ELIGIBILITY CHECKLIST

INVESTIGATOR / CENTRE	
18-017 Genmab GCT3013 expansie	**Dr. Lugtenburg**

PATIENT INITIALS	DATE OF BIRTH	SCREENING NUMBER
[__][__] [__]	[__][__]/[__][__][__]/[__][__]	[__][__][__][__][__]

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

INCLUSION CRITERIA The investigator must ensure that only patients who meet the following inclusion and exclusion criteria are offered enrolment in the study.	**YES**	**NO**
1. Patient must be 18 years of age or older	☐	☐
2. Patient must meet the following entry criteria for the applicable expansion cohort: a. **For expansion part R/R aNHL cohort:** i. Documented CD20+ mature B-cell neoplasm according to WHO classification Swerdlow et al., 2016 (Swerdlow et al., 2016) or WHO classification 2008 based on representative pathology report 1. Diffuse large B-cell lymphoma (de novo or transformed from all indolent subtypes including Richter's transformation), including: b. Patients with "double-hit" or "triple-hit" DLBCL (technically classified in WHO 2016 as HGBCL, with MYC and BCL2 and/or BCL6 translocations) *Note*: Other double-/triple-hit lymphomas are not eligible 2. Other aggressive B-NHL: a. Primary mediastinal large B-cell lymphoma b. High-grade B-cell lymphoma c. Follicular lymphoma grade 3B ii. Relapsed or refractory disease and previously treated with at least 2 lines of systemic antineoplastic therapy including at least 1 anti-CD20 monoclonal antibody-containing therapy *Note*: 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. iii. Either failed prior autologous hematopoietic stem cell transplantation (HSCT), or ineligible for autologous HSCT due to ag, ECOG performance status or comorbidities and/or insufficient response to prior treatment. **b. For expansion part R/R iNHL cohort:** i. Documented CD20+ mature B-cell neoplasm according to WHO classification Swerdlow et al., 2016 (Swerdlow et al., 2016) or WHO classification 2008 based on representative pathology report 1. Histologic confirmed FL grade 1, 2, or 3A at initial diagnosis without clinical or pathological evidence of transformation 2. Marginal zone lymphomas (nodal, extranodal, and splenic) 3. Small lymphocytic lymphoma ii. Relapsed or refractory disease previously treated with at least 2 lines of systemic antineoplastic therapy including at least 1 anti-CD20 monoclonal antibody-containing therapy *Note*: 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. iii. Previously treated with an alkylating agent or lenalidomide iv. Relapsed or refractory to the last prior line therapy. Previous lymphoma therapy is defined as 1 of the following: At least 2 months of single-agent therapy, at least 2 consecutive cycles of combination therapy, autologous HSCT, immunomodulatory therapy, or radioimmunotherapy		☐

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c. For expansion part R/R MCL cohort: i. Documented CD20+ MCL according to WHO classification Swerdlow et al., 2016 or WHO classification 2008 based on representative pathology report with either cyclin D1 overexpression or presence of the translocation t(11;14). ii. Stage II-IV with a need for treatment. iii. Previously treated with at least 2 prior lines of systemic antineoplastic therapy including at least 1 prior anti-CD20 mAb-containing regimen. iv. Previously treated with a BTKi and either progressing (relapsed or refractory) or intolerant to BTKi v. Relapsed or refractory to the most recent line of therapy. *Note:* 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. vi. If bridging therapy with BTKi is administered during the screening period, the patient must be able to undergo a repeat baseline PET-CT (and bone marrow aspirate/biopsy, if applicable) to assess baseline disease status prior to first administration of GEN3013 (if bridging therapy to the start of GEN3013 administration is more than 2 weeks).		
3. Measurable disease: a. Fluorodeoxyglucose (FDG)-avid lymphomas: Measurable disease with computerized tomography (CT) (or magnetic resonance imaging [MRI]) scan with involvement of 2 or more clearly demarcated lesions/nodes with a long axis >1.5 cm and short axis >1.0 cm (or 1 clearly demarcated lesion/node with a long axis >2.0 cm and short axis ≥1.0 cm) AND FDG positron emission tomography (PET) scan that demonstrates positive lesion(s) compatible with CT (or MRI) defined anatomical tumor sites b. FDG-nonavid lymphomas: Measurable disease with CT (or MRI) scan with involvement of 2 or more clearly demarcated lesions/nodes with a long axis >1.5 cm and short axis >1.0 cm or 1 clearly demarcated lesion/node with a long axis >2.0 cm and short axis ≥1.0 cm.	☐	☐
4. ECOG 0, 1 or 2 (see Appendix 5).	☐	☐
5. Lymphocyte counts < 5 x 10E9/L. For MCL: <50 x 10E9/L	☐	☐
6. platelet counts ≥ 75 x 10E9/L or, in the presence of bone marrow involvement or splenomegaly, ≥ 50 × 10E9/L	☐	☐
7. ANC ≥1.0 x 10E9/L, growth factor support allowed in case of bone marrow involvement	☐	☐
8. Patient must meet the following criteria regarding time since previous neoplastic agent(s): a. At least 4 weeks from last dose of non-investigational systemic chemotherapy b. At least 4 weeks or 5 half-lives from last dose of other non-investigational antineoplastic agents, whichever is shorter (except any anti-CD20 mAb or BTKi) c. At least 5 half-lives from last dose of investigational agents except for prior chimeric antigen receptor T-cell (CAR-T) therapy from which 30 days must pass prior to first GEN3013 administration.	☐	☐
9. Resolution of toxicities from prior therapy to a grade that does not contraindicate trial participation in the opinion of the investigator	☐	☐
10. If receiving glucocorticoid treatment at screening, must be a maximum daily dose of prednisone 10 mg (or equivalent) and a total of no more than 140 mg over the last 14 days prior to the first dose of GEN3013	☐	☐
11. Before the first dose of GEN3013, during the trial and for 12 months after last administration of GEN3013, a woman must be either a. Not of childbearing potential*: premenarchal; postmenopausal (> 45 years of age with amenorrhea for at least 12 months or any age with amenorrhea for at least 6 months and a serum follicle stimulating hormone [FSH] level > 40 IU/L or mIU/mL); permanently sterilized (e.g., bilateral tubal occlusion [which includes tubal ligation procedures as consistent with local regulations], hysterectomy, bilateral salpingectomy, bilateral oophorectomy); or otherwise be incapable of pregnancy b. Of childbearing potential and practicing a highly effective method of birth control (as defined	☐	☐

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by the EU Clinical Trial Facilitation Group) consistent with local regulations regarding the use of birth control methods for patients participating in clinical trials: e.g., established use of oral, injected or implanted combined (estradiol and progesterone containing) hormonal contraception; placement of an intrauterine device (IUD) or intrauterine system (IUS); male partner sterilization (the vasectomized partner should be the sole partner for that patient); true abstinence (when this is in line with the preferred and usual lifestyle of the patient) *If the childbearing potential changes after start of the trial (e.g., woman who is not heterosexually active becomes active, premenarchal woman experiences menarche) a woman must begin a highly effective method of birth control, as described under 31b		
12. A man who is sexually active with a woman of childbearing potential must agree to use a barrier method of birth control (that is the use of condom) during the trial and for 12 months after receiving the last dose of GEN3013	☐	☐
13. Women must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the trial and for 12 months after receiving the last dose of GEN3013. Men must also not donate sperm during the trial and for 12 months after receiving the last dose of GEN301	☐	☐
14. The patient understands the purpose of the trial and procedures required for the trial and is capable of giving signed informed consent as which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol	☐	☐
15. The patient must consent to provide sample(s) for evaluation of DNA.	☐	☐

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EXCLUSION CRITERIA Any potential patient who meets any of the following criteria will be excluded from participating in the trial.	**YES**	**NO**
1. PrimaryCNS lymphoma or CNS involvement by lymphoma at screening as confirmed by mandatory magnetic resonance imaging (MRI)/computed tomography (CT)scan (brain) and, if clinically indicated, by lumbar puncture.	☐	☐
2. 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 (CR) of > 2 years duration	☐	☐
3 AST, and /or ALT > 3 x ULN	☐	☐
4. Total bilirubin > 1.5 x ULN, unless bilirubin rise is due to Gilbert's syndrome or non-hepatic origin.	☐	☐
5. Estimated GFR <45 mL/min/1.73m² (see Appendix 1)	☐	☐
6. known clinically significant cardiac disease, including: - onset of unstable angina pectoris within 6 months of signing ICF - acute myocardial infarction within 6 months of signing ICF - congestive heart failure (grade 3 or 4 as classified by the New York Heart a Association (see Appendix 2) and or known decrease ejection fraction of <45%	☐	☐
7. Chronic ongoing infectious diseases requiring treatment (excluding prophylactic treatment) at the time of enrolment or within the previous 2 weeks prior to the first dose of GEN3013	☐	☐
8. Confirmed history or current autoimmune disease or other diseases resulting in permanent immunosuppression or requiring permanent immunosuppressive therapy. Low-dose (<10mg/day)prednisolone (or equivalent) for rheumatoid arthritis or similar conditions is allowed	☐	☐
9. Seizure disorder requiring therapy (such as steroids or anti-epileptics)	☐	☐
10. Any prior therapy with an investigational bispecific antibody targeting CD3 and CD20	☐	☐
11. Prior treatment with chimeric antigen receptor T-cell (CAR-T) therapy within 30 days prior to first GEN3013 administration	☐	☐
12. Eligible for curative salvage therapy with high dose therapy with HSCT rescue	☐	☐
13. Autologous HSCT within 100 days prior to first GEN3013 administration, or any prior allogeneic HSCT or solid organ transplantation	☐	☐
14. Active hepatitis B or ongoing hepatitis C infection that has not bee cured. If laboratory evidence for a chronic infection with hepatitis B close monitoring and prophylactic therapy is required (see Section 6.6.1.3)	☐	☐
15. Known human immunodeficiency virus (HIV) infection	☐	☐
16. Exposed to live or live attenuated vaccine within 4 weeks prior to signing ICF	☐	☐
17. Pregnancy or breast feeding	☐	☐
18. Patient has any condition for which, in the opinion of the investigator, participation would not be in the best interest of the patient (e.g., compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments	☐	☐
19. Contraindication to all uric acid lowering agents	☐	☐

Checked by:_____ **Signature**_____

Date of registration:_____