	INVESTIGATOR / CENTER
	Dr. Lugtenburg / Erasmus MC

PATIENT INITIALS	DATE OF BIRTH
[__][__][__]	**[__][__] / [__][__][__] / [__][__][__][__]**

SUBJECT NUMBER	GENDER	DATE INFORMED CONSENT
[__][__][__][__][__][__][__]	**Male / Female**	**[__][__] / [__][__][__] / 20[__][__]**

INCLUSION CRITERIA			
		YES	**NO**
1.	Must be at least 18 years of age	☐	☐
2.	Subject (or their legally acceptable representative) must sign an ICF indicating that the purpose of the trial and the procedures required for the trial are understood, and indicating that the subject is willing to participate in the trial prior to initiating any other trial-related assessments or procedures.	☐	☐
3.	ECOG PS score of 0-2.	☐	☐
4.	One of the confirmed histologies below with CD20-positivity: a) DLBCL, NOS (according to the WHO 2016 classification), including de novo or histologically transformed from FL b) "Double-hit" or "triple-hit" DLBCL (technically classified in WHO 2016 as HGBCL, with MYC and BCL2 and/or BCL6 translocations), including de novo or histologically transformed from FL • Note: other double-/triple-hit lymphomas and those classified in WHO 2016 as HGBCL, NOS are not eligible c) FL Grade 3B.	☐	☐
5.	CD20-positivity at representative (previous or current) tumor biopsy based on the pathology report.	☐	☐
6.	Relapsed or refractory disease and previously treated with at least 1 line of systemic antineoplastic therapy including anti-CD20 mAb-containing combination chemotherapy since lymphoma diagnosis (ie, having received R-CHOP or an equivalent regimen that would be considered adequate first-line treatment for DLBCL); • Relapsed disease is defined as disease that has recurred ≥6 months after completion of therapy. Refractory disease is defined as disease that either progressed during therapy or progressed within 6 months (< 6 months) of completion of therapy.	☐	☐
7.	Failed previous HDT-ASCT or not eligible for HDT-ASCT at screening. If ineligible for HDT-ASCT, the decision must have been based on age, performance status, comorbidity, and/or insufficient response to prior treatment.	☐	☐
8.	Has measurable disease: a. An FDG-PET scan demonstrating positive lesion(s) compatible with CT- or MRI-defined anatomical tumor sites b. ≥1 measurable nodal lesion (long axis >1.5 cm and short axis >1.0 cm) and/or ≥1 measurable extranodal lesion (long axis >1.0 cm) on CT scan or MRI.	☐	☐
9.	Absolute neutrophil count ≥1.0 x 10^9 /L (growth factor permitted)	☐	☐
10.	Platelet count >75 x 10^9 /L (or >50 x 10^9 /L if bone marrow involvement or splenomegaly).	☐	☐
11.	Alanine aminotransferase and aspartate aminotransferase level ≤3 times the upper limit of normal (xULN), unless enzyme elevation is due to a non-hepatic origin.	☐	☐
12.	Total bilirubin level ≤2 xULN, unless bilirubin rise is due to Gilbert's syndrome or of non-hepatic origin.	☐	☐

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INCLUSION CRITERIA (vervolg)			
		YES	**NO**
13.	Estimated GFR ≥50 mL/min/1.73 m^2.	☐	☐
14.	PT/INR/aPTT ≤1.5 xULN, unless receiving anticoagulation.	☐	☐
15.	A female subject with reproductive potential (Appendix 10) must agree to use adequate contraception during the trial, and for 12 months after the last administration of trial treatment. Adequate contraception is defined as highly effective methods of contraception • Note: If the reproductive potential changes after start of the trial (eg, female subject who is not heterosexually active becomes active, premenarchal female subject experiences menarche), a female subject must begin adequate contraception (ie, highly effective methods of contraception), as described in Appendix 10.	☐	☐
16.	A female subject of childbearing potential must have a negative serum (beta-hCG) pregnancy test at screening and a negative serum or urine pregnancy test before treatment administration on Day 1 of every cycle.	☐	☐
17.	A female subject must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the entire trial, until 12 months after the last administration of trial treatment.	☐	☐
18.	A male subject who is sexually active with a female of reproductive potential and has not had a vasectomy must agree to use a barrier method of birth control (ie, condom) and must agree not to donate sperm during the trial and for 12 months after receiving the last administration of trial treatment.	☐	☐
19.	Life expectancy >2 months on SOC treatment.	☐	☐

EXCLUSION CRITERIA			
		YES	**NO**
1.	Primary CNS tumor or known CNS involvement as assessed by brain MRI at screening or by CT and lumbar puncture (if MRI contraindicated).	☐	☐
2.	Any prior therapy with a bispecific antibody targeting CD3 and CD20.	☐	☐
3.	History of severe allergic or anaphylactic reactions to anti-CD20 antibody therapy.	☐	☐
4.	Contraindication to any component of SOC regimen selected prior to randomization.	☐	☐
5.	Major surgery within 4 weeks prior to randomization.	☐	☐
6.	Chemotherapy and other non-investigational antineoplastic agents (except CD20 mAbs) within 4 weeks or 5 half-lives (whichever is shorter) prior to randomization.	☐	☐
7.	Any investigational drug within 4 weeks or 5 half-lives, whichever is longer, prior to randomization.	☐	☐
8.	ASCT within 100 days of randomization.	☐	☐
9.	Treatment with CAR-T therapy within 100 days prior to randomization.	☐	☐
10.	Receiving immunosuppressive therapy, including more than the equivalent of 20 mg of prednisolone daily, unless for disease control.	☐	☐
11.	Seizure disorder requiring anti-epileptic therapy.	☐	☐
12.	Vaccination with live vaccines within 28 days prior to randomization.	☐	☐
13.	Clinically significant cardiovascular disease, including: a. Myocardial infarction within 1 year prior to randomization, or unstable or uncontrolled disease/condition related to or affecting cardiac function (eg, unstable angina, congestive heart failure, New York Heart Association Class III-IV) cardiac arrhythmia (CTCAE Version 5.0 Grade 2 or higher), or clinically significant ECG abnormalities; b. Stroke within 6 months prior to randomization;	☐	☐
14.	Screening 12-lead ECG showing a baseline QT interval as corrected by Fridericia's formula (QTcF) >470 msec	☐	☐
15.	Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results	☐	☐

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EXCLUSION CRITERIA (vervolg)			
		YES	**NO**
16.	Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection requiring systemic treatment at time of randomization.	☐	☐
17.	Known history of seropositivity for HIV infection.	☐	☐
18.	Active HBV (DNA PCR-positive) or hepatitis C (RNA PCR-positive infection). Subjects with evidence of prior HBV but who are PCR-negative are permitted in the trial but should receive prophylactic antiviral therapy. Subjects who received treatment for HCV that was intended to eradicate the virus may participate if hepatitis C RNA levels are undetectable.	☐	☐
19.	Has 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 complete response of >2 years duration	☐	☐
20.	Has known or suspected allergies, hypersensitivity, or intolerance to epcoritamab or its excipients (refer to the Investigator's Brochure for more information).	☐	☐
21.	Contraindication to all uric acid lowering agents.	☐	☐
22.	A woman of childbearing potential with a positive serum or urine pregnancy test at screening. Female subjects must also agree not to breastfeed during the entire trial and until 12 months after the last administration of study drug.	☐	☐
23.	Clinically significant liver disease, including active hepatitis, current alcohol abuse, or cirrhosis.	☐	☐
24.	Suspected active or latent tuberculosis as documented by interferon gamma release assay.	☐	☐
25.	Receiving immunostimulatory agent.	☐	☐
26.	Prior allogeneic hematopoietic stem cell transplantation	☐	☐

Checked by:_____**Signature**_____

Date of registration:_____