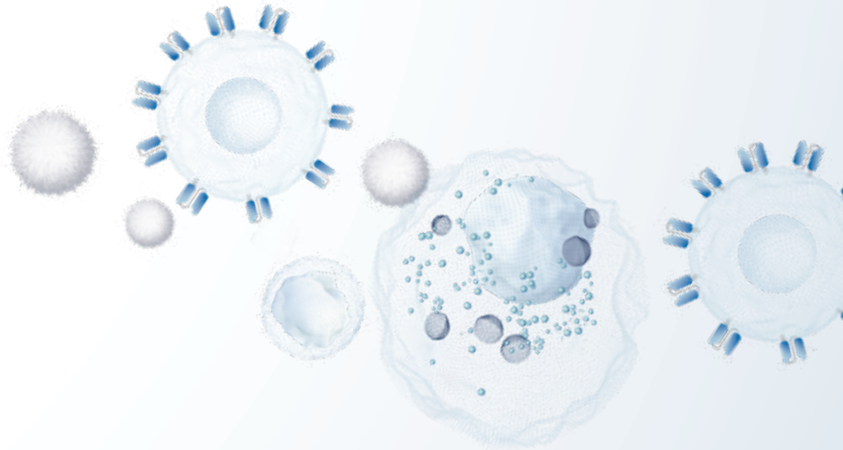
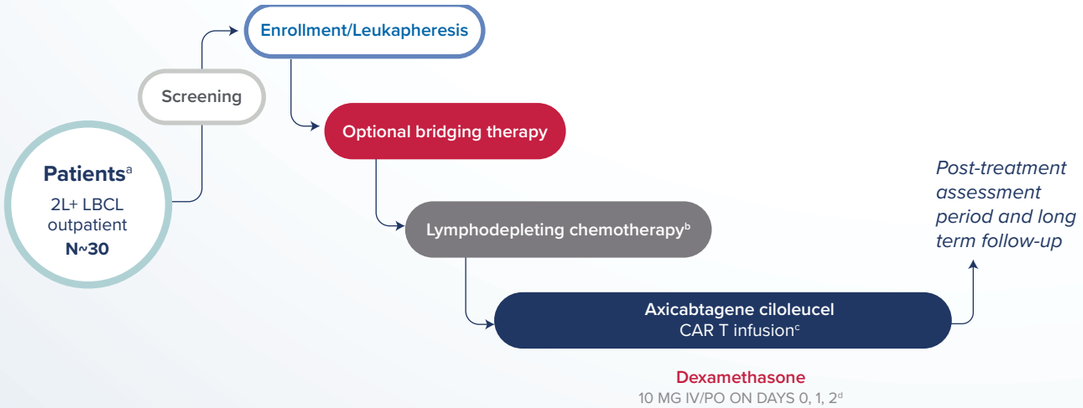
ClinicalTrials.gov Identifier: NCT05459571

ZUMA-24: A Phase 2 Open-Label, Multicenter Study Evaluating the Safety and Efficacy of Axicabtagene Ciloleucel Concomitant With Prophylactic Steroids in Subjects With Relapsed or Refractory Large B-Cell Lymphoma in the Outpatient Setting



Study Design[1,2]



[a]Assesed by Investigator Assessment.
[b]A lymphodepleting chemotherapy regimen consisting of cyclophosphamide 500 mg/m^2 and fludarabine 30 mg/m^2 will be administered on Days -5, -4, and -3.
[c]Single IV infusion of 2 X 10^6 CAR-T cells/kg on Day 0.
[d]Dexamethasone is given prior to axicabtagene ciloleucel on Day 0.

2L, second line; CAR, chimeric antigen receptor; IV, intravenous; LBCL, large B-cell lymphoma; PO, by mouth.

Endpoints[1,2]

Primary Endpoint

- Incidence rate and severity of CRS and neurologic events

Secondary Endpoints

- 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/TESAEs
- Change in EQ5D-5L
- Efficacy (ORR, CR rate, DOR, PFS, EFS, OS)[a]
- Peak serum levels of relevant biomarkers

Continued on next page

CR, complete response; CRS, cytokine release syndrome; DOR, duration of response; EFS, event-free survival; EQ-5D-5L, European Quality of Life Five Dimensions Five Levels Scale; ICU, intensive care unit; ORR, objective response rate;OS, overall survival; PFS, progression-free survival; TEAEs, treatment-emergent adverse events; TESAE, treatment-emergent serious adverse events.

The safety and efficacy of these investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available.

IHQ-UNB-5641 May 2024

Continued from previous page

Key Eligibility Criteria[1,2,a]

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

[a]Other protocol defined Inclusion/Exclusion criteria may apply.

CD, cluster of differentiation; DLBCL, diffuse large B-cell lymphoma; EBV, Epstein-Barr virus; ECOG PS, Eastern Cooperative Oncology Group performance status; HGBL, high-grade B-cell lymphoma; LBCL, large B-cell lymphoma.

Key Eligibility Criteria (cont'd)

Key Exclusion Criteria

- Received more than 1 line of therapy for LBCL
- History of autologous or allogeneic stem cell transplant
- Prior CD19 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

CD, cluster of differentiation; CNS, central nervous system; LBCL, large B-cell lymphoma; IV, intravenous.

References

1. ClinicalTrials.gov website. Accessed February 27, 2024. https://clinicaltrials.gov/ct2/study/NCT05459571
2. Data on file. Kite Pharma, Inc. 2022.

The safety and efficacy of these investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available.

IHQ-UNB-5641 May 2024