PRESENTED BY:
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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:
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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
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If you have any questions about this program, please contact:
Nadia Said
nsaid@sphase.com
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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.

Sponsored by Pharmacyclics LLC, an AbbVie company, and Janssen Biotech, Inc.
IMBRUVICA® as a frontline CLL treatment

You are invited to attend a live educational event to discuss IMBRUVICA® as a frontline CLL treatment.

DISCLOSURE
This promotional educational activity is not accredited.

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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 (extracranial 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 anticoagulant or antiplatelet 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 post-surgery 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, 6% 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 6%) have occurred in patients treated with IMBRUVICA®, particularly in patients with cardiovascular 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 a 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, 6% 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%).

The most common Grade 3 or 4 non-hematologic adverse reactions (≥5%) in MCL patients were pneumonia (7%), abdominal pain (6%), atrial fibrillation (6%), 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

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

CYRPA 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.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL, WM) were thrombocytopenia (67%, 53%, 43%), diarrhea (51%, 48%, 37%), nausea (11%, 3%, 13%), neutropenia (47%, 46%, 44%), musculoskeletal pain (51%, 32%, NA), fatigue (41%, 29%, 21%), bruising (50%, 29%, 16%), nasopharyngitis (51%, 24%, 21%), rash (25%, 23%, 22%), and upper respiratory tract infection (34%, 10%, 19%).

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

See multiple ADR terms.

Not applicable: no associated ADRs.

Please see accompanying full Prescribing Information.

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