ZUMA-7 SUBJECT ELIGIBILITY based on protocol date 21 Nov 2017

5.1. Inclusion Criteria

101. Histologically proven DLBCL including transformation from FL
102. Relapsed or refractory disease after first-line chemoimmunotherapy
o Refractory disease defined as no complete remission to first-line therapy; subjects who are intolerant to first-line therapy are excluded
 Progressive disease (PD) as best response to first-line therapy
 Stable disease (SD) as best response after at least 4 cycles of first-line therapy (eg, 4 cycles of R-CHOP)
 Partial response (PR) as best response after at least 6 cycles, and biopsy-proven residual disease or disease progression ≤ 12 months from initiation of therapy
o Relapsed disease defined as complete remission to first-line therapy followed by biopsyproven disease relapse ≤ 12 months of initiating first-line therapy
103. Subjects must have received adequate first-line therapy including at a minimum:
o Anti-CD20 monoclonal antibody unless investigator determines that tumor is CD20 negative, and
o An anthracycline containing chemotherapy regimen
104. Intent to proceed to HDT and ASCT if response to second-line therapy
105. Subjects must have radiographically documented disease
106. No known history or suspicion of central nervous system (CNS) involvement by lymphoma

107. At least 2 weeks or 5 half-lives, whichever is shorter, must have elapsed since any prior systemic cancer therapy at the time the subject provides consent
108. Age 18 years or older at the time of informed consent
109. ECOG performance status of 0 or 1
110. Adequate bone marrow, renal, hepatic, pulmonary and cardiac function defined as:
o Absolute neutrophil count (ANC) ≥1000/µL
o Platelet count ≥ 75,000/µL
o Absolute lymphocyte count ≥ 100/µL
o Creatinine clearance (as estimated by Cockcroft Gault) ≥ 60 mL/min
o Serum alanine aminotransferase/aspartate aminotransferase (ALT/AST) ≤ 2.5 upper limit of normal (ULN)
o Total bilirubin ≤ 1.5 mg/dl, except in subjects with Gilbert's syndrome
o Cardiac ejection fraction ≥ 50%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant electrocardiogram (ECG) findings
o No clinically significant pleural effusion
o Baseline oxygen saturation > 92% on room air
111. Females of childbearing potential must have a negative serum or urine pregnancy test (females who have undergone surgical sterilization or who have been postmenopausal for at least 2 years are not considered to be of childbearing potential)

5.2. Exclusion Criteria

201. History of malignancy other than nonmelanoma skin cancer or carcinoma in situ (eg cervix, bladder, breast) unless disease free for at least 3 years
202. History of Richter's transformation of CLL or PMBCL
203. History of autologous or allogeneic stem cell transplant
204. Received more than one line of therapy for DLBCL
205. Prior CD19 targeted therapy
206. Treatment with systemic immunostimulatory agents (including but not limited to interferon and IL-2) within 6 weeks or 5 half-lives of the drug, whichever is shorter, prior to the first dose of axicabtagene ciloleucel or SOC

207. Prior chimeric antigen receptor therapy or other genetically modified T-cell therapy, or prior randomization into ZUMA-7
208. History of severe, immediate hypersensitivity reaction attributed to aminoglycosides
209. Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous (IV) antimicrobials for management. Simple urinary tract infection (UTI) and uncomplicated bacterial pharyngitis are permitted if responding to active treatment.
210. Known history of infection with human immunodeficiency virus (HIV) or hepatitis B (HBsAg positive) or hepatitis C virus (anti-HCV positive). If there is a positive history of treated hepatitis B or hepatitis C, the viral load must be undetectable per quantitative polymerase chain reaction (PCR) and/or nucleic acid testing.

211. Active tuberculosis
212. Presence of any indwelling line or drain (eg, percutaneous nephrostomy tube, indwelling Foley catheter, biliary drain, or pleural/peritoneal/pericardial catheter). Dedicated central venous access catheters such as a Port-a-Cath or Hickman catheter are permitted.
213. Subjects with detectable cerebrospinal fluid malignant cells or known brain metastases, or with a history of cerebrospinal fluid malignant cells or brain metastases
214. History or presence of non-malignant CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement
215. Subjects with cardiac atrial or cardiac ventricular lymphoma involvement
216. History of myocardial infarction, cardiac angioplasty or stenting, unstable angina, New York Heart Association Class II or greater congestive heart failure, or other clinically significant cardiac disease within 12 months of enrollment
217. Requirement for urgent therapy due to tumor mass effects such as bowel obstruction or blood vessel compression
218. History of autoimmune disease, requiring systemic immunosuppression and/or systemic disease modifying agents within the last 2 years.
219. History of idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening. History of radiation pneumonitis in the radiation field (fibrosis) is allowed.
220. History of symptomatic deep vein thrombosis or pulmonary embolism within 6 months of enrollment
221. Any medical condition likely to interfere with assessment of safety or efficacy of study treatment
222. History of severe immediate hypersensitivity reaction to tocilizumab or any of the agents used in this study
223. Treatment with a live, attenuated vaccine within 6 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during the course of the study
224. Women of childbearing potential who are pregnant or breastfeeding because of the potentially dangerous effects of chemotherapy on the fetus or infant. Subjects of either sex who are not willing to practice birth control from the time of consent and at least 6 months after the last dose of axicabtagene ciloleucel or SOC chemotherapy
225. In the investigators judgment, the subject is unlikely to complete all protocol-required study visits or procedures, including follow-up visits, or comply with the study requirements for participation