Tecartus® (brexucabtagene autoleucel)

Use of tocilizumab biosimilars for Risk Evaluation and Mitigation Strategy (REMS) Program

Kite, a Gilead Company is providing this document to US Healthcare Professionals in response to your unsolicited request for medical information. Some of the information contained in this response may be outside of the US FDA-approved Prescribing Information. Kite does not intend to offer an opinion regarding the clinical relevance of these data nor the advisability of administering any drug in a manner inconsistent with its approved labeling. Please refer to the product labeling for complete product information.

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 Infomation[1]

According to the TECARTUS US Prescribing Information (USPI), cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Ensure that a minimum of two doses of tocilizumab are available for each patient prior to infusion of TECARTUS. Monitor patients daily for at least seven days for patients with mantle cell lymphoma (MCL) and at least 14 days for patients with acute lymphoblastic leukemia (ALL) at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for four weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

Because of the risk of CRS and neurologic toxicities, TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS. The required components of the YESCARTA and TECARTUS REMS are:

- Healthcare facilities that dispense and administer TECARTUS must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within two hours after TECARTUS infusion, if needed for treatment of CRS.

Further information is available at https://www.yescartatecartusrems.com/ or 1-844-454-KITE (5483).

Available Data

The Tecartus USPI refers to use and availability of "tocilizumab" for treatment of severe or life-threatening Cytokine Release Syndrome (CRS) for patients receiving Tecartus. The USPI is agnostic of a specific brand name for tocilizumab, however it should be noted that currently only ACTEMRA® (tocilizumab) has an approved indication for the treatment of CAR T-cell induced CRS, while other recently approved tocilizumab biosimilars do not.[2]

TYENNE® (tocilizumab-aazg) and TOFIDENCE® (tocilizumab-bavi) are US Food and Drug Administration (FDA) approved biosimilars to the reference product ACTEMRA® (tocilizumab), and the US FDA considers both biosimilars to be highly similar to and have no clinically meaningful differences, in terms of safety or effectiveness, from the existing approved reference product. This means that health care professionals can prescribe either product instead of the original biologic.[2]

Of note, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Version 1.2025 – Management of CAR T-Cell-Related Toxicities states, "an FDA-approved biosimilar is an appropriate substitute for any recommended systemic biologic therapy in the NCCN Guidelines."[3] Use of tocilizumab biosimilars for the treatment of CAR T-cell induced CRS should be at the discretion of the treating physician.

Please refer to the YESCARTA and TECARTUS REMS Program website for a complete list of program requirements.[4]

References

1. TECARTUS® (brexucabtagene autoleucel) [US Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc. 2024
2. Data on File. Kite Pharma.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Management of Immunotherapy-Related Toxicities, Version 1.2025 – December, 20, 2024.
4. YESCARTA and TECARTUS Risk Evaluation and Mitigation Strategy (REMS) Program. https://www.yescartatecartusrems.com/. Kite Pharma, Inc. 2024. Accessed February 25, 2025.

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.

Follow Up

For any additional questions, please contact Kite Medical Information at:

☎1-844-454-KITE (1-844-454-5483) or ✉ medinfo@kitepharma.com

Adverse Event Reporting

Please report all adverse events to:

Kite ☎ 1-844-454-KITE (1-844-454-5483)

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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