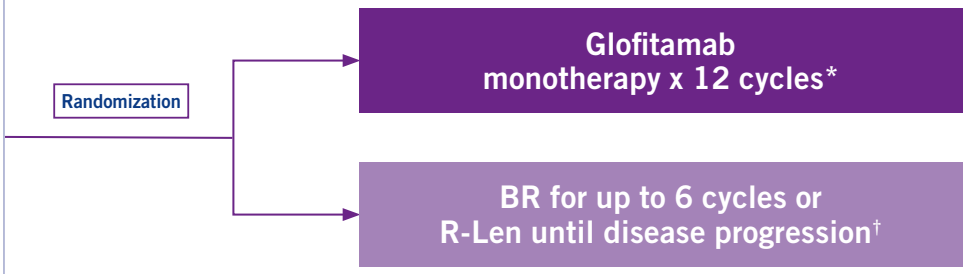
Now Enrolling in Hematologic Malignancies

Phase III • NCT06084936 • GLOBRYTE

A Phase III, Open-Label, Multicenter Randomized Study Evaluating Glofitamab as a Single Agent Versus Investigator's Choice in Patients With Relapsed/Refractory Mantle Cell Lymphoma

Key Eligibility Criteria

- **Histologically-confirmed MCL with documentation of either overexpression of cyclin D1 or the presence of t(11:14)**
- **Relapsed or refractory disease**
- **At least 1 line of prior systemic therapy including a BTK inhibitor and additional systemic therapy option**
- **At least one bi-dimensionally measurable (defined as at least 1.5 cm) nodal lesion, or one bi-dimensionally measurable (at least 1 cm) extranodal lesion, as measured on CT scan**



Study Endpoints

Primary Outcome Measure:

- Progression-free survival (PFS)

Select Secondary Outcome Measures:

- Complete response (CR) rate
- Objective response rate (ORR)
- Overall survival
- Time to deterioration in physical functioning/fatigue
- Investigator-assessed PFS, CR rate, and ORR
- Duration of complete response
- Duration of Response
- Time to deterioration in lymphoma symptoms
- Serum concentration of glofitamab
- Incidence of anti-drug antibodies

Select Eligibility Criteria

Other Key Inclusion Criteria:

- Life expectancy at least 12 weeks
- Confirmed availability of tumor tissue, unless deemed unsafe per investigator assessment
- ECOG performance status of 0, 1, or 2
- Negative HIV test at screening
- Adequate hematological function

Key Exclusion Criteria:

- Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 3 months after the final dose of tocilizumab, 2 months after the final dose of glofitamab, whichever is longer
- Leukemic, non-nodal MCL
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies (or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products
- Contraindication to obinutuzumab or rituximab, and either bendamustine or lenalidomide
- Prior treatment with glofitamab or other bispecific antibodies targeting both CD20 and CD3
- Prior treatment with CAR-T cell therapy
- Treatment with systemic therapy or BTK inhibitors, or any investigational agent for the purposes of treating cancer within 2 weeks or 5 half-lives (whichever is shorter) prior to first study treatment
- Significant or extensive cardiovascular disease
- Prior solid organ transplantation or allogenic stem cell transplant
- Eligibility for SCT
- Active autoimmune disease requiring treatment

Find out if your patients with hematologic malignancies are eligible for enrollment. For more information

Visit:	Call:	Email:
ClinicalTrials.gov	Genentech Trial Information Support Line at **1-888-662-6728** (US and Canada)	**global-roche-genentech-trials@gene.com**

ClinicalTrials.gov Identifier: NCT06084936

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*Participants will receive two 1000 mg pretreatments of IV obinutuzumab on Cycle 1 Day 1 (cycle length = 21 days).

†Cycle length = 28 days.

BR=bendamustine + rituximab; **BTK**=Bruton's tyrosine kinase; **CAR**=Chimeric antigen receptor; **CD**=cluster of differentiation; **CT**=computed tomography; **ECOG**=Eastern Cooperative Oncology Group; **MCL**=Mantle Cell Lymphoma; **R-Len**=rituximab + lenalidomide; **SCT**=stem cell transplantation.

Information is consistent with ClinicalTrials.gov as of October 16, 2024. Products under investigation have not been approved for use outside of the clinical trial setting. This information is presented only for the purposes of providing an overview of clinical trials and should not be construed as a recommendation for use of any product for unapproved purposes.

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