

PLEASE JOIN US FOR A CLINICAL DISCUSSION ON AN FDA-APPROVED 1L CLL TREATMENT

# GAZYVA® (OBINUTUZUMAB) FOR CHRONIC LYMPHOCYTIC LEUKEMIA

## Indication

GAZYVA® (obinutuzumab), in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).

## Discussion Objectives:

- Review the efficacy and safety results from Arm 2 vs Arm 3 of the CLL-11 study, which evaluated GAZYVA + chlorambucil (Clb) vs rituximab + Clb in first-line CLL
- Explore the proposed mechanisms of action of GAZYVA
- Review the dosing and administration of GAZYVA in previously untreated patients with CLL

<b>Presented by:</b> Gabriella Magarelli, RN, ACNP-BC John Theurer Cancer Center Hackensack University Medical Center  <b>Date:</b> Tuesday, September 8, 2015	<b>Hosted by:</b> Abid Siddiq Genentech  <b>Location:</b> Rat's Restaurant 16 Fairgrounds Road Trenton, NJ 08619 609-584-7800	<b>Schedule of events:</b> 6:00 PM Registration 6:30 PM Program and dinner 8:00 PM Closing statements  <b>Registration:</b> Please register for this event by 9/1/2015. Register online at <a href="http://www.genersvp.com">www.genersvp.com</a> with reference event code PRF52768 or RSVP to Abid Siddiq at <a href="mailto:siddiq.abid@gene.com">siddiq.abid@gene.com</a> or 215-205-4557
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## Important Safety Information

### Boxed WARNINGS: HEPATITIS B VIRUS REACTIVATION and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- Hepatitis B Virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients receiving CD20-directed cytolytic antibodies, including GAZYVA. Screen all patients for HBV infection before treatment initiation. Monitor HBV positive patients during and after treatment with GAZYVA. Discontinue GAZYVA and concomitant medications in the event of HBV reactivation
- Progressive Multifocal Leukoencephalopathy (PML) including fatal PML, can occur in patients receiving GAZYVA

This is a Genentech promotional activity. NOTE: No continuing nursing education (CNE) credit will be awarded.

Please see Important Safety Information on back. For additional Important Safety Information, please see the accompanying full Prescribing Information, including Boxed WARNINGS.



**We look forward to your participation!**

## **Additional Warnings and Precautions**

- **Infusion Reactions:** GAZYVA can cause severe and life-threatening infusion reactions. For patients with Grade 4 infusion reactions, including but not limited to anaphylaxis, acute life-threatening respiratory symptoms, or other life-threatening infusion reaction, stop and permanently discontinue GAZYVA therapy. Premedicate patients with acetaminophen, an antihistamine, and a glucocorticoid. Closely monitor patients during the entire infusion. Infusion reactions within 24 hours of receiving GAZYVA have occurred. For Grades 1, 2, or 3 infusion reactions, interrupt or discontinue infusion for reactions
- **Tumor Lysis Syndrome (TLS):** TLS can occur within 12-24 hours after the first infusion. Patients with high tumor burden and/or high circulating lymphocyte count ( $>25 \times 10^9/L$ ) are at greater risk for TLS and should receive appropriate tumor lysis prophylaxis with antihyperuricemics and hydration beginning 12-24 hours prior to the infusion of GAZYVA
- **Infections:** Serious bacterial, fungal, and new or reactivated viral infections can occur during and following GAZYVA therapy. Fatal infections have been reported. Do not administer GAZYVA to patients with an active infection
- **Neutropenia:** Severe neutropenia can occur. Monitor patients with Grade 3 to 4 neutropenia frequently with regular laboratory tests until resolution. Neutropenia can also be of late onset and/or prolonged
- **Thrombocytopenia:** Fatal hemorrhagic events have been reported. Severe thrombocytopenia can occur. Monitor all patients for thrombocytopenia. In patients with Grade 3 or 4 thrombocytopenia, monitor platelet counts and bleeding frequently until resolution and consider dose delays of GAZYVA and chlorambucil or dose reductions of chlorambucil. Management of hemorrhage may require blood product support

## **Additional Important Safety Information**

- Grade 3/4 adverse reactions were: neutropenia (33%), infusion reactions (20%), thrombocytopenia (10%), anemia (4%), leukopenia (4%), diarrhea (2%), urinary tract infection (1%), pyrexia ( $<1\%$ ), and nasopharyngitis ( $<1\%$ )
- The most common adverse reactions (incidence  $\geq 10\%$ ) were: infusion reactions (66%), neutropenia (38%), thrombocytopenia (14%), nausea (12%), anemia (11%), pyrexia (10%), cough (10%), and diarrhea (10%)

**You are encouraged to report side effects to Genentech and the FDA. You may contact Genentech by calling 1-888-835-2555. You may contact the FDA by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or calling 1-800-FDA-1088.**

**Please see the accompanying full Prescribing Information for additional Important Safety Information, including Boxed WARNINGS.**