GCT3013-02 - Subject Eligibility

A Phase 1b/2, Open-Label Trial to Assess the Safety and Preliminary Efficacy of Epcoritamab GEN3013; DuoBody®-CD3xCD20) in Combination with Other Agents in Subjects with B-cell Non-Hodgkin Lymphoma

Inclusion Criteria *(cycle "Y" if subject meets criteria for inclusion – patient is not eligible if "N" is circled for any of the criteria listed below)*

1.	Be at least 18 years of age	Y	N	
2.	Must sign an informed consent form (ICF) prior to any screening procedures indicating that they understand the purpose of and procedures required for the trial and are willing to participate in the trial prior to any other trial-related assessments or procedures.	Y	N	
3.	Acceptable organ function defined as: (provide **anonymized** lab report) ANC ≥1.0 × 10^9/L (growth factor use is allowed) — Y / N			
	Platelet count >75 x 10^9/L, or ≥50 x 10^9/L if bone marrow infiltration or splenomegaly — Y / N			
	ALT level ≤2.5 times the ULN — Y / N			
	Total bilirubin level ≤2 × ULN — Y / N			
	EGFR >50 mL/min (using Cockcroft-Gault Formula) — Y / N			
	PT, INR, and aPTT ≤ 1.5 x ULN, unless receiving anticoagulant — Y / N			
4.	**ARM 1 - Subject eligibility criteria** (epcoritamab + R-CHOP) ○ Documented DLBCL (de novo or histologically transformed) ○ Date of diagnosis (dd/mmm/yyyy): _____/_____/_____ ○ International Prognostic Index score ≥3 ○ Eligible to receive R-CHOP per investigator determination. Investigators to confirm that subjects who are ≥80 years old are eligible to receive R-CHOP according to the protocol, without preplanned dose reductions ○ LVEF within institutional normal limits by MUGA or echocardiography at screening	Y	N	NA

5.	**ARM 2 - Subject eligibility criteria** (epcoritamab + R^2) ○ Relapse/Refractory FL, grade 1, 2 or 3a, stage II, III, or IV ○ Previously treated with at least 1 prior anti-neoplastic agent, including anti-CD20 antibody ○ Must have a need for treatment initiation based on symptoms and/or disease burden ○ Eligible to receive R2 per investigator determination ○ Use 2 forms of contraception consistent with local regulations for females of childbearing potential regarding the use of birth control methods for subjects receiving lenalidomide or continuously abstain from heterosexual sex during the following time periods related to this trial for at least 28 days before starting trial drug (refer to Appendix 14-Lenalidomide Pregnancy Risk Minimization Plan) ○ Negative serum (beta-hCG) pregnancy test for female of childbearing potential screening (within 10-14 days of C1Day1)? ○ Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking lenalidomide.	Y	N	NA
	ARM 3 - Subject eligibility criteria (epcoritamab + BR) ○ Newly diagnosed, previously untreated FL grade 1, 2, or 3a, stage II, III, or IV ○ Eligible to receive BR per investigator determination	Y	N	NA
	ARM 4 - Subject eligibility criteria_(epcoritamab + R-DHAP) ○ Documented DLBCL (de novo or histologically transformed) according ○ Relapsed or refractory to prior therapy ○ Eligible for HDT-ASCT ○ Eligible to receive R-DHAP per investigator determination	Y	N	NA
	ARM 5 - Subject eligibility criteria (epcoritamab + GemOx) ○ Documented DLBCL (de novo or histologically transformed) ○ Relapsed or refractory to prior therapy? ○ Ineligible for HDT-ASCT due to age, PS, or comorbidity? ○ Eligible to receive GemOx per investigator determination?	Y	N	NA

Exclusion Criteria: *(Circle Y for each exclusion criteria that may apply – patient is not eligible for study if Y is circled for any of the criteria listed below)*

1.	History of severe allergic or anaphylactic reactions to anti-CD20 mAb therapy or known allergy or intolerance to any component or excipient of epcoritamab?	Y	N	NA
2.	Chemotherapy, radiation therapy, or major surgery within 4 weeks prior to the first dose of trial treatment	Y	N	
3.	Treatment with an anti-cancer antibody or an investigational drug within 4 weeks or 5 half-lives, whichever is shorter, prior to the first dose of trial treatment	Y	N	
4.	Treatment with CAR-T therapy within 30 days prior to first dose of trial treatment	Y	N	
5.	Vaccination with live vaccines within 28 days prior to the first dose of trial treatment	Y	N	
6.	Clinically significant cardiac disease, including: ○ Myocardial infarction within 1 year prior to the 1st dose of epcoritamab, or unstable or uncontrolled disease/condition related to or affecting cardiac function (see protocol Appendix 5), cardiac arrhythmia (CTCAE Version 4 Grade 2 or higher), or clinically significant ECG abnormalities ○ Screening 12-lead ECG showing a baseline QTcF >470 msec	Y	N	
7.	Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results	Y	N	
8.	Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at trial enrollment or significant infections within 2 weeks prior to the first dose of trial treatment	Y	N	
9.	CNS lymphoma or known CNS involvement by lymphoma at screening as confirmed by MRI/CT scan of the brain and, if clinically indicated, by lumbar puncture	Y	N	
10.	Active positive tests for hepatitis B virus or hepatitis C virus indicating acute or chronic Infection	Y	N	
11.	History of HIV antibody positivity	Y	N	
12.	Positive test results for HTLV-1	Y	N	

13.	Suspected active or latent tuberculosis	Y	N	
14.	Known past or current malignancy other than inclusion diagnosis, except for: a. Cervical carcinoma of Stage 1B or less b. Non-invasive basal cell or squamous cell skin carcinoma c. Non-invasive, superficial bladder cancer d. Prostate cancer with a current PSA level < 0.1 ng/mL e. Any curable cancer with a CR of > 2 years duration	Y	N	
15.	Neuropathy >grade 1	Y	N	
16.	Female who is pregnant, breast-feeding, or planning to become pregnant while enrolled in this trial or within 12 months after the last dose of epcoritamab	Y	N	NA
17.	Male who plans to father a child while enrolled in this trial or within 12 months after the last dose of epcoritamab	Y	N	NA
18.	Subject has any condition for which, in the opinion of the investigator, participation would not be in the best interest of the subject (eg, compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments	Y	N	

19.	**ARM 1 - Subject exclusion criteria** o Prior therapy for DLBCL with the exception of nodal biopsy o Contraindication to any of the individual drugs of the R-CHOP regimen	Y	N	NA
	ARM 2 - Subject exclusion criteria o FL Grade 3b o Histologic evidence of transformation to an aggressive lymphoma o Contraindication to rituximab or lenalidomide o Prior allogeneic HSCT o Autologous HSCT within 3 months of the first dose of epcoritamab o Unwilling or unable to take aspirin prophylaxis (subjects with low or intermediate risk for o thromboembolism) or prophylactic anticoagulant (if high risk for a thromboembolic event)	Y	N	NA
	ARM 3 - Subject exclusion criteria o FL grade 3b o Histologic evidence of transformation to an aggressive lymphoma o Prior therapy for FL with the exception of nodal biopsy	Y	N	NA
	ARM 4 - Subject exclusion criteria o Contraindication to any of the individual drugs of the R-DHAP regimen	Y	N	NA
	ARM 5 - Subject exclusion criteria o Contraindication to any of the individual drugs of the GemOx regimen	Y	N	NA