THE FIRST AND ONLY BTKi APPROVED IN FOLLICULAR LYMPHOMA

BRUKINSA® + Obinutuzumab reduced the relative risk of progression or death by 50% vs obinutuzumab alone[1]

Approx. 70% of patients had sustained responses at 18 months with BRUKINSA® + Obinutuzumab[1]

Reference

1. Zinzani PL, Mayer J, Flowers CR, et al. ROSEWOOD: A Phase II Randomized Study of Zanubrutinib Plus Obinutuzumab Versus Obinutuzumab Monotherapy in Patients With Relapsed or Refractory Follicular Lymphoma. J Clin Oncol. 2023; 41(33):5107-5117

Abbreviated Prescribing Information

Presentation: BRUKINSA® (zanubrutinib) capsules 80mg. **Indication:** BRUKINSA® as monotherapy is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. BRUKINSA® as monotherapy is indicated for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based therapy. BRUKINSA® as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL). BRUKINSA® in combination with obinutuzumab is indicated for the treatment of adult patients with refractory or relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. **Dosage & Administration:** The recommended total daily dose of BRUKINSA® is 320 mg. The daily dose may be taken either once daily (four 80 mg capsules) or divided into two doses of 160 mg twice daily (two 80 mg capsules). **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special Warnings & Precautions:** (1) Haemorrhage: Warfarin or other vitamin K antagonists should not be administered concomitantly with BRUKINSA®. Patients should be monitored for signs and symptoms of bleeding and monitor complete blood counts. Consider the risks and benefits of anticoagulant or antiplatelet therapy when co-administered with BRUKINSA®, (2) Infections: Consultation with a liver disease expert physician is recommended for patients who test positive for HBV or have positive hepatitis B serology, before initiating treatment. Patients should be monitored and managed according to the medical standards to prevent hepatitis B reactivation. Consider prophylaxis according to standard of care in patients who are at increased risk for infections. Patients should be monitored for signs and symptoms of infection and treat appropriately, (3) Cytopenia: Monitor complete blood counts monthly during treatment, (4) Second primary malignancies including skin cancer: Advise patients to use sun protection, (5) Atrial fibrillation and flutter: Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate, (6) Women of childbearing potential: Women of childbearing potential must use a highly effective method of contraception while taking BRUKINSA®, (7) BRUKINSA® contains sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. **Undesirable effects:** The most commonly occurring adverse reactions (≥20%) were neutropenia, thrombocytopenia, upper respiratory tract infection, haemorrhage/haematoma, rash, bruising, anaemia, musculoskeletal pain, diarrhoea, pneumonia and cough. Refer to the full prescribing information for other undesirable effects. **Interactions:** If a strong and moderate CYP3A inhibitor must be used, reduce the BRUKINSA® dose for the duration of the inhibitor use. Concomitant use with strong and moderate CYP3A inducers should be avoided. No clinically significant differences in BRUKINSA® pharmacokinetics were observed when co administered with gastric acid reducing agents. **Pregnancy & Lactation:** BRUKINSA® should not be used during pregnancy. Breast-feeding should be discontinued during treatment with BRUKINSA®. **Full prescribing information should be consulted prior to prescribing.**

VV-QDOC-229771 Approved on 28 Jan 2025

BeOne

BeOne Medicines (Hong Kong) Co., Ltd.
Room 1002, Level 10, Two Chinachem Central,
26 Des Voeux Road Central, Central, Hong Kong

Brukinsa® zanubrutinib 80mg capsules