AOU Città della Salute e della Scienza di Torino – PO Molinette

Titolo:	A pivotal Phase II randomised, multi-centre, open-label study to evaluate the efficacy and safety of MB-CART2019.1 compared to standard of care therapy in participants with relapsed/refractory diffuse large B-cell lymphoma (R-R DLBCL), who are not eligible for high-dose chemotherapy and autologous stem cell transplantation (DALY-2)
Patologia:	DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), RECIDIVA
Tipo di Studio:	INTERVENTISTICO, RANDOMIZZATO
Fase:	II
Principali criteri di inclusione:	Histologically proven DLBCL and associated subtypes, according to the WHO 2016 classification including: DLBCL, NOS, HGBL, High-grade BCL, NOS. • Primary (thymic) large mediastinal BCL. • Disease transformed from an earlier diagnosis of low-grade lymphoma (e.g., an indolent pathology such as follicular lymphoma, marginal zone lymphoma) into DLBCL with DLBCL disease progression subsequent to DLBCL-directed systemic treatment. • Follicular lymphoma Grade 3B. Relapsed or refractory disease after first-line chemoimmunotherapy: • Refractory disease defined as no CR to first-line therapy (e.g., R-CHOP). − PD after at least 2 full cycles of first-line therapy. − SD after 4 cycles of first-line therapy. − PR as best response after at least 6 cycles of first-line therapy and biopsy-proven persistent disease (except where prohibited due to comorbidities) within ≤ 12 months after completion of first-line treatment. • Relapsed disease defined as complete remission to first-line therapy followed by biopsy-proven disease progression (except where prohibited due to comorbidities) within ≤ 12 months after completion of first-line treatment. Participant must have received adequate first-line therapy containing at least the combination of an anthracycline-based regimen and rituximab (anti-CD20 monoclonal

	antibody). Local therapies (e.g., radiotherapies) will not be considered as line of therapy if performed during the same line of treatment.
Principali criteri di esclusione:	
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