

You are cordially invited
to attend a live educational program

IMBRUVICA[®] (ibrutinib):

Single-Agent Therapy for Previously Treated
Chronic Lymphocytic Leukemia (CLL) and del 17p CLL

PROGRAM OVERVIEW

- Introduce IMBRUVICA[®] as a single-agent treatment option for previously treated CLL and patients with del 17p CLL
- Discuss the safety and efficacy profile of IMBRUVICA[®]
- Review oral, once-daily dosing and administration

PRESENTED BY:

Nakhle Saba, MD

Assistant Professor of Clinical Medicine
Tulane University
New Orleans, LA

Saturday, July 18, 2015

12:30 PM – Registration

12:40 PM - Presentation

Roosevelt Hotel

123 Baronne Street
New Orleans, LA 70112
(504) 648-1200

IMPORTANT SAFETY INFORMATION

Warnings and Precautions include hemorrhage, infections, cytopenias, atrial fibrillation, second primary malignancies, tumor lysis syndrome, and embryo-fetal toxicity. Please see additional Important Safety Information on reverse side.

Please see accompanying full Prescribing Information.

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TO RSVP, GO TO:

[http://imbruvica.sphasereg.com/default.aspx?PID=2802&R
SID=660](http://imbruvica.sphasereg.com/default.aspx?PID=2802&R SID=660)

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:

Merribeth Bazzell

mbazzell@pcyc.com

(985) 789-6738

Please provide event details when you RSVP

If you have any questions about this program,
please contact
Brittany Hickcox

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imbruvica[®]
(ibrutinib) 140mg capsules

IMBRUVICA[®] (ibrutinib):

Single-Agent Therapy for Previously Treated Chronic Lymphocytic Leukemia (CLL) and del 17p CLL

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INDICATIONS

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

- **Chronic lymphocytic leukemia (CLL) who have received at least one prior therapy**
- **Chronic lymphocytic leukemia (CLL) 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 (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. 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 non-fatal 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[®]. Monitor patients for fever and infections and evaluate promptly.

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, 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. If atrial fibrillation persists, consider the risks and benefits of IMBRUVICA[®] treatment and dose modification.

Second Primary Malignancies - Other malignancies (range, 5 to 14%) including non-skin carcinomas (range, 1 to 3%) have occurred in patients treated with IMBRUVICA[®]. The most frequent second primary malignancy was non-melanoma skin cancer (range, 4 to 11%).

Tumor Lysis Syndrome - Tumor lysis syndrome has been reported with IMBRUVICA[®] therapy. Monitor patients closely and take appropriate precautions in patients at risk for tumor lysis syndrome (e.g. high tumor burden).

Embryo-Fetal Toxicity - Based on findings in animals, IMBRUVICA[®] can cause fetal harm when administered to a pregnant woman. Advise pregnant while taking IMBRUVICA[®]. 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 (≥25%) in patients with B-cell malignancies (MCL, CLL, WM) were thrombocytopenia, neutropenia, diarrhea, anemia, fatigue, musculoskeletal pain, bruising, nausea, upper respiratory tract infection, and rash. Seven percent of patients receiving IMBRUVICA[®] discontinued treatment due to adverse events.

DRUG INTERACTIONS

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

CYP3A Inducers - Avoid co-administration 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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(ibrutinib) 140mg capsules


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