

CLINICAL BENEFIT OF NEW THERAPIES INDICATED IN DIFFUSE LARGE B-CELL LYMPHOMA

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BACKGROUND AND IMPORTANCE

The European Society for Medical Oncology (ESMO) and the European Hematology Association (EHA) recently developed and validated the **Magnitude of Clinical Benefit (BC) Scale in Hematology (MCBS:H)**, a standardized, objective, and reproducible tool that quantifies the expected BC of treatments for hematologic malignancies.

AIM AND OBJECTIVES

To assess the **BC** of **recently approved DLBCL therapies** and compare it with current **therapeutic positioning**.

MATERIAL AND METHODS

Observational, retrospective study (March 2025) evaluating studies supporting recent DLBCL therapy approvals using ESMO-MCBS:H. Variables: therapy, indication, funding, BC assessment, trial, study type, form, efficacy, safety, QoL, and score. Sources: PubMed and Ministry of Health Therapeutic Positioning Reports.

RESULTS

Therapy	Indication (line)	Funding-Status	Clinical-Trial	ESMO-MCBS:H Type	BC Assessment	Score
Axicabtagene-Ciloleucel	Second	Yes	ZUMA-7: Randomized, phase III, multicenter, open-label, controlled vs. ASCT	2A (improved OS)	Demonstrated superiority	4
Tisagenlecleucel	Third/higher	Yes	C2201: Phase II, multicenter, open-label, single-arm	3	Without evidence of improved ORR vs. historical cohorts	4
Polatuzumab-Vedotin/Rituximab/Bendamustine	Second(not eligible-ASCT)	Yes	GO29365: Phase Ib/II, multicenter, open-label, controlled vs. Rituximab/bendamustine	2A (OS improvement)	Option in non-candidates for ASCT/CAR-T	4
Polatuzumab-Vedotin/R-CHP	First	Not	GO39942 (POLARIX): Phase III, multicenter, randomized, double-blind vs. R-CHOP	2B (OS diff. not significant)	Results do not support substitution for vincristine	1
Tafasitamab/Lenalidomide	Second(not eligible-ASCT)	Yes	MOR208C203 (L-MIND) : Phase II, open-label, single-arm	3	With certain limitations; alternative for ineligible patients	3
Epcoritamab	Third/higher	Yes	GCT3013-01 (EPCORE-NHLI): Phase I/II, multicenter, open-label, single-arm	3	With limitations; convenient alternative to IV therapies	3
Loncastuximab-Tesirine	Third/higher	Not	LOTIS-2: Phase II, multicenter, open-label, single-arm	3	Option for ineligible/refractory CAR-T patients	3

Determine the key outcomes evaluated for each therapy in the full abstract.

CONCLUSION AND RELEVANCE

The ESMO-MCBS:H proved a reliable and objective tool, validating BC assessments and supporting clinical decisions. CAR-T therapies and Polatuzumab-R/Bendamustine showed substantial benefit, unlike Polatuzumab-R-CHP, consistent with its non-funding. The scale is useful but requires critical appraisal of study design.

