

ALPHA3 Clinical Trial

Now enrolling!

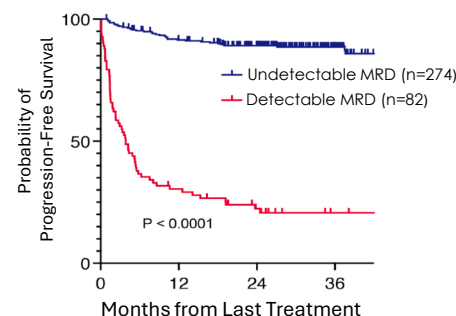
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Changing the Paradigm: Using off-the-shelf CAR T cells as consolidation for patients with LBCL who are MRD positive after 1L therapy

ALPHA3: Study Rationale

- Approximately 1 out of 3 LBCL patients who respond to standard 1L therapy (R-CHOP, Pola-R-CHP, DA-EPOCH-R) will experience recurrence; current management for all patients in remission is to watch and wait for disease progression.
- Among patients whose disease recurs, less than 15% will receive any CAR T therapy.¹ Up to 20% will receive no salvage therapy at all.²
- MRD assessment at the end of 1L therapy stratifies patients according to relapse risk, creating an opportunity to consolidate MRD+ remission and prevent recurrence.
- Cema-cel is an allogeneic, off-the-shelf anti-CD19 CAR T product.
- Cema-cel and a related product demonstrated potent anti-tumor activity and good tolerability in Phase 1 trials in relapsed/refractory LBCL.³
- ALPHA3 Hypothesis: Administration of cema-cel to LBCL patients in clinical/radiographic remission but MRD+ by ctDNA will lead to improvement in disease outcomes**

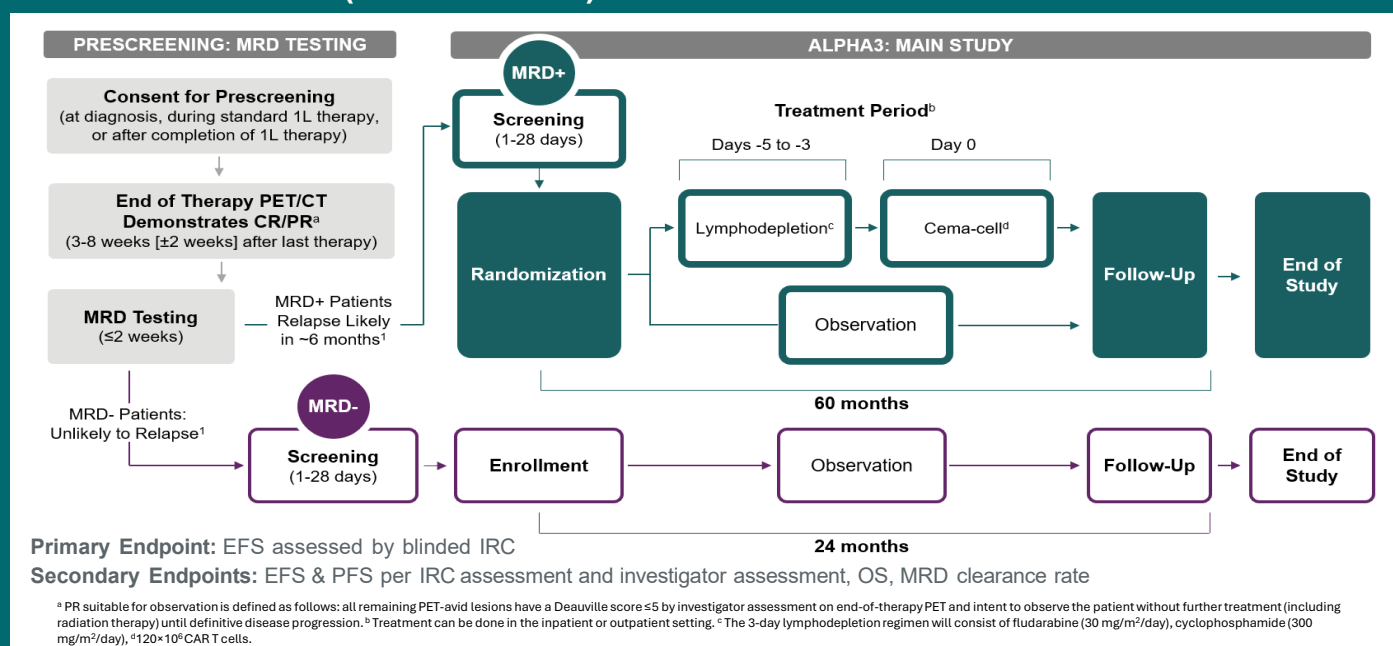
MRD Predicts Risk of Relapse⁴⁻⁶



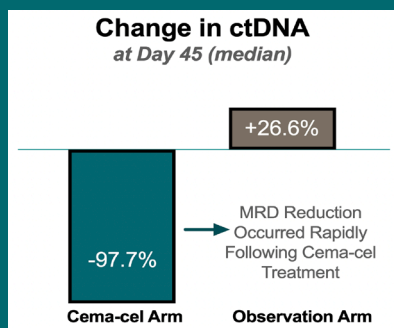
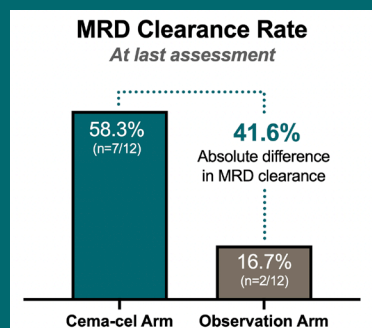
Patients who are MRD+ at the end of front-line R-CHOP are more likely to experience disease relapse.^{4,7}

Low Disease Burden Sets the Stage for Improved Treatment Safety and Efficacy

ALPHA3 Phase 2 (NCT06500273): A Global Pivotal Randomized Controlled Trial



ALPHA3 Interim Analysis: Encouraging MRD clearance and favorable safety profile



Data cut 09-Feb-2026	Cema-cel Arm (N=12)
CRS (Any Grade)	0%
ICANS (Any Grade)	0%
GvHD (Any Grade)	0%
Treatment-related serious AEs	0%
Treatment-related hospitalizations	0%

Key Study Eligibility Criteria

Prescreening / MRD Testing		Main Study Screening	
Criteria for MRD Testing		Key Inclusion Criteria	Key Exclusion Criteria
Histologically confirmed diagnosis of DLBCL, ^a HGBCL, PMBCL, DLBCL or HGBL transformed from FL or MZL, or FL3B and at least 1 of the following clinical criteria: IPI score of 2-5 at diagnosis, Ann Arbor stage III or IV disease at diagnosis, equivocal response at interim or EOT PET/CT		MRD+ by ctDNA-based testing ^d	Prior treatment with CD19-targeted therapies
Completed a full course of standard 1L therapy (must have included an anthracycline and an anti-CD20 monoclonal antibody); for example: • R-CHOP • Pola-R-CHP • DA-EPOCH-R		ECOG PS of 0, 1, or 2	History of CNS involvement, transformation from other malignancy (Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma, chronic lymphocytic lymphoma/small lymphocytic lymphoma), or T-cell/histiocyte-rich LBCL
Anticipated remission at the completion of 1L treatment		CR or PR suitable for observation ^b at the completion of 1L treatment based on PET/CT scan evaluation per Lugano 2014 criteria	History of clinically significant CNS dysfunction (e.g., seizure disorder [uncontrolled in last 12 months], cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, cerebral edema)
MRD samples available for submission • Adequate tumor specimen from initial diagnosis adequate blood sample collected after final 1L treatment		Adequate hematologic, cardiac, pulmonary, renal, and hepatic function	Treatment with systemic immunosuppressive agents within 2 weeks or 5 half-lives (whichever is shorter) prior to enrollment ^c

^aIncludes DLBCL not otherwise specified, Epstein-Barr virus+ DLBCL, DLBCL with IRF4/MUM1 rearrangement, high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma, and follicular lymphoma grade 3B. ^bPR suitable for observation is defined as intent to observe the patient without further treatment (including radiation therapy) until definitive disease progression. ^cCorticosteroids for physiologic replacement (<10 mg/day of prednisone equivalents) is acceptable. ^dPatients found to be MRD negative may enroll in an observational MRD-negative part of the study if they meet all inclusion criteria.
1L, first line; CAR, chimeric antigen receptor; cema-cel, cemacabtagene ansegedleucel; CNS, central nervous system; CR, complete response; CT, computed tomography; DA-EPOCH-R, dose-adjusted rituximab, etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event free survival; EOT, end of therapy; FL, follicular lymphoma; HGBCL, high-grade B-cell lymphoma; IPI, International Prognostic Index; IRC, independent review committee; LBCL, large B-cell lymphoma; MRD, minimal residual disease; MZL, marginal zone lymphoma; FL3B, follicular lymphoma grade 3B; OS, overall survival; PET, positron emission tomography; PFS, progression-free survival; PMBCL, primary mediastinal B-cell lymphoma; pola-R-CHP, polatuzumab vedotin, rituximab, cyclophosphamide, doxorubicin, and prednisone; PR, partial response; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone.

ALPHA3 Clinical Trial Locations Near You:

References:

¹Puckrin, et al. Real-World Eligibility for Second-Line Chimeric Antigen Receptor T Cell Therapy in Large B Cell Lymphoma: A population-Based Analysis. *Transplant Cell Ther.* 2022;28(4):P218E1-218E4. doi:10.1016/j.jct.2022.01.024.
²Dogliotti et al. Real Life Clinical Outcomes of Relapsed/Refractory Diffuse Large B Cell Lymphoma in the Rituximab Era: The STRIDER Study. *Cancer Med.* 2024;Jul19;13(14):e7448. doi:10.1002/cam4.7448.
³Locke, et al. Allogeneic Chimeric Antigen Receptor T-Cell Products Cemacabtagene Ansegedleucel/ ALLO-50 in Relapsed/Refractory Large B-Cell Lymphoma: Phase I Experience From the ALPHA2/ALPHA Clinical Studies. *J Clin Oncol* (2025) v43:1695-1705. doi:10.1200/JCO-24-01933.
⁴Roschewski M, Kurtz D M, Westin J R, et al. Remission Assessment by Circulating Tumor DNA in Large B-Cell Lymphoma. *J Clin Oncol* 10.1200/JCO-25-01534
⁵Stepan, L., et al. Circulating tumor DNA Assessment of Disease Response in Large B-cell Lymphoma: Lisocaptagene Maraleucel Versus Autologous Stem Cell Transplant Standard Therapy. *J Clin Oncol.* 2026. 10.1200/JCO-25-03051
⁶Circulating Tumor DNA Minimal Residual Disease Assay; study is using investigational Foresight Diagnostics Clarity Test.
⁷Based on unpublished diagnostic data provided by Foresight Diagnostics

Further information about this study, including study centers, can be found here:



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