

You are cordially invited  
to attend a live educational program

## IMBRUVICA<sup>®</sup> (ibrutinib):

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

### PROGRAM OVERVIEW

- Introduce IMBRUVICA<sup>®</sup> as a single-agent treatment option for previously treated CLL and patients with del 17p CLL
- Discuss the safety and efficacy profile of IMBRUVICA<sup>®</sup>
- 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.

Sponsored by Pharmacyclics, Inc., and Janssen Biotech,

#### TO RSVP, GO TO:

<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](mailto: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

[bhickcox@sphase.com](mailto:bhickcox@sphase.com)

(770) 984-5174

**imbruvica<sup>®</sup>**  
(ibrutinib) 140mg capsules

# IMBRUVICA<sup>®</sup> (ibrutinib):

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

### DISCLOSURE

This promotional educational activity is not accredited.

In adherence with PhRMA guidelines and the policies of Janssen Biotech, Inc., and Pharmacyclics, Inc., spouses or other guests are not permitted to attend company-sponsored programs. For all attendees, please be advised that information related to the event, such as your name and the value and purpose of any educational item, meal, or other items of value you receive, may be publicly disclosed. If you are

licensed in any state or other jurisdiction, or are an employee or contractor of any organization or governmental entity that limits or prohibits meals from pharmaceutical companies, please identify yourself so that you (and we) are able to comply with such requirements. Thank you for your cooperation.

The program content is developed by Janssen Biotech, Inc., and Pharmacyclics, Inc. Speakers present on disease state education on behalf of the company and are required to present information in compliance with FDA requirements about its medicines.

The personal information you provide will be used to contact you about your request to attend the Janssen Biotech, Inc., and Pharmacyclics, Inc., educational program using your preferred method of communication as indicated by you.

This information will be shared with Janssen Biotech, Inc., and Pharmacyclics, Inc., their affiliates, and a third party for the purpose of completing your registration for this program and as required by law.

### INDICATIONS

**IMBRUVICA<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup>.

The mechanism for the bleeding events is not well understood. IMBRUVICA<sup>®</sup> may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies. Consider the benefit-risk of withholding IMBRUVICA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup>. Monitor complete blood counts monthly.

**Atrial Fibrillation** - Atrial fibrillation and atrial flutter (range, 6 to 9%) have occurred in patients treated with IMBRUVICA<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> can cause fetal harm when administered to a pregnant woman. Advise pregnant while taking IMBRUVICA<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> dose.

Please see accompanying full Prescribing Information.

© Pharmacyclics, Inc. 2015.  
© Janssen Biotech, Inc. 2015.  
PRC-01042 04/15

 pharmacyclics<sup>®</sup>

  
imbruvica<sup>®</sup>  
(ibrutinib) 140mg capsules

  
janssen  
PHARMACEUTICAL COMPANY  
of Johnson & Johnson