World Journal of Gastroenterology

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World J Gastroenterol 2025 December 7; 31(45): 112336

DOI: 10.3748/wjg.v31.i45.112336

ISSN 1007-9327 (print) ISSN 2219-2840 (online)

EDITORIAL

Emerging role of lisocabtagene maraleucel chimeric antigen receptor-T cell in nodal and gastrointestinal follicular lymphoma

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Specialty type: Gastroenterology and hepatology

Provenance and peer review: Invited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's classification

Scientific Quality: Grade B, Grade B, Grade C, Grade C

Novelty: Grade A, Grade C, Grade C, Grade C

Creativity or Innovation: Grade B, Grade C, Grade C, Grade C

Scientific Significance: Grade A, Grade B, Grade C, Grade D

P-Reviewer: Chen XY, Deputy Director, China; Kanda T, MD, Professor, Japan; Rath S, MD, Senior Researcher, India

Received: July 28, 2025

Revised: October 2, 2025

Accepted: October 31, 2025

Published online: December 7, 2025

Processing time: 130 Days and 0.9 Hours

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Abstract

Chimeric antigen receptor (CAR)-T cell therapy has emerged as a transformative treatment option for relapsed or refractory follicular lymphoma (FL), particularly in patients in whom multiple lines of conventional therapy have failed. Among cluster of differentiation (CD) 19-targeted products, lisocabtagene maraleucel (liso-cel) offers distinct advantages owing to its defined $CD4^+/CD8^+$ composition and favorable safety profile. Compared with diffuse large B-cell lymphoma, FL patients consistently achieve higher overall response rates and exhibit lower rates of severe cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome, supporting the rationale for expanding CAR-T cell therapy in this subgroup. This editorial review the current CD19-directed CAR-T cell therapy landscape, focusing on the pivotal TRANSCEND FL trial, which demonstrated a 97% overall response rate and 94% complete response rate, with a minimal incidence of severe CRS or neurotoxicity. Comparative insights highlight the advantages of liso-cel over other CAR-T cell products, such as axicabtagene ciloleucel and tisagenlecleucel in terms of toxicity, logistics, and outpatient feasibility. The implications for gastrointestinal FL (GI-FL), a subtype often excluded from CAR-T cell studies, were also addressed, emphasizing the need to include advanced-stage GI-FL cases in future evaluations. With ongoing improvements in manufacturing, accessibility, and biomarker development, liso-cel is well-positioned to become a central component in the evolving treatment paradigm for FL. However, challenges remain regarding durability of response, cost, and access, which warrant careful discussion.

Key Words: Chimeric antigen receptor-T cell therapy; Lisocabtagene maraleucel; Follicular lymphoma; Gastrointestinal follicular lymphoma; Nodal follicular lymphoma

Core Tip: Chimeric antigen receptor (CAR)-T therapy, particularly lisocabtagene maraleucel (liso-cel), offers a promising option for patients with relapsed or refractory and relapsed follicular lymphoma (FL), demonstrating high response rates and a favorable safety profile in the TRANSCEND FL trial. Compared to other CAR-T products, liso-cel shows advantages in toxicity, logistics, and feasibility. This editorial emphasizes its relevance for gastrointestinal FL, a subgroup often underrepresented in studies, and calls for broader inclusion and real-world validation to optimize CAR-T use across FL subtypes.

Citation: Watanabe T. Emerging role of lisocabtagene maraleucel chimeric antigen receptor-T cell in nodal and gastrointestinal follicular lymphoma. *World J Gastroenterol* 2025; 31(45): 112336
URL: https://www.wjgnet.com/1007-9327/full/v31/i45/112336.htm
DOI: https://dx.doi.org/10.3748/wjg.v31.i45.112336

INTRODUCTION

Follicular lymphoma (FL) is the most common subtype of indolent B-cell non-Hodgkin lymphomas in adults, characterized by slow progression but frequent relapses and eventual resistance to standard therapies[1-3]. Over the past two decades, the introduction of chemoimmunotherapy with anti-cluster of differentiation (CD) 20 monoclonal antibodies, particularly rituximab-based regimens, has significantly improved patient outcomes[4-6]. However, despite these advances, a subset of patients remains refractory or experiences early relapse, highlighting the need for novel therapeutic strategies[7,8].

Recent years have witnessed the emergence of chimeric antigen receptor (CAR)-T cell therapy as a transformative modality for relapsed/refractory B-cell lymphomas[9-11]. Importantly, compared to diffuse large B-cell lymphoma and other B-cell malignancies, FL patients tend to achieve higher response rates and lower incidences of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) after CD19 CAR-T cell therapy (Figure 1), providing a compelling rationale for its application in this subgroup[12,13]. Among the currently available CD19 CAR-T cell products, axicabtagene ciloleucel (axi-cel), tisagenlecleucel (tisa-cel), and lisocabtagene maraleucel (liso-cel) represent distinct options, each with unique strengths and limitations[14-16].

In this editorial, we summarize the therapeutic potential of liso-cel in the treatment of nodal and gastrointestinal FL (GI-FL), compare it with other CAR-T cell products, and discuss future directions for clinical practice.

TRANSCEND FL TRIAL: EFFICACY AND SAFETY

In the pivotal TRANSCEND FL (No. NCT04245839) trial, liso-cel achieved an overall response rate of 97% and a complete response rate of 94%[14]. The median age was 63 years, with the majority of patients having received ≥ 3 prior lines of therapy and nearly half presenting with high tumor burden, highlighting the refractory nature of the cohort[17]. The estimated 12-month progression-free survival and overall survival rates exceeded 85%[18,19].

One of the most critical advantages of liso-cel is its safety profile. Grade ≥ 3 CRS occurred in 0% of patients, while grade ≥ 3 ICANS occurred in only 3%[14]. A summary of adverse events, including hematologic toxicities and infections, has been incorporated into an expanded Table 1 for clarity.

COMPARATIVE PERSPECTIVE: LISO-CEL *VS* OTHER CAR-T PRODUCTS

Three CD19-directed CAR-T products axi-cel, tisa-cel, and liso-cel have been approved for B-cell malignancies[20]. Axi-cel demonstrated strong efficacy but at the cost of higher toxicity, with grade ≥ 3 CRS and ICANS rates up to 13% and 28%, respectively[14,21]. Tisa-cel showed favorable safety but variable efficacy and longer manufacturing times[22,23]. Liso-cel offers balanced efficacy and lower toxicity, permitting outpatient use in select centers[14,24]. These differences in efficacy, safety, and logistics underscore the importance of individualized selection among the three CAR-T products[25-27]. Furthermore, real-world data continue to validate these findings, demonstrating that liso-cel maintains comparable efficacy with reduced incidence of high-grade immune toxicities even in older or comorbid patients[28-30].

CLINICAL IMPLICATIONS FOR GI-FL

GI-FL is a relatively rare entity, usually diagnosed at early stages[31]. However, the Ann Arbor staging system often fails to capture the organ-confined and mucosal patterns typical of GI-FL[32,33]. Modified Lugano or tumor node metastasis/Paris staging systems, which account for depth of invasion and extra-nodal spread, may be more appropriate for clinical practice[34,35].

Table 1 Chimeric antigen receptor-T cell therapy clinical trials in relapsed/refractory follicular lymphoma

Ref.	Product	Target	Patients (*n*)	ORR/CR (%)	PFS/OS	Main AEs
Morschhauser *et al*[30]	Liso-cel	CD19	94 (FL)	97/73	NR/NR (30-month DOR 80%)	Neutropenia, anemia, low CRS/ICANS
Fowler *et al*[28]	Tisa-cel	CD19	97 (FL)	86/69	12-month PFS 67%; 12-month OS 92%	Neutropenia, ICANS (grade ≥ 3: 4%)
Jacobson *et al*[14]	Axi-cel	CD19	146 (FL)	94/79	17-month PFS 65%; 17-month OS 88%	CRS (any: 82%, ≥ 3: 7%), ICANS (≥ 3: 19%)
Shadman *et al*[21]	MB-106	CD20	28 (FL)	96/75	NR	Low CRS; no ICANS

FL: Follicular lymphoma; ORR: Overall response rate; CR: Complete response; PFS: Progression-free survival; OS: Overall survival; AE: Adverse event; CD: Cluster of differentiation; Liso-cel: Lisocabtagene maraleucel; Tisa-cel: Tisagenlecleucel; Axi-cel: Axicabtagene ciloleucel; NR: Not reached; DOR: Duration of response; CRS: Cytokine release syndrome; ICANS: Immune effector cell-associated neurotoxicity syndrome.

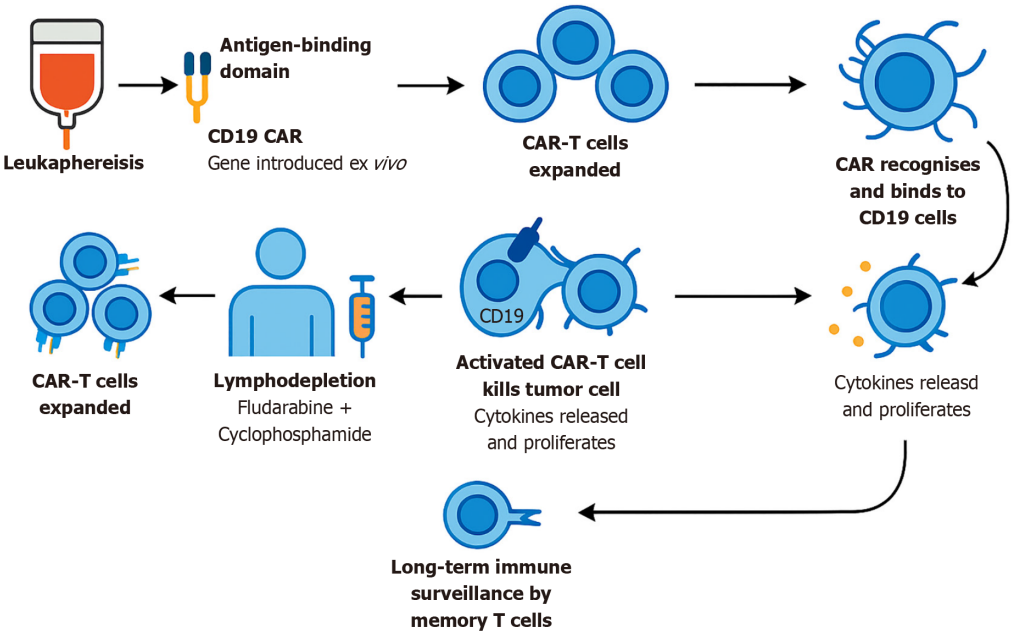

Figure 1 Mechanism of action of cluster of differentiation 19-directed chimeric antigen receptor-T cell therapy (lisocabtagene maraleucel). Schematic representation of the mechanism of action of lisocabtagene maraleucel. Peripheral blood mononuclear cells are collected by leukapheresis and transduced *ex vivo* with a lentiviral vector encoding the cluster of differentiation (CD) 19-directed chimeric antigen receptor (CAR) construct, consisting of an antigen-binding domain, transmembrane, and intracellular signaling domains. Following lymphodepleting chemotherapy with fludarabine and cyclophosphamide, the engineered CAR-T cells are reinfused into the patient. Upon recognition and binding to CD19 on malignant B cells, CAR-T cells are activated, proliferate, release cytokines, and induce tumor cell killing. Long-term immune surveillance is mediated by memory T cells. CD: Cluster of differentiation; CAR: Chimeric antigen receptor.

Although most GI-FL patients are managed with "watch-and-wait" or local therapy, a subset with advanced or transformed disease may require systemic treatment[36,37]. Liso-cel, with its favorable safety profile, represents a potential option[14,21,38]. Nevertheless, cost remains a major barrier, as CAR-T therapies are priced at several hundred thousand United States dollars or equivalent, with significant implications for reimbursement and access in Japan and worldwide [39].

Future guidelines for GI-FL should integrate histological, anatomical, molecular, and cytogenetic perspectives through multicenter collaborations to ensure tailored treatment strategies. Efforts to reduce manufacturing time, expand outpatient delivery, and address cost barriers are essential for broader adoption[30,40].

In conclusion, liso-cel is a promising therapeutic modality for FL, with high efficacy, manageable toxicity, and potential curative benefits in advanced GI-FL. Its role should be considered alongside bispecific antibodies and targeted small molecules as part of a rapidly evolving therapeutic landscape.

FUTURE DIRECTIONS

The emergence of CAR-T cell therapy, particularly liso-cel, has advanced FL treatment, including select GI-FL cases[14,21,29]. Ongoing challenges include durability of response, long-term monitoring, and sequencing with other novel agents [23,25,27]. Predictive biomarkers such as baseline tumor burden, cytokine profiles, and molecular features are under investigation to guide patient selection and optimize outcomes[14,40]. Future guidelines for GI-FL should integrate histological, anatomical, molecular, and cytogenetic perspectives through multicenter collaborations to ensure tailored treatment strategies[33,35,40]. Efforts to reduce manufacturing time, expand outpatient delivery, and address cost barriers are essential for broader adoption[39,40].

CONCLUSION

Liso-cel is a promising therapeutic modality for FL, with high efficacy, manageable toxicity, and potential curative benefits in advanced GI-FL. Its role should be considered alongside bispecific antibodies and targeted small molecules as part of a rapidly evolving therapeutic landscape.

ACKNOWLEDGEMENTS

We would like to thank Dr. Watanabe T, Miss Watanabe M and Mrs. Watanabe T for their assistance in writing the manuscript and providing valuable suggestions.

FOOTNOTES

Author contributions: Watanabe T solely contributed to this manuscript.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

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S-Editor: Fan M
L-Editor: A
P-Editor: Zhao YQ

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