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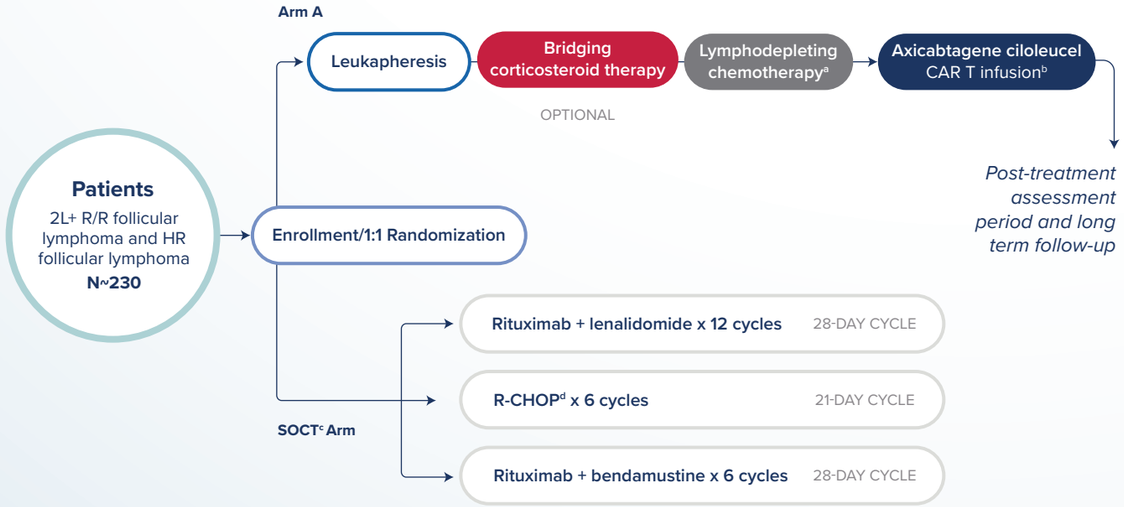
ZUMA-22: A Phase 3 Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of Axicabtagene Ciloleucel Versus Standard of Care Therapy in Subjects With Relapsed/Refractory Follicular Lymphoma

Study Design[1-3]



[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.

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[1-3]

Primary Endpoint

- PFS[a]

Secondary Endpoints

- 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

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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 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.

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Key Eligibility Criteria[1-3,a]

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
  - 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; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HBsAg, hepatitis B surface antigen; PCR, polymerase chain reaction; POD24, progression of disease within 24 months; R/R, relapsed/refractory.

Key Eligibility Criteria (cont'd)

Key Exclusion Criteria (cont'd)

- History of autoimmune disease
- History or presence of a CNS disorder
- Known history or 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.

References

1. ClinicalTrials.gov. Accessed February 27, 2024. https://clinicaltrials.gov/ct2/study/NCT05371093.
2. Data on file. Kite Pharma, Inc. 2022.
3. Clinicaltrialsregister.eu website.

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