gene forms a protein known as a kinase. This protein is partly responsible for enabling cancer cells to survive and grow.

Alunbrig works by specifically blocking ALK kinase. By blocking this protein, Alunbrig is able to slow down the growth and spread of the cancer.

[1] ALK inhibitors: cancer drugs that inhibit the protein anaplastic lymphoma kinase (ALK).

Use

Alunbrig is a prescription-only medicine authorised as a tablet in the dosage strengths 30 mg, 90 mg and 180 mg.

Alunbrig may only be used if a mutation of the ALK gene has been identified using a molecular biological test suitable for the specific mutation.

The recommended dose is one 90 mg tablet once daily for the first 7 days of treatment, followed by one 180 mg tablet once daily.

Alunbrig should be taken at the same time each day.

The tablet should be swallowed whole with a glass of water, with or without food. The tablets may not be chewed, crushed or dissolved before they are taken.

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

Efficacy

The efficacy of Alunbrig was evaluated on the basis of the studies "ALTA 1L" and "ALTA".

1. ALTA 1L

The ALTA 1L study investigated 275 adult patients aged between 27 and 89 years with advanced ALK-positive NSCLC who had not previously received a treatment targeted against ALK.

Half of the patients received Alunbrig 180 mg once a day (after a 7-day induction phase of 90 mg daily) and half received crizotinib twice a day.

An independent review committee evaluated progression-free survival (PFS[2]). In the first interim analysis, the median PFS with the Alunbrig treatment had not yet been reached. In other words, the disease had progressed in less than half of the patients treated with Alunbrig. In the second interim analysis, the median PFS was 24 months for the Alunbrig treatment compared to a median PFS of 11 months for the treatment with crizotinib, i.e. the PFS of the patients was more than doubled.

At the time of authorisation of Alunbrig, meaningful data on overall survival are not yet available. The study has not yet been concluded at the time of authorisation and further data will continue to be recorded.

2. ALTA

The ALTA study was designed to support the ALTA 1L study and serve as the basis for the authorisation of Alunbrig as second-line treatment. This study investigated 222 adult patients aged between 18 and 82 years with locally advanced or metastatic ALK-positive NSCLC who experienced disease progression during treatment with crizotinib.

Half of the patients received Alunbrig 90 mg once daily and half received 180 mg once daily (after a 7-day induction phase of 90 mg daily).

The primary endpoint of the study was the confirmed objective overall response rate (ORR), which should be over 20%. The primary endpoint was achieved in both groups, with an ORR of 52% in the lower-dose arm and 56% in the higher-dose arm.

[2] Progression-free survival (PFS): period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Precautions, undesirable effects & risks

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

Alunbrig may cause side effects, which must be reported to the doctor without delay. The most common serious side effects in patients treated with Alunbrig are high blood pressure, visual disturbances, increased blood level of creatine phosphokinase in tests (may indicate muscle damage), increased blood levels of amylase or lipase in tests (may indicate inflammation of the pancreas), increased blood levels of liver enzymes in tests or increased blood sugar.

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

The disease of metastatic NSCLC has a fatal outcome in all cases. However, the specific treatment with ALK inhibitors can prolong survival by several years. Although medicines with the same mode of action are already authorised, there is still a substantial medical need for new and more effective drugs with fewer side effects.

A significant prolongation in PFS was demonstrated in the above-mentioned clinical trial on efficacy in the first-line treatment with Alunbrig in ALK-positive NSCLC.

As regards the second-line treatment of ALK-positive NSCLC patients previously treated with crizotinib, the corresponding study showed an overall response rate for the Alunbrig treatment that is clinically significant compared to the historical data for chemotherapy.

The final reports for the above-mentioned clinical trials will yield further findings on the efficacy and safety of Alunbrig.

Based on all the available data, the benefits of Alunbrig outweigh the risks. Swissmedic has therefore authorised the medicinal product Alunbrig with the active substance brigatinib for the treatment of adult patients with ALK-positive NSCLC who have not yet received treatment with an ALK inhibitor. Alunbrig has also been authorised as a second-line treatment of ALK-positive NSCLC in patients previously treated with crizotinib.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Alunbrig®

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

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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