

## Study Design<sup>1,2</sup>

### Phase 2

R/R LBCL  
 N=40

#### Single arm

Axicabtagene ciloleucel: Consisting of a single IV infusion of CAR-transduced autologous T cells on Day 0 (following dexamethasone 10 mg) at a target dose of  $2 \times 10^6$  cells/kg.

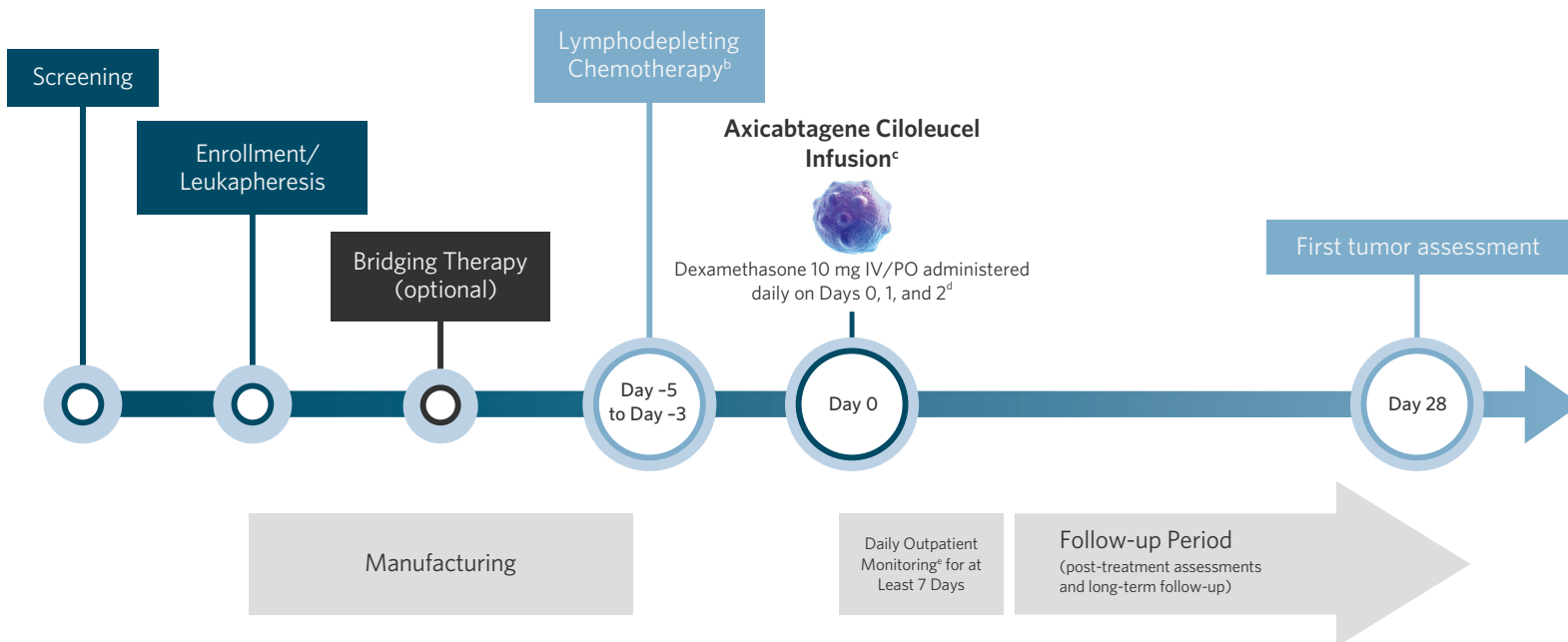
#### Primary End Point

- Incidence rate and severity of CRS and neurologic events

#### Secondary End Points

- Time to onset and duration of CRS and neurologic events
- Duration of initial hospitalization and duration of ICU admission during first hospitalization after axicabtagene ciloleucel infusion
- Rates of hospitalization: proportion of hospitalized participants within 72 hours, 7 days, 14 days, and 30 days
- Blood levels of axicabtagene ciloleucel CAR T-cells over time
- Proportion of ICU admitted participants
- TEAEs/TSAEs
- Change in EQ5D-5L
- Efficacy (ORR, CR rate, DOR, PFS, EFS, OS)<sup>a</sup>
- Peak serum levels of relevant biomarkers

## Treatment Schema<sup>2</sup>



<sup>a</sup>Assessed by Investigator Assessment. <sup>b</sup>A lymphodepleting chemotherapy regimen consisting of cyclophosphamide 500 mg/m<sup>2</sup> and fludarabine 30 mg/m<sup>2</sup> will be administered on Days -5, -4, and -3. <sup>c</sup>Single IV infusion of  $2 \times 10^6$  CAR-T cells/kg on Day 0. <sup>d</sup>Dexamethasone is given prior to axicabtagene ciloleucel on Day 0. <sup>e</sup>Patients and caregivers will be required to stay within 1 hour driving distance from the treatment center for at least 4 weeks after infusion.

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](https://ClinicalTrials.gov) for more information on trial eligibility criteria and other study details. ClinicalTrials.gov Identifier: NCT05459571.

# Eligibility Criteria<sup>1,2</sup>

## Key Inclusion Criteria

- 18 Years and older
- Histologically confirmed LBCL, including the following types defined by WHO 2016 classification, by local pathology laboratory assessment, are eligible as defined below:
  - DLBCL not otherwise specified
  - HGBL with or without MYC and BCL2 and/or BCL6 rearrangement
  - DLBCL associated with chronic inflammation; EBV + DLBCL
  - Primary mediastinal (thymic) LBCL
  - Primary cutaneous DLBCL, leg type
  - Transformation of follicular lymphoma to DLBCL will also be included
- Relapsed or refractory disease after first-line chemotherapy
- Individuals must have received adequate prior therapy including:
  - Anti-CD20 monoclonal antibody AND
  - An anthracycline-containing chemotherapy regimen.
- At least 1 measurable lesion according to the Lugano Response Criteria for Malignant Lymphoma. Lesions that have been previously irradiated will be considered measurable only if progression has been documented following completion of radiation therapy.
- ECOG PS of 0 or 1
- Individual agrees to outpatient treatment setting and to adhere to the prespecified clinical monitoring requirements

## Key Exclusion Criteria

- Received more than 1 line of therapy for LBCL
- History of autologous or allogeneic stem cell transplant
- Prior CD 19 targeted therapy
- Prior chimeric antigen receptor therapy or other genetically modified T-cell therapy
- Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management. Simple urinary tract infection and uncomplicated bacterial pharyngitis are permitted if responding to active treatment and after consultation with the Kite medical monitor
- Individuals with detectable cerebrospinal fluid malignant cells, brain metastases, or with a history of CNS lymphoma or primary CNS lymphoma. DLBCL epidural involvement should be considered as positive CNS disease
- In the investigator's judgment, the individual is unlikely to complete all protocol-required study visits or procedures, including follow-up visits, or comply with the study requirements for participation

*Note: Other protocol defined Inclusion/Exclusion criteria may apply*

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**References:** 1. ClinicalTrials.gov. Accessed September 12, 2022. <https://clinicaltrials.gov/ct2/show/NCT05459571>. 2. Data on file. Kite Pharma, Inc. 2022.

CAR, chimeric antigen receptor; CD, cluster of differentiation; CNS, central nervous system; CR, complete response; CRS, cytokine release syndrome; DLBCL, diffuse large B-cell lymphoma; DOR, duration of response; EBV, Epstein-Barr virus; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event free survival; EQ-5D-5L, European quality of life five dimensions five levels scale; HGBL, high-grade B-cell lymphoma; IV, intravenous; LBCL, large B-cell lymphoma; NE, neurologic event; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PO, by mouth; TEAE, treatment-emergent adverse event; WHO, World Health Organization.



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