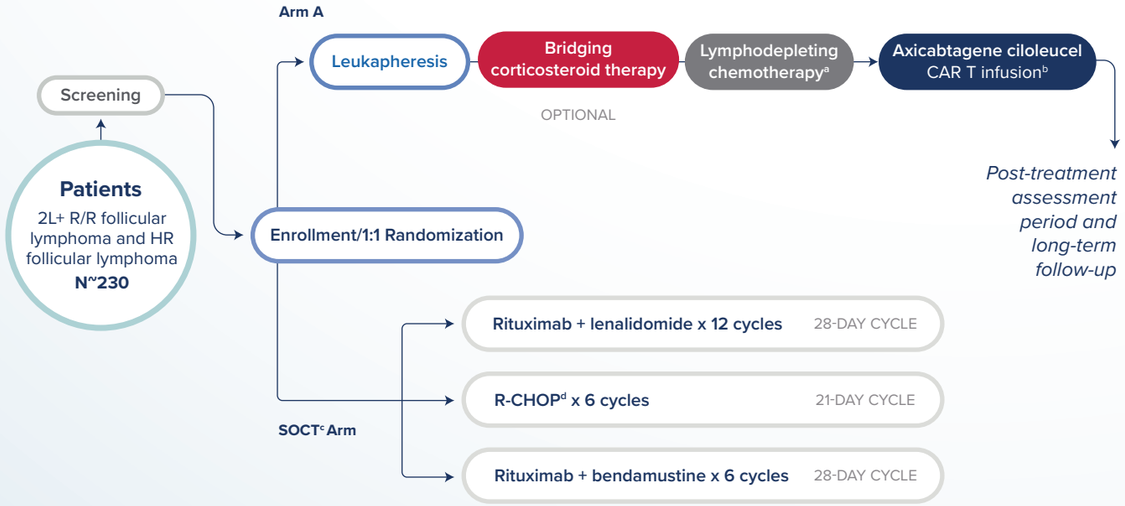
ClinicalTrials.gov Identifier: NCT05371093

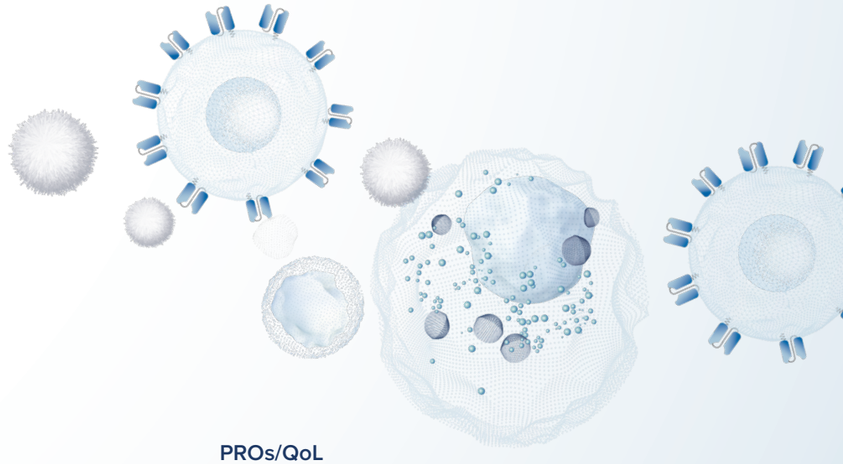
ZUMA-22: A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of Axicabtagene Ciloleucel Versus Standard of Care Therapy in Subjects With Relapsed/Refractory Follicular Lymphoma

Study Design[1,2]



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

2L, second line; CAR, chimeric antigen receptor; HR, high-risk; R/R, relapsed/refractory; R-CHOP, rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone; SOCT, standard of care therapy.



Endpoints[1,2]

Primary Endpoint

- PFS[e]

Secondary Endpoints

- CR rate[e]
- ORR[e]
- DOR[e]
- Duration of CR[e]
- OS
- EFS[e]
- 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

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[e]Blinded Central Assessment per Lugano Classification.

CR, complete response; DOR, duration of response; 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; 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; QoL, quality of life; TEAEs, treatment-emergent adverse events; TTNT, time to next treatment; VAS, visual analog scale.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that they will become commercially available.

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Key Eligibility Criteria[1,2,a]

Key Inclusion Criteria

- ≥18 years of age
- 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

Key Exclusion Criteria

- Presence of large B cell lymphoma or transformed FL
- Small lymphocytic lymphoma
- Lymphoplasmacytic lymphoma
- Full-thickness involvement of the gastric wall by lymphoma
- 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

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

CAR, chimeric antigen receptor; CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PCR, polymerase chain reaction; POD24, progression of disease within 24 months.

Key Eligibility Criteria (cont'd)[1,2]

Key Exclusion Criteria (cont'd)

- History or presence of a CNS disorder
- Known history of CNS lymphoma involvement
- History of clinically significant cardiac disease within 6 months of randomization
- Neuropathy greater than grade 2
- 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
- Presence of any indwelling line or drain (eg, percutaneous nephrostomy tube, indwelling Foley catheter, biliary drain, G-J tube, pleural/peritoneal/pericardial catheter, or Ommaya reservoirs). Dedicated central venous access catheters such as Port-a-Cath or Hickman catheter are permitted

CNS, central nervous system; G-J tube, gastrostomy-jejunostomy tube.

References

1. ClinicalTrials.gov. Accessed July 8, 2024. https://www.clinicaltrials.gov/study/NCT05371093.
2. Data on file. Kite Pharma, Inc. 2022.

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