PLEASE JOIN US FOR A CLINICAL DISCUSSION

GAZYVA® (OBINUTUZUMAB) FOR FIRST-LINE CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) AND R/R FOLLICULAR LYMPHOMA*

Program Overview:

- Review efficacy and safety data supporting the following indications:
  - GAZYVA® (obinutuzumab), in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL)
  - GAZYVA® (obinutuzumab), in combination with bendamustine followed by GAZYVA monotherapy, is indicated for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen
- Review the efficacy and safety results from the CLL-11 study, which evaluated GAZYVA + chlorambucil vs rituximab + chlorambucil in first-line CLL
- Review the efficacy and safety results from the GADOLIN study, which evaluated GAZYVA plus bendamustine followed by GAZYVA monotherapy, compared to bendamustine alone, in patients with follicular lymphoma who had no response to or who progressed within 6 months of therapy with a rituximab-containing regimen
- Communicate important safety information for GAZYVA, including adverse reactions and management of infusion-related reactions
- Discuss the dosing and administration of GAZYVA for each indication

Audience:

This oncology program has been developed for nurse discussion and participation.

Presented by:

Gabriella Magarelli, RN, ACNP-BC

John Theurer Cancer Center

Hackensack University Medical Center

Schedule of events:

5:30 pm Registration

6:00 pm Program and meal

7:00 pm Closing statements

Hosted by:

Jeanette Reed

Genentech

Location:

Restaurant Serenade

6 Roosevelt Ave

Chatham, NJ 07928

Date:

6/1/2016

Registration:

Please register for this event by

5/30/2016

Register online at www.genersvp.com

with reference event code PRF56662

or RSVP to Jeanette Reed

973-615-0397

reedj8@gene.com

Indications

GAZYVA® (obinutuzumab) is a CD20-directed cytolytic antibody and is indicated:

- in combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL)
- in combination with bendamustine followed by GAZYVA monotherapy, for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen

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**

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This is a Genentech promotional activity. Note: no continuing medical education (CME) credit will be awarded.

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

GAZYVA® obinutuzumab injection

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Additional Warnings and Precautions

- **Infusion Reactions:** GAZYVA can cause severe and life-threatening infusion reactions. Sixty-five percent of patients with CLL experienced a reaction to the first 1000 mg infused of GAZYVA and 38% of patients with iNHL experienced a reaction on Day 1 during treatment with GAZYVA in combination with bendamustine. 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):** Tumor lysis syndrome, including fatal cases, has been reported in patients receiving GAZYVA. Patients with high tumor burden, high circulating lymphocyte count (>25 x 10^9/L) or renal impairment are at greater risk for TLS and should receive appropriate tumor lysis prophylaxis with antihyperuricemics and hydration 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 and life-threatening 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:** Severe and life-threatening thrombocytopenia has been reported during treatment with GAZYVA in combination with chlorambucil or bendamustine. Fatal hemorrhagic events during Cycle 1 have been reported in patients with CLL treated with GAZYVA. 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 chemotherapy or dose reductions of chemotherapy. Management of hemorrhage may require blood product support

Additional Important Safety Information CLL

- Grade 3/4 adverse reactions in CLL were: neutropenia (33%), infusion reactions (20%), thrombocytopenia (10%), anemia (4%), leukopenia (4%), diarrhea (2%), urinary tract infection (1%), pyrexia (<1%), cough (<1%), and nasopharyngitis (<1%)
- The most common adverse reactions (incidence ≥10%) in CLL were: infusion reactions (66%), neutropenia (38%), thrombocytopenia (14%), nausea (12%), anemia (11%), pyrexia (10%), cough (10%), and diarrhea (10%)
- Adverse reactions rates and laboratory abnormalities from the Stage 2 phase are consistent with the rates in Stage 1. In addition to the adverse reactions observed in Stage 2, in Stage 1 back pain (5% vs. 2%), anemia (12% vs. 10%) and cough (10% vs. 7%) were observed at a higher incidence in the GAZYVA treated patients. The incidence of Grade 3-4 back pain (<1% vs. 0%), cough (0% vs. <1%) and anemia (5% vs. 4%) was similar in both treatment arms. With regard to laboratory abnormalities, in Stage 1 hyperkalemia (33% vs. 18%), creatinine increased (30% vs. 20%) and alkaline phosphatase increased (18% vs. 11%) were observed at a higher incidence in patients treated with GAZYVA with similar incidences of Grade 3-4 abnormalities between the two arms

Additional Important Safety Information iNHL

- The safety of GAZYVA was evaluated based on a safety population of 392 patients with indolent NHL (iNHL), of whom 81% had follicular lymphoma. In patients with follicular lymphoma, the most common adverse reactions that were seen were consistent with the overall population who had iNHL
- Grade 3/4 adverse reactions in iNHL were: neutropenia (33%), infusion reactions (11%), thrombocytopenia (10%), urinary tract infection (3%), upper respiratory tract infection (2%), pyrexia (1%), asthenia (1%), sinusitis (1%), and pain in extremity (1%)
- The most common adverse reactions (incidence ≥10%) in iNHL were: infusion reactions (69%), neutropenia (35%), nausea (54%), fatigue (39%), cough (26%), diarrhea (27%), constipation (19%), pyrexia (18%), thrombocytopenia (15%), vomiting (22%), upper respiratory tract infection (13%), decreased appetite (18%), arthralgia (12%), sinusitis (12%), anemia (12%), asthenia (11%), and urinary tract infection (10%)
- During the monotherapy period with GAZYVA, the most common Grade 3-4 adverse reactions in iNHL were neutropenia (10%), and anemia, febrile neutropenia, thrombocytopenia, sepsis, upper respiratory tract infection, and urinary tract infection (all at 1%)

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Additional Important Safety Information (cont'd)

iNHL

- During the monotherapy period with GAZYVA, the most common adverse reactions in iNHL patients were cough (15%), upper respiratory tract infections (12%), neutropenia (11%), sinusitis (10%), diarrhea (8%), infusion related reactions (8%), nausea (8%), fatigue (8%), bronchitis (7%), arthralgia (7%), pyrexia (6%), nasopharyngitis (6%), and urinary tract infections (6%)

WE LOOK FORWARD TO YOUR PARTICIPATION

Minnesota, Vermont, the **Department of Defense**, the **Department of Veterans Affairs**, and other Federal Entities have restrictions on receiving in-kind benefits (eg, meals, valet parking) at company-sponsored events. You are accountable for understanding such restrictions and complying with them. If you are licensed in or affiliated with any of these states or federal agencies, Genentech policies may restrict you from consuming any portion of the Genentech-sponsored meal at this program or from receiving any other in-kind benefit from Genentech (eg, valet parking) in connection with the program.

When you RSVP, please indicate whether you will accept or opt out of Genentech's in-kind benefits (eg, meals, valet parking) at the program. If you choose to opt out you may either pay for the meal and parking on your own, or not consume anything at the program. For all program attendees who receive Genentech's in-kind benefits at this program, Genentech will report the attendee's name and the value received as required by federal and state disclosure laws (for more information on the federal law please visit http://sunshine.gene.com). The meal cost may vary by event location and be up to $125 per person (exceptions may apply).

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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, or calling 1-800-FDA-1088.

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