ZUMA-7
A Phase 3, Randomized Study Evaluating the Efficacy of Axicabtagene Ciloleucel Versus Standard-of-Care Therapy in Patients With Relapsed/Refractory DLBCL

Currently enrolling patients at sites in the United States and Europe. Contact Kite Medical Information for clinical trial inquiries: 1-844-454-KITE (5483)

Clinicaltrials.gov: NCT03391466
The safety and efficacy of these investigational agents and/or uses have not been established. Visit clinicaltrials.gov for more information on trial inclusion and exclusion criteria.

Primary Endpoint
• Event-free survival

Key Secondary Endpoints
• Objective response rate
• Overall survival

Secondary Endpoints
• Progression-free survival
• Duration of response
• Patient-reported outcomes
• Safety

Patients will receive a 3-day lymphodepleting regimen consisting of fludarabine 30 mg/m²/d + cyclophosphamide 500 mg/m²/d (days −5 to −3) followed by 2 rest days (day −2 and day −1). On day 0, patients will receive a single infusion of axicabtagene ciloleucel administered intravenously at 2 × 10⁶ anti-CD19 CAR T cells/kg.

Patients will receive 2-3 cycles of investigator’s choice of combination chemotherapy regimen (eg, R-I CE) administered every 2-3 weeks.

Defined as death, disease progression, or new lymphoma therapy.


ASCT, autologous stem cell transplantation; DLBCL, diffuse large B cell lymphoma; R/R, relapsed/refractory.
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KEY INCLUSION CRITERIA

• Histologically proven DLBCL, including transformation from FL
• Relapsed or refractory disease after 1L chemoimmunotherapy
  – Refractory disease defined as no CR to 1L therapy
  • PD as best response to 1L therapy
  • SD as best response after ≥4 cycles of 1L therapy
  • PR as best response after ≥6 cycles and biopsy-proven residual disease or PD ≤12 mo from initiation of therapy
  – Relapsed disease defined as CR to 1L therapy followed by biopsy-proven disease relapse ≤12 mo of initiation of 1L therapy
• Adequate 1L therapy
  – Anti-CD20 monoclonal antibody, unless tumor is CD20 negative
  – An anthracycline-containing chemotherapy regimen
• Intent to proceed to HDT and ASCT
• Age ≥18 years at the time of informed consent
• ECOG PS 0-1
• Adequate bone marrow, renal, hepatic, pulmonary, and cardiac function

KEY EXCLUSION CRITERIA

• More than one line of therapy for DLBCL
• Prior CD19-targeted therapy
• Prior CAR or other genetically modified T cell therapy
• Prior randomization into ZUMA-7
• History of Richter’s transformation of CLL
• History of ASCT or allogeneic SCT
• Clinically significant infection or cardiopulmonary disease
  – Indwelling lines or drains (dedicated central venous access catheters allowed)
• History or presence of nonmalignant CNS disorder or CSF malignant cells or brain metastases
• History of autoimmune disease
• History of DVT or PE within 6 mo of enrollment

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