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Public Summary SwissPAR dated 29 December 2023

Brukinsa® (active substance: zanubrutinib)

Indication extension in Switzerland: 29 August 2023

Medicinal product (hard capsule) for the treatment of adults with chronic lymphocytic leukaemia (CLL)

About the medicinal product

Brukinsa, containing the active substance zanubrutinib, is used in adults with chronic lymphocytic leukaemia (CLL). The patients have already received at least one prior treatment.

CLL is a blood cancer of the lymphocytes (white blood cells) that also affects the lymph nodes.

Since this is a rare, life-threatening disease, Brukinsa has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Swissmedic already granted Brukinsa authorisation for the treatment of adults with Waldenström's macroglobulinaemia (WM) on 8 February 2022.

Mode of action

Brukinsa works by specifically blocking Bruton tyrosine kinase. Bruton tyrosine kinase is an enzyme[1] that is partly responsible for the survival and growth of CLL cancer cells. By blocking this enzyme, Brukinsa can reduce the number of CLL cancer cells and slow the progression of the disease.

Indication

Brukinsa, containing the active substance zanubrutinib, is a prescription-only medicine and has been authorised as hard capsules in the dosage strength 80 mg.

The recommended dose is 4 capsules daily. 4 capsules once a day or 2 capsules twice a day, morning and evening. Brukinsa should be taken at approximately the same time each day, with or without food. The capsules must be swallowed whole with a glass of water. The capsules must not be opened, dissolved, or chewed before swallowing.

[1] Enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

Efficacy

The efficacy of Brukinsa for the treatment of adults with CLL was investigated in a study (BGB-3111-305) with 652 patients.

The study was conducted in patients with CLL who had received at least one prior treatment. Half of the participants received 320 mg Brukinsa daily and the other half received 420 mg ibrutinib daily (active substance already approved for the treatment of CLL).

The primary endpoint of the study was the objective response rate (ORR)[2], assessed by the investigator using pre-defined criteria. The objective response rate as assessed by the investigator was significantly higher for Brukinsa compared to ibrutinib (78.3% versus 62.5%).

The results of the secondary endpoints of progression-free survival (PFS)[3], as assessed by the investigator and the independent review committee (IRC), and overall survival (OS)[4] also showed an advantage of Brukinsa over ibrutinib.

Precautions, undesirable effects, & risks

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

Brukinsa may cause side effects, which must be reported to the doctor without delay. The most common undesirable effects (≥10%) in patients treated with Brukinsa are neutropenia (low count of a particular group of white blood cells), thrombocytopenia (low platelet count), upper respiratory tract infection, bleeding/haematoma incl. bruising, skin rash, anaemia (low red blood cell count), musculoskeletal pain, diarrhoea, pneumonia, cough, fatigue, urinary tract infection, constipation and dizziness.

All precautions, risks, and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Although chronic lymphocytic leukaemia (CLL) is a rare disease, it is the most common form of leukaemia in the western world, with an estimated incidence of approx. 5–10 cases per 100,000 people every year in Switzerland. Although considerable progress has been made in the treatment of CLL, the disease remains incurable and there is a considerable medical need for safe and effective treatment options.

The data from study BGB-3111-305 show an advantage in overall survival (OS) for Brukinsa compared to ibrutinib. The safety profile of Brukinsa is also comparable to that of ibrutinib, with a lower incidence of atrial fibrillation.

Since CLL is a cancer that typically lasts for a long time, the final reports from these clinical trials should provide further information

[2] Objective response rate: the ORR is defined as the percentage of patients who respond to the treatment.

[3] 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.

[4] Overall survival (OS): refers to the period between the start of treatment and the death of the patient.

in future about the efficacy and safety of Brukinsa.

Based on all the available data, the benefits of Brukinsa outweigh the risks. Swissmedic has therefore authorised the indication extension for Brukinsa for the treatment of adults with CLL who have received at least one prior treatment.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Brukinsa

Information for patients (package leaflet): Information for patients Brukinsa

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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