Tecartus® (brexucabtagene autoleucel) Use in Burkitt Lymphoma

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The full indication, important safety information, and boxed warnings for cytokine release syndrome, neurologic toxicities and secondary hematological malignancies are available at:
https://www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf

Relevant Prescribing Information[1]

TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL). This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

There is no information in the TECARTUS US Prescribing information regarding the use of TECARTUS in patients with Burkitt lymphoma.

Clinical Studies

ZUMA-3 and ZUMA-2 Studies

ZUMA-3 was a multicenter, single arm, phase 1/2 study to evaluate the efficacy and safety of TECARTUS in adult patients with relapsed/refractory B-precursor acute lymphoblastic leukemia (ALL).[2] Patients with a diagnosis of Burkitt leukemia/lymphoma, according to World Health Organization (WHO) classification were excluded from ZUMA-3.[2,3]

The ZUMA-2 Phase 2 study is a single-arm, open-label, registrational, multicenter, global study assessing the safety and efficacy of TECARTUS, an anti-CD19 chimeric antigen receptor (CAR) T cell therapy, in patients with mantle cell lymphoma (MCL) who relapsed or were refractory to 1-5 prior therapies, including Bruton's tyrosine kinase inhibitor (BTKi) therapy. There is no information regarding Burkitt lymphoma (BL) in ZUMA-2.[4]

ZUMA-25 Study

ZUMA-25 (NCT05537766) is a Phase 2, open-label, multicenter study evaluating the safety and efficacy of brexucabtagene autoleucel in adults with rare B-cell malignancies. The study uses a basket study design with separate, indication-specific substudies, to investigate relapsed/refractory Waldenström macroglobulinemia (r/r WM), r/r Richter transformation (r/r RT), r/r Burkitt lymphoma (r/r BL), and r/r hairy cell leukemia (r/r HCL).[5]

Please note this study is currently active, but no longer recruiting and is estimated to be completed by March, 2025.[5]

Additional information from this study can be found using the link provided in the citation details below.

It is at the discretion of the treating physician to clinically evaluate whether to use TECARTUS in patients with BL.

The decision to treat a patient with a product for a non-approved indication is an independent medical decision by the treating physician for their patients. We cannot offer an opinion or recommendation on administering Tecartus in a manner inconsistent with its respective approved labeling.

References

1. Tecartus® (brexucabtagene autoleucel) [US Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc. 2024
2. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021;S0140-6736(21)01222-8. DOI: 10.1016/S0140-6736(21)01222-8
3. [Supplementary Appendix] Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021;S0140-6736(21)01222-8. DOI: 10.1016/S0140-6736(21)01222-8
4. Wang M, Munoz J, Goy A, et al. KTE-X19 CAR T-cell therapy in relapsed or refractory mantle-cell lymphoma. *N Engl J Med*. 2020;382:1331-42. DOI: 10.1056/NEJMoa1914347
5. ClinicalTrials.gov. Study of Brexucabtagene Autoleucel in Adults with Rare B-cell Malignancies (ZUMA-25) (NCT05537766). Available at: https://www.clinicaltrials.gov/study/NCT05537766 [Accessed November 2024]

Abbreviations

ALL=acute lymphoblastic leukemia
BL=Burkitt lymphoma
BTKi= Bruton's tyrosine kinase inhibitor
CAR=chimeric antigen receptor
HCL=hairy cell leukemia
MCL= mantle cell lymphoma
r/r=relapsed/refractory
RT=Richter transformation
USPI=US Prescribing Information
WHO=World Health Organization
WM=Waldenström macroglobulinemia

Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the TECARTUS® (brexucabtagene autoleucel) US Prescribing Information available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf.

Follow Up

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FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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