imbruvica®
(ibrutinib) 140mg capsules

CLL/SLL

MCL

You are invited to attend an educational event on

IMBRUVICA® (ibrutinib) with a focus on CLL/SLL and MCL*

*Indicated for the treatment of patients with MCL who have received at least one prior therapy. Accelerated approval was granted for the MCL indication based on overall response rate. Continued approval for the MCL indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Program Overview:

- IMBRUVICA® overview, mechanism of action, and clinical trial data
- Dosing, administration, safety information, and patient support services

PRESENTED BY:

Kara Saggiomo, MSN, RN, APOCNP, APN-C

Cancer Institute of New Jersey

New Brunswick, NJ

Wednesday, December 6, 2017

6:30 PM Registration

7:00 PM Presentation

Steakhouse 85

85 Church Street,

New Brunswick, NJ 08901

TO RSVP, GO TO:

http://bit.ly/Steakhouse85

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:

Maureen Crowley

mcrowl16@its.jnj.com | (908) 268-4084

Please provide event details when you RSVP
If you have any questions about this
program, please contact

Shelby Ramos

sramos@sphase.com | (678) 385-0316

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia (61%), thrombocytopenia (62%), diarrhea (43%), anemia (41%), musculoskeletal pain (30%), rash (30%), nausea (29%), bruising (30%), fatigue (29%), hemorrhage (22%), and pyrexia (21%).

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:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy.

Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

- Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).
- Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) with 17p deletion.
- Waldenström's macroglobulinemia (WM).
- Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.

Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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 29% of patients. Cases of progressive multifocal leukoencephalopathy (PML) and *Pneumocystis jirovecii* pneumonia (PJP) 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, 13% to 29%), thrombocytopenia (range, 5% to 17%), and anemia (range, 0% to 13%) based on laboratory measurements occurred in patients treated with single agent IMBRUVICA®. Monitor complete blood counts monthly.

Atrial Fibrillation - Atrial fibrillation and atrial flutter (range, 0% 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 follow dose modification guidelines.

Hypertension - Hypertension (range, 0% to 17%) has occurred in patients treated with IMBRUVICA® with a median time to onset of 4.6 months (range, 0.03 to 22 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, 3% 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, 2% 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. Advise men to avoid fathering a child during the same time period.

ADVERSE REACTIONS
The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were neutropenia* (61%), thrombocytopenia* (62%), diarrhea (43%), anemia* (41%), musculoskeletal pain (30%), rash (30%), nausea (29%), bruising (30%), fatigue (29%), hemorrhage (22%), and pyrexia (21%).

* Based on adverse reactions and/or laboratory measurements (noted as platelets, neutrophils, or hemoglobin decreased).

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%).

The most common Grade 3 or 4 non-hematologic adverse reactions (≥5%) in MZL patients were pneumonia (10%), fatigue (6%), diarrhea (5%), rash (5%), and hypertension (5%).

Approximately 6% (CLL/SLL), 14% (MCL), 11% (WM) and 10% (MZL) of patients had a dose reduction due to adverse reactions. Approximately 4%-10% (CLL/SLL), 9% (MCL), and 9 % (WM [9%] and MZL [13%]) of patients discontinued due to adverse reactions. Most common adverse reactions leading to discontinuation were pneumonia, hemorrhage, atrial fibrillation, rash, and neutropenia (1% each) in CLL/SLL patients and subdural hematoma (1.8%) in MCL patients. The most common adverse reactions leading to discontinuation were interstitial lung disease, diarrhea, and rash (1.6% each) in WM and MZL 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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PRC-02757 05/17