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You are invited to attend a live educational event to discuss

IMBRUVICA® as a frontline CLL treatment

PROGRAM OVERVIEW

- Describe the clinical characteristics of chronic lymphocytic leukemia (CLL)
- Examine efficacy, dosing, and safety profile established in the RESONATE™-2 trial in frontline CLL for patients 65 years of age or older
- Review updated NCCN guidelines in the treatment of CLL

PRESENTED BY:
Kara Saggiomo, MSN, RN, APOCNP, APN-C
Cancer Institute of New Jersey
New Brunswick, NJ

Wednesday, April 6, 2016
6:30 PM Registration
7:00 PM Presentation

Due Mari Pesce
78 Albany Street
New Brunswick, NJ 08901
(732) 296-1600

TO RSVP, GO TO:
www.mydomeprogramregistration.com
Enter Code: 2016-00664

Please note:
Your e-mail address is required for registration. The information you provide will only be used to facilitate your attendance at this program.

YOU MAY ALSO RSVP TO:
Jeff Lynch
jlynch1@its.jnj.com
(917) 566-1471

Please provide event details when you RSVP.

If you have any questions about this program, please contact:

Nadia Said
nsaid@sphase.com
(678) 529-6283

WARNINGS AND PRECAUTIONS

hemorrhage, infections, cytopenias, atrial fibrillation, hypertension, second primary malignancies, tumor lysis syndrome, and embryo-fetal toxicity

ADVERSE REACTIONS

Adverse reactions ≥20% in patients across 3 CLL registration studies were thrombocytopenia (53%), diarrhea (48%), neutropenia (46%), anemia (37%), musculoskeletal pain (32%), fatigue (29%), bruising (25%), nausea (24%), rash (23%), pyrexia (21%), and cough (20%).

Please see the Important Safety Information on the back and the accompanying full Prescribing Information.

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INDICATIONS

IMBRUVICA® is a kinase inhibitor indicated for the treatment of patients with:

· Chronic lymphocytic leukemia (CLL)

· Chronic lymphocytic leukemia with 17p deletion

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage - Fatal bleeding events have occurred in patients treated with IMBRUVICA®. Grade 3 or higher bleeding events (intracranial hemorrhage [including subdural hematoma], gastrointestinal bleeding, hematuria, and post-procedural hemorrhage) have occurred in up to 6% of patients. Bleeding events of any grade, including bruising and petechiae, occurred in approximately half of patients treated with IMBRUVICA®.

The mechanism for the bleeding events is not well understood. IMBRUVICA® may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies and patients should be monitored for signs of bleeding. Consider the benefit-risk of withholding IMBRUVICA® for at least 3 to 7 days pre- and postsurgery depending upon the type of surgery and the risk of bleeding.

Infections - Fatal and nonfatal infections have occurred with IMBRUVICA® therapy. Grade 3 or greater infections occurred in 14% to 26% of patients. Cases of progressive multifocal leukoencephalopathy (PML) have occurred in patients treated with IMBRUVICA®. Evaluate patients for fever and infections and treat appropriately.

Cytopenias - Treatment-emergent Grade 3 or 4 cytopenias including neutropenia (range, 19% to 29%), thrombocytopenia (range, 5% to 17%), and anemia (range, 0% to 9%) occurred in patients treated with IMBRUVICA®. Monitor complete blood counts monthly.

Atrial Fibrillation - Atrial fibrillation and atrial flutter (range, 6% to 9%) have occurred in patients treated with IMBRUVICA®, particularly in patients with cardiac risk factors, hypertension, acute infections, and a previous history of atrial fibrillation. Periodically monitor patients clinically for atrial fibrillation. Patients who develop arrhythmic symptoms (eg, palpitations, lightheadedness) or new-onset dyspnea should have an ECG performed. Atrial fibrillation should be managed appropriately and if it persists, consider the risks and benefits of IMBRUVICA® treatment and dose modification.

Hypertension - Hypertension (range, 6% to 17%) has occurred in patients treated with IMBRUVICA® with a median time to onset of 4.5 months (range, 0.03 to 18.40 months). Monitor patients for new-onset hypertension or hypertension that is not adequately controlled after starting IMBRUVICA®. Adjust existing antihypertensive medications and/or initiate antihypertensive treatment as appropriate.

Second Primary Malignancies - Other malignancies (range, 5% to 16%) including non-skin carcinomas (range, 1% to 4%) have occurred in patients treated with IMBRUVICA®. The most frequent second primary malignancy was non-melanoma skin cancer (range, 4% to 13%).

Tumor Lysis Syndrome - Tumor lysis syndrome has been infrequently reported with IMBRUVICA® therapy. Assess the baseline risk (eg, high tumor burden) and take appropriate precautions. Monitor patients closely and treat as appropriate.

Embryo-Fetal Toxicity - Based on findings in animals, IMBRUVICA® can cause fetal harm when administered to a pregnant woman. Advise women to avoid becoming pregnant while taking IMBRUVICA® and for 1 month after cessation of therapy. 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 (≥20%) in patients with B-cell malignancies (MCL, CLL, WM) were thrombocytopenia* (57%, 53%, 43%), diarrhea (51%, 48%, 37%), anemia* (41%, 37%, 13%), neutropenia* (47%, 46%, 44%), musculoskeletal pain (37%, 32%†, NA‡), fatigue (41%, 29%, 21%), bruising (30%, 25%†, 16%†), nausea (31%, 24%, 21%), rash (25%, 23%†, 22%†), and upper respiratory tract infection (34%, 19%, 19%).

*Based on adverse reactions and/or laboratory measurements (noted as platelets, neutrophils, or hemoglobin decreased).
†Includes multiple ADR terms.
‡Not applicable; no associated ADRs.

The most common Grade 3 or 4 non-hematologic adverse reactions (≥5%) in MCL patients were pneumonia (7%), abdominal pain (5%), atrial fibrillation (5%), diarrhea (5%), fatigue (5%), and skin infections (5%).

Approximately 4% (CLL), 14% (MCL), and 11% (WM) of patients had a dose reduction due to adverse reactions.

Approximately 4%-10% (CLL), 9% (MCL), and 6% (WM) of patients discontinued due to adverse reactions. Most frequent adverse reactions leading to discontinuation were pneumonia, subdural hematomas, and atrial fibrillation (1% each) in CLL patients and subdural hematoma (1.8%) in MCL patients.

DRUG INTERACTIONS

CYP3A Inhibitors - Avoid coadministration with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA® dose.

CYP3A Inducers - Avoid coadministration with strong CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment - Avoid use in patients with moderate or severe baseline hepatic impairment. In patients with mild impairment, reduce IMBRUVICA® dose.

Please see accompanying full Prescribing Information.

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