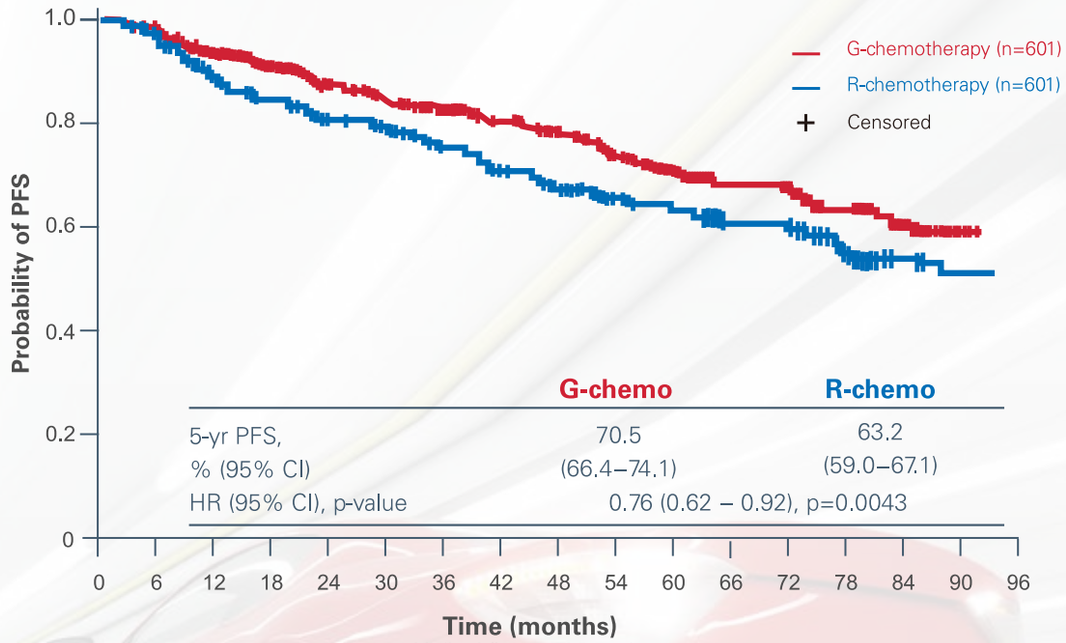
GAZYVA is the first and only anti-CD20 antibody offers superior PFS vs MabThera to your first line FL patients.[1]



No. of patients at risk:

G-chemotherapy	601	574	539	512	491	467	446	430	406	368	334	269	182	98	53	4
R-chemotherapy	601	563	512	471	447	429	404	373	349	328	304	247	176	88	52	3

Reference:
1. Townsend W., et at, EHA library 06/12/20; 293659; EP1170

Abbreviated Prescribing Information

GAZYVA® (Obinutuzumab) 1,000 mg/40 mL Concentrate for Solution for Infusion **Indications:** In combination with chlorambucil for treatment of previously untreated chronic lymphocytic leukemia (CLL) in adult patients with comorbidities making them unsuitable for full-dose fludarabine based therapy. In combination with chemotherapy followed by Gazyva maintenance therapy in patients achieving a response for the treatment of patients with previously untreated advanced follicular lymphoma. In combination with bendamustine followed by Gazyva maintenance for the treatment of patients with follicular lymphoma (FL) who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen. **Dosage and Administration:** Prophylaxis and premedication for tumour lysis syndrome (TLS) is recommended. Prophylaxis and premedication for infusion related reactions (IRRs) is mandatory for CLL and recommended for FL. Interrupt, reduce the rate of infusion or discontinue treatment base on the grade of IRRs. *For CLL (in combination with chlorambucil):* The recommended dose in combination with chlorambucil is 1,000 mg over Day 1 and Day 2, (or Day 1 continued), and on Day 8 and Day 15 in the first 28 day treatment cycle. For cycles 2 to 6, the recommended dose in combination with chlorambucil is 1,000 mg on Day 1 of each cycle. *For FL (for previously untreated advanced FL):* The recommended induction dose is Six 28-day cycles in combination with bendamustine or, Six 21-day cycles in combination with CHOP, with 2 additional cycles of Gazyva alone or, Eight 21-day cycles in combination with CVP. The maintenance dose for patient who achieve a complete or partial response to induction treatment should continue to receive Gazyva 1,000mg as single agent maintenance once every 2 months for 2 years until disease progression (whichever occurs first). *For FL (who did not response or progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen):* The recommended dose in combination with bendamustine is 1,000mg on Day 1, Day 8 and Day 15 of the first 28 day treatment cycle. For cycles 2 to 6, the recommended dose in combination with bendamustine is 1,000 mg on Day 1 of each 28 day treatment cycle. Patients who respond to induction treatment (i.e. the initial 6 treatment cycles) with Gazyva in combination with bendamustine or have stable disease should continue to receive Gazyva 1,000 mg as single agent maintenance therapy once every 2 months for two years or until disease progression (whichever occurs first). **Warnings and Precautions:** Efficacy in FLIPI low risk (0-1) patients is inconclusive, therapy choice for them should be considered carefully. IRRs frequently observed, predominantly during infusion of the first 1,000mg. If the patient experiences an IRR, the infusion should be managed according to the grade of the reaction. Patients must not receive further GAZYVA infusions if they experience acute life-threatening respiratory symptoms, Grade 4 IRR or second occurrence of Grade 3 IRR. Hypotension may occur during infusions, consider withholding anti-hypertensive treatments temporarily. Cases of hypersensitivity with immediate & delayed onset is reported, stop infusion and permanently discontinue treatment if a hypersensitivity reaction during or after an infusion is suspected. Increased risk of TLS in patients with a high tumour burden and/or a high circulating lymphocyte count and/or renal impairment. Premedicate with uricostatics or a suitable alternative such as urate oxidase and adequate hydration 12-24 hours prior to infusion. Risk of severe neutropenia, including febrile neutropenia. Cases of late onset neutropenia and prolonged neutropenia reported. Risk of severe thrombocytopenia. Monitor regular laboratory tests closely until resolution. Increased risk of neutropenia and thrombocytopenia in patients with renal impairment. Caution in patients with underlying cardiac disease, worsening of cardiac conditions may occur as part of an IRR and can be fatal. Caution in patients with a history of recurring or chronic infections; avoid administration in the presence of an active infection. Risk of hepatitis B virus (HBV) reactivation, perform HBV screening before treatment initiation. Cases of progressive multifocal leukoencephalopathy (PML) reported. Consider the diagnosis of PML in patients with new-onset or changes to pre-existing neurologic manifestations, and withhold treatment during the investigation of potential PML. Vaccination with live virus vaccines not recommended during treatment and until B cell recovery. **Contraindications:** Hypersensitivity to obinutuzumab or to any of the excipients. **Interactions:** No formal drug-drug interaction studies performed. A risk for interactions with concomitantly used medicinal products cannot be excluded. No pharmacokinetic interaction is expected with drugs metabolised by CYP450, UGT enzymes or transporters such as P-glycoprotein. The combination of GAZYVA with chlorambucil, bendamustine, CHOP or CVP may increase the risk of neutropenia. **Use in Special Populations:** GAZYVA should not be administered to pregnant women unless the possible benefit outweighs the potential risk. Women of childbearing potential must use effective contraception during and for 18 months after treatment. Avoid breast-feeding during treatment and for 18 months after the last dose. Limited data in patients with severe renal impairment. No data in patients with impaired hepatic function or in children under 18 years. **Adverse Effects:** *Very common:* Upper respiratory tract infection, sinusitis, urinary tract infection, pneumonia, herpes zoster, neutropenia, thrombocytopenia, anaemia, leukopenia, headache, insomnia, cough, diarrhoea, constipation, alopecia, pruritus, arthralgia, back pain, pyrexia, asthenia, IRRs. *Common:* oral herpes, rhinitis, pharyngitis, lung infection, influenza, nasopharyngitis, squamous cell carcinoma of skin, lymph node pain, TLS, hyperuricaemia, hypokalaemia, depression, anxiety, ocular hyperaemia, atrial fibrillation, cardiac failure, hypertension, nasal congestion, rhinorrhoea, oropharyngeal pain, dyspepsia, colitis, haemorrhoids, night sweats, eczema, musculoskeletal chest pain, pain in extremity, bone pain, dysuria, urinary incontinence, chest pain, white blood cell count decreased, neutrophil count decreased, weight increased.

Full prescribing information should be consulted prior to prescribing.

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GAZYVA® obinutuzumab