DISCUSSION OF BRUKINSA® FOR ADULT PATIENTS WITH WALDENSTRÖM’S MACROGLOBULINEMIA (WM)

ABOUT

Join us for an informative discussion on the trial data for BRUKINSA® in Waldenström’s macroglobulinemia (WM), as well as a review of its dosage and administration.

Healthcare professionals including hematologist oncologists, medical oncologists, pharmacists, PAs, NPs, and RNs are encouraged to participate in this interactive dialogue.

DATE & TIME

November 9, 2022
6:00 PM

LOCATION

Bacco Ristorante
29410 Northwestern Highway
Southfield, MI 48034

COVID-19 Requirements: Please note that certain venues may require proof of vaccination for program attendees. Please check with the program host for more information.

RSVP

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SPEAKER

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INDICATION

BRUKINSA® (zanubrutinib) is a kinase inhibitor indicated for the treatment of adults with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Waldenström’s macroglobulinemia (WM).
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

The MCL and MZL indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hemorrhage: Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.4% of patients treated with BRUKINSA monotherapy. Hemorrhage events of any grade, excluding purpura and petechiae, occurred in 35% of patients.

In accordance with the updated PhRMA Code, BeiGene is no longer able to provide alcohol as part of this educational program.

Participants can purchase their own alcoholic beverages directly from the venue.

Spouses and other guests who are not healthcare professionals may not attend this event. Please be aware that if you are a licensed US physician, the meal associated with this program is reportable under the Federal Open Payments/Sunshine Act. State laws and federal entities may restrict your ability to receive meals offered in connection with this event. You are responsible for complying with any restrictions or limitations related to such requirements.

YOU'RE INVITED
**IMPORTANT SAFETY INFORMATION (CONT.)**

**Warnings and Precautions (cont.)**

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections: Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 27% of patients, most commonly pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias: Grade 3 or 4 cytopenias, including neutropenia (26%), thrombocytopenia (11%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was nonmelanoma skin cancer reported in 8% of patients. Other second primary malignancies included malignant solid tumors (4.0%), melanoma (1.7%) and hematologic malignancies (1.2%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias: Atrial fibrillation and atrial flutter were reported in 3.2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension and acute infections may be at increased risk. Grade 3 or higher events were reported in 1.1% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity: Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

**Adverse Reactions**

The most common adverse reactions, including laboratory abnormalities, in ≥ 30% of patients included neutrophil count decreased (54%), upper respiratory tract infection (47%), platelet count decreased (41%), hemorrhage (35%), lymphocyte count decreased (31%), rash (31%) and musculoskeletal pain (30%).

**Drug Interactions**

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with moderate or strong CYP3A inducers.

**Specific Populations**

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

Please see full Prescribing Information for BRUKINSA (zanubrutinib).