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SCIENCE MEDICINES HEALTH

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Brukinsa (*zanubrutinib*)

An overview of Brukinsa and why it is authorised in the EU

What is Brukinsa and what is it used for?

Brukinsa is a medicine for treating adults with the following types of blood cancers that affect a type of white blood cell called B lymphocytes or B cells:

- Waldenström's macroglobulinaemia (also known as lymphoplasmacytic lymphoma). Brukinsa is used on its own in patients who have not been treated before and who cannot receive chemo-immunotherapy (a type of cancer treatment), or in patients who have received at least one prior therapy;
- Marginal zone lymphoma (MZL). Brukinsa is used on its own when the disease has come back after at least one prior therapy targeting a protein on B lymphocytes called CD20;
- Chronic lymphocytic leukaemia (CLL). Brukinsa is used on its own in patients for the treatment of CLL.
- Follicular lymphoma (FL). Brukinsa is used in combination with another cancer medicine, obinutuzumab, in adult patients whose disease has come back or has not responded to at least two prior therapies.

Brukinsa contains the active substance zanubrutinib.

How is Brukinsa used?

Brukinsa can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

Brukinsa is available as capsules to be taken by mouth.

The doctor may decide to interrupt and reduce the dose or stop treatment if serious side effects occur. The doctor may also decide to reduce the dose if Brukinsa is taken together with certain other medicines.

For more information about using Brukinsa, see the package leaflet or contact your doctor or pharmacist.

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How does Brukinsa work?

The active substance in Brukinsa, zanubrutinib, blocks the action of an enzyme known as Bruton's tyrosine kinase (BTK). BTK is important for the growth of B cells, including the abnormal B cells in patients with Waldenström's macroglobulinaemia, MZL, CLL or FL. By blocking the action of BTK, the medicine is expected to slow the progression of the disease.

What benefits of Brukinsa have been shown in studies?

Waldenström's macroglobulinaemia

In a main study in 201 patients with Waldenström's macroglobulinaemia who had not received a BTK inhibitor before, the effects of Brukinsa were compared with those of ibrutinib, another BTK inhibitor that is authorised in the European Union (EU). Brukinsa showed similar effects to those of ibrutinib. After 20 months of treatment on average, about 28% of patients (29 out of 102) who received Brukinsa had almost no signs of cancer (very good partial response) compared with 19% (19 out of 99) of patients who received ibrutinib. Beneficial effects were seen both, in patients who had not been treated before and in those whose cancer had come back or not responded to previous treatment.

Marginal zone lymphoma

The main study of Brukinsa in marginal zone lymphoma involved 66 patients whose cancer had come back or did not respond to previous treatment targeting CD20. Overall, around 68% (45 out of 66) had at least a partial response after an average of 28 months of treatment: 26% (17 out of 66) had a complete response (no signs of cancer) and 42% (28 out of 66) had a partial response.

Chronic lymphocytic leukaemia

The benefits of Brukinsa in chronic lymphocytic leukaemia have been investigated in two main studies, both of which are ongoing. In the first study, involving patients with either CLL or small lymphocytic leukaemia whose disease had not been treated before, Brukinsa was compared with bendamustine in combination with rituximab. After about 23 months of treatment on average, death or signs that the cancer was progressing occurred in about 15% of patients (36 out of 241) who received Brukinsa compared with about 30% (71 out of 238) of those who received bendamustine in combination with rituximab.

In the second study, patients with CLL or small lymphocytic leukaemia whose disease had not improved (refractory) or had come back (relapsed) following treatment with at least one prior therapy, Brukinsa was compared with ibrutinib. Brukinsa showed similar effects to those of ibrutinib. After about 14 months of treatment on average, the disease responded to treatment in about 78% of patients (162 out of 207) who received Brukinsa compared with about 63% (130 out of 208) of those who received ibrutinib.

Follicular lymphoma

In a study involving 217 patients with follicular lymphoma whose cancer had come back or did not respond to previous treatment, Brukinsa given with obinutuzumab for 48 months was compared with obinutuzumab alone. Around 69% (100 out of 145) of those treated with Brukinsa and obinutuzumab had at least a partial response to treatment (a decrease in the extent of cancer in the body) after an average of 28 months of treatment compared to 46% (33 out of 72) of those treated with obinutuzumab alone.

What are the risks associated with Brukinsa?

For the full list of side effects and restrictions of Brukinsa, see the package leaflet.

The most common side effects with Brukinsa (which may affect more than 1 in 5 people) include neutropenia (low levels of neutrophils, a type of white blood cell), upper respiratory tract (nose and throat) infection, haemorrhage (bleeding), bruising, rash, musculoskeletal pain (pain in the muscles and bones), pneumonia (infection of the lungs), diarrhoea and cough.

The most common serious side effects with Brukinsa (which may affect up to 1 in 10 people) include neutropenia, pneumonia, hypertension (high blood pressure), anaemia, haemorrhage and thrombocytopenia (low levels of blood platelets, components that help the blood to clot).

Why is Brukinsa authorised in the EU?

Brukinsa was shown to be effective at slowing the progression of Waldenström's macroglobulinaemia both in patients who had not been treated before and in those whose cancer had not responded to previous treatment. Brukinsa was also shown to be effective in treating MZL and FL that had come back or not responded to previous therapy. In addition, Brukinsa was shown to be effective in treating CLL when the disease was not previously treated or when it had come back or not responded to at least one prior therapy. The side effects of Brukinsa are considered manageable.

The European Medicines Agency decided that Brukinsa's benefits are greater than its risks and it can be authorised for use in the EU.

What information is still awaited for Brukinsa?

The company that markets Brukinsa will provide results from a study comparing Brukinsa with lenalidomide, both given in combination with rituximab, in patients with marginal zone lymphoma whose disease has come back or not responded to prior therapy.

What measures are being taken to ensure the safe and effective use of Brukinsa?

The company that markets Brukinsa will provide results from two studies to confirm the medicine's effectiveness and safety.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Brukinsa have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Brukinsa are continuously monitored. Suspected side effects reported with Brukinsa are carefully evaluated and any necessary action taken to protect patients.

Other information about Brukinsa

Brukinsa received a marketing authorisation valid throughout the EU on 22 November 2021.

Further information on Brukinsa can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/brukinsa.

This overview was last updated in 12-2023.