CAR T-Cell Therapy Study

# ZUMA-22

KT-US-473-0133

## A Phase 3 Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of Axicabtagene Ciloleucel Versus Standard of Care Therapy in Subjects With Relapsed/Refractory Follicular Lymphoma

**NOW ENROLLING**

**Contact:**
medinfo@kitepharma.com

## Study Design[1,2]

**Phase 3**
R/R FL
(2L POD24 and 3L)
(N≈230)

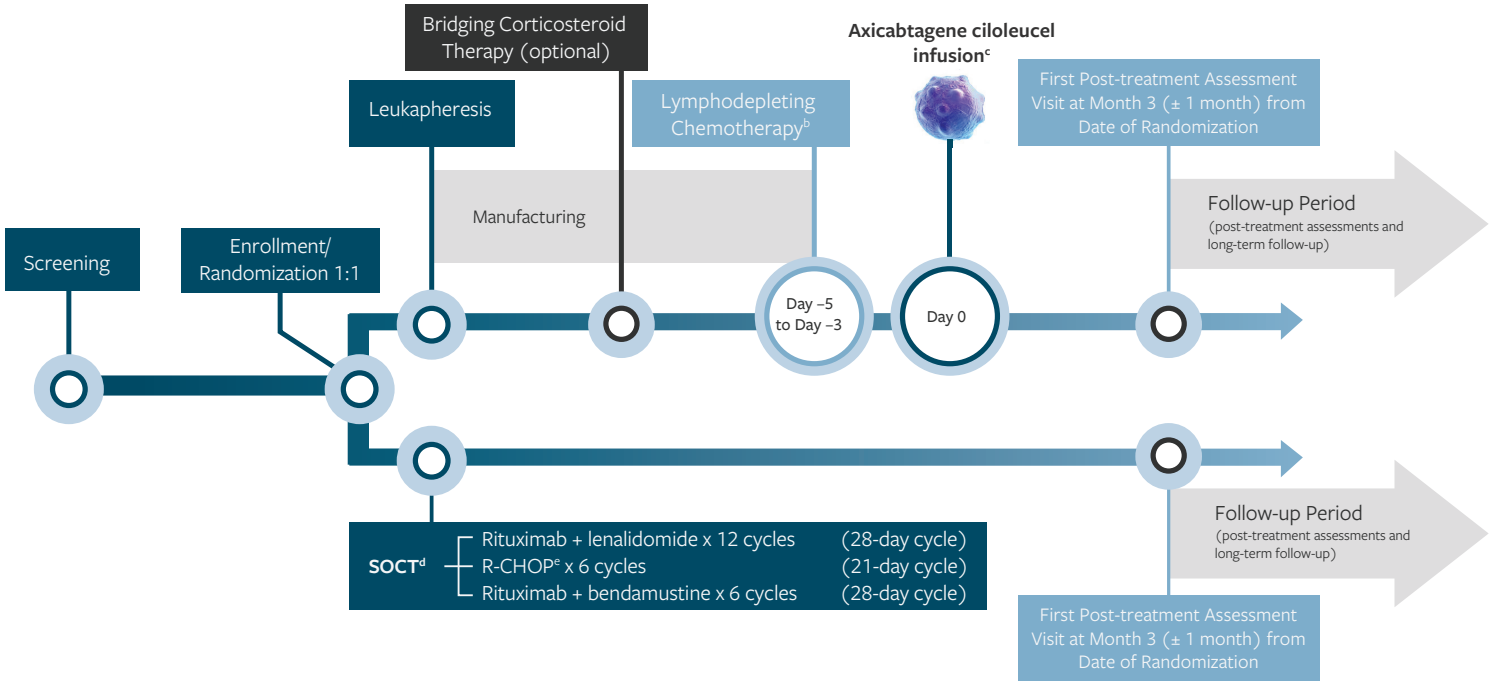
**Arm A**
Axicabtagene ciloleucel infusion

**Arm B**
SOCT—investigator's choice of one of the following therapies:
- Rituximab + lenalidomide
- R-CHOP
- Rituximab + bendamustine

**Primary End Point**
- PFS[a]

**Secondary End Points**
- CR rate[a]
- ORR[a]
- DOR[a]
- Duration of CR[a]
- OS
- EFS[a]
- TTNT
- Percentage of participants experiencing TEAEs
- Percentage of participants experiencing clinically significant changes in safety laboratory values
- PROs/QoL
  - —Change from baseline EORTC QLQ-C30
    - Global health status QoL scale
    - Physical functioning domain
  - —Change from baseline NHL-LG20
    - Global health status QoL scale
    - Physical functioning domain
  - —Changes from baseline in the EQ-5D-5L
  - —Changes from baseline in the VAS scores

## Treatment Schema[2]




[a]Blinded Central Assessment per Lugano Classification. [b]Fludarabine 30 mg/m$^2$ IV & cyclophosphamide 500 mg/m$^2$ IV on Days −5, −4, and −3. [c]Single IV infusion of 2x10$^6$ CAR T-cells/kg on Day 0. [d]SOCT should start between 2 and 9 days after randomization. [e]The CHOP regimen may include a prednisone-equivalent dose of any corticosteroid per institutional guidelines.

**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: NCT05371093.

# Eligibility Criteria[1,2]

### Key Inclusion Criteria

- Histologically-confirmed FL (Grade 1, 2, or 3a)
- R/R disease after first-line chemoimmunotherapy and high-risk disease with relapse or progression within 24 months of the initial course of chemoimmunotherapy (ie, POD24), Or R/R disease after ≥2 prior systemic lines of therapy
- At least 1 measurable lesion per the Lugano Classification (Cheson 2014)
- Adequate renal, hepatic, pulmonary, and cardiac function
- ECOG PS of 0 or 1
- 18 Years and older

### Key Exclusion Criteria

- Transformed FL
- FL Grade 3b
- Prior CD19-targeted therapy
- Prior CAR therapy or other genetically modified T-cell therapy
- Uncontrolled fungal, bacterial, viral, or other infection
- Active infection with HIV, HBV or HCV
  - —Note: Patients who are HIV-positive are eligible if taking appropriate anti-HIV medications, having an undetectable viral load by quantitative PCR, and a CD4 count >200 cells/μL
  - —Note: Patients with a positive history of HBV or HCV are eligible to enroll with an undetectable viral load
    - —If seropositive for HBV (hepatitis B surface antibody and/or hepatitis B core antibody positive) patients are eligible if HBsAg negative
- History or presence of a CNS disorder
- Known history or CNS lymphoma involvement
- History of clinically significant cardiac disease within 6 months of randomization
- Females who are pregnant or breastfeeding
- Individuals of both genders who are not willing to practice birth control
- History of autoimmune disease resulting in or requiring systemic immunosuppression and/or systemic disease-modifying agents within the last 2 years

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

**Nearest Trial Site:**

**PI at Nearest Trial Site:**

**PI's Contact Information:**

**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: NCT05371093.

**References: 1.** ClinicalTrials.gov. Accessed May 3, 2023. https://clinicaltrials.gov/ct2/show/NCT05371093. **2.** Data on file. Kite Pharma, Inc. 2022.

CAR, chimeric antigen receptor; CD, cluster of differentiation; CNS, central nervous system; CR, complete response; CT, computed tomography; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; EQ-5D-5L, European quality of life five dimensions five levels scale; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer-Quality of Life Questionnaire-30; FL, follicular lymphoma; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HR, high-risk; NHL-LG20, global health status quality of life scale of low grade non-hodgkin lymphoma-20; ORR, objective response rate; OS, overall survival; PCR, polymerase chain reaction; PFS, progression-free survival; PRO, patient-reported outcome; PFS, progression-free survival; QoL, quality of life; R/R, relapsed/refractory; R-CHOP, Rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone; SOCT, standard of care therapy; TEAEs, treatment-emergent adverse events; TTNT, time to next treatment; VAS, visual analog scale.

Kite
A GILEAD Compan

This material is funded and developed by Kite, a Gilead Company.



ClinicalTrials.gov

Gilead Clinical Trials