CAR T-Cell Therapy Study

ZUMA-23

KT-US-484-0136

An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Participants with High-Risk Large B-Cell Lymphoma

NOW ENROLLING

Contact:
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Study Design[1,2]

Phase 3

1L high-risk
(IPI ≥ 4)
LBCL
N≈300

One cycle
R-chemotherapy

Axi-cel Arm
Axicabtagene ciloleucel infusion

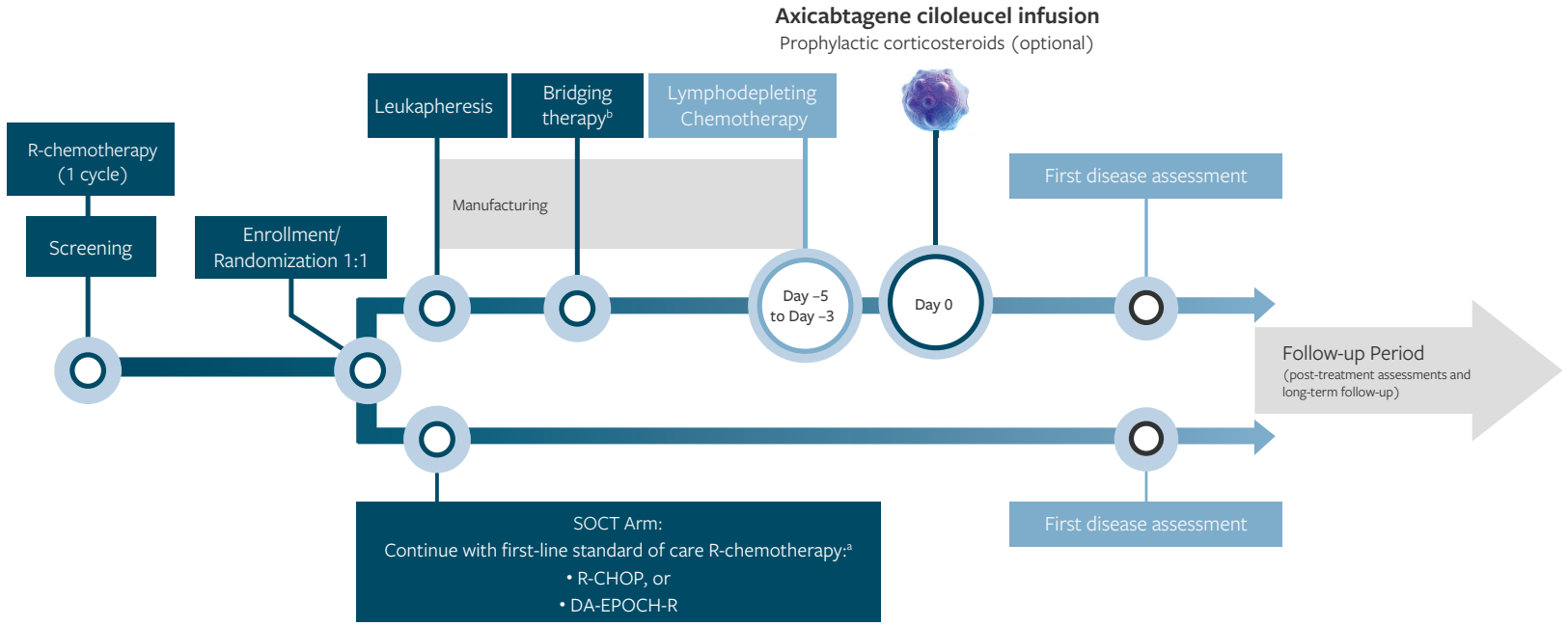
SOCT Arm
Continue with first-line standard of care R-chemotherapy:[a]
- R-CHOP, or
- DA-EPOCH-R

Primary End Point
- EFS

Key Secondary End Points
- PFS
- OS

Secondary End Points
- CR rate
- AEs, SAEs, deaths and changes in safety laboratory values
- PROs/QOL

Treatment Schema[2]



[a]Participants will receive the investigator's choice of either R-CHOP or DA-EPOCH-R for a total of 6 cycles (21-day cycle).
[b]Bridging therapy with R-CHOP or DA-EPOCH-R will be administered during the cell manufacturing period.

The safety and efficacy of these investigational agents or investigational uses of marketed products have not been established. These uses have not been approved by the US Food and Drug Administration or other regulatory authorities. There is no guarantee that these therapies or uses will be commercialized. Please visit ClinicalTrials.gov for more information on trial eligibility criteria and other study details. ClinicalTrials.gov Identifier: NCT05605899.

Eligibility Criteria[1,2]

Key Inclusion Criteria

- 18 Years and older
- Histologically confirmed LBCL based on 2016 WHO classification by local pathology lab assessment, including the following:
  - — DLBCL, NOS
  - — HGBL (including HGBL with MYC and BCL2 and/or BCL6 rearrangements (DHL/THL) based on FISH analysis, and HGBL-NOS

    Note: Transformed DLBCL from follicular lymphoma or from marginal zone lymphoma is eligible if no prior treatment with anthracycline-containing regimen
- High-risk disease defined as an IPI score of 4 or 5 at initial diagnosis
- Ann Arbor Stage III or IV disease
- Have received only 1 cycle of R-chemotherapy
- Adequate bone marrow, renal, hepatic, pulmonary, and cardiac function
- Females of childbearing potential must have a negative serum or urine pregnancy test

Key Exclusion Criteria

- The following WHO 2016 subcategories by local assessment
  - — T-cell/histiocyte-rich LBCL
  - — Primary DLBCL of the CNS
  - — Primary mediastinal (thymic) LBCL
  - — B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma
  - — Burkitt lymphoma
- Presence of malignant cells detected in the CSF, brain metastases, or a history of CNS involvement of lymphoma
- Presence of cardiac lymphoma involvement
- Any prior treatment for LBCL other than the 1 cycle of R-chemotherapy
- Patients positive for HIV
  - —*Note: Patients with a history of HIV and taking appropriate anti-HIV medications, with an undetectable viral load by PCR and a CD4 count >200 cells/μL are eligible to enroll*
- Patients with a history of acute or chronic active hepatitis B or C infection
  - —*Note: Patients with a history of treated hepatitis B or C infection and undetectable viral load are eligible to enroll*
- Medical conditions likely to interfere with assessment of safety or efficacy of study treatment. Please refer to protocol for further details

Note: Other protocol defined Inclusion/Exclusion criteria may apply

Nearest Trial Site:

PI at Nearest Trial Site:

PI's Contact Information:

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References: 1. ClinicalTrials.gov. Accessed May 3, 2023. https://clinicaltrials.gov/ct2/show/NCT05605899. **2.** Data on file. Kite Pharma, Inc. 2022.

CD4, cluster of differentiation 4; CNS, central nervous system; CSF, cerebrospinal fluid; DA-EPOCH-R, dose-adjusted etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, and rituximab; DHL, double-hit lymphoma; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; FISH, fluorescence in situ hybridization; HGBL, high-grade B-cell lymphoma; HIV, human immunodeficiency virus; IPI, International Prognostic Index; LBCL, large B-cell lymphoma; NOS, not otherwise specified; PCR, polymerase chain reaction; PI, primary investigator; R-CHOP, Rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone; THL,triple-hit lymphoma; WHO, World Health Organization.

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