Indication & Important Safety Information

Indication

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.

GAZYVA® (obinutuzumab), in combination with chemotherapy followed by GAZYVA monotherapy in patients achieving at least a partial remission, is indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma (FL).

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.

Contraindications

- GAZYVA is contraindicated in patients with known hypersensitivity reactions (e.g. anaphylaxis) to obinutuzumab or to any of the excipients, or serum sickness with prior obinutuzumab use.

Please see the accompanying full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.
Important Safety Information (cont)

Additional Warnings and Precautions

- **Infusion-Related Reactions:** Premedicate patients with glucocorticoid, acetaminophen, and antihistamine. Monitor patients closely during infusions. Interrupt, reduce rate, or discontinue for infusion-related reactions based on severity.

- **Hypersensitivity Reactions Including Serum Sickness:** Discontinue GAZYVA permanently.

- **Tumor Lysis Syndrome (TLS):** Premedicate with antihyperuricemics and adequate hydration, especially for patients with high tumor burden, high circulating lymphocyte count or renal impairment. Correct electrolyte abnormalities, provide supportive care, and monitor renal function and fluid balance.

- **Infections:** Do not administer GAZYVA to patients with an active infection. Patients with a history of recurring or chronic infections may be at increased risk of infection.

- **Neutropenia:** In patients with Grade 3 to 4 neutropenia, monitor laboratory tests until resolution and for infection. Consider dose delays and infection prophylaxis, as appropriate.

- **Thrombocytopenia:** Monitor platelet counts and for bleeding. Transfusion may be necessary.

- **Immunization:** Avoid administration of live virus vaccines during GAZYVA treatment and until B-cell recovery.

- **Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

**Additional Important Safety Information**

The most common adverse reactions (incidence ≥20% and ≥2% greater in the GAZYVA treated arm) were:

- Previously untreated CLL: infusion-related reactions (66%), and neutropenia (38%)
- Relapsed or refractory NHL: infusion-related reactions (67%), fatigue (40%), neutropenia (37%), upper respiratory tract infection (36%), cough (31%), and musculoskeletal pain (28%)
- Previously untreated NHL: infusion-related reactions (72%), neutropenia (53%), upper respiratory tract infection (50%), cough (35%), constipation (32%), and diarrhea (30%)

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 full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.