EudraCT-Nr.
2022-XXXXX-XX

Sponsor: IKF
A prospective multicenter phase 2 study of the chemotherapy-free combination of intravenous rituximab in combination with the antibody-drug conjugate polatuzumab vedotin and the bispecific antibody glofitamab in patients above 60 years of age with previously untreated DLBCL ineligible for a standard R-CHOP chemotherapy and all patients above 80 years of age.

R-Pola-Glo

Study Protocol Version XX (XX.XX.XX)

Study Synopsis

Clinical study title	A prospective multicenter phase 2 study of the chemotherapy-free combination of intravenous rituximab in combination with the antibody-drug conjugate polatuzumab vedotin and the bispecific antibody glofitamab in patients above 60 years of age with previously untreated DLBCL ineligible for R-CHOP chemotherapy and all patients above 80 years of age.
Phase of study	II
Short title	Rituximab (R) in combination with polatuzumab vedotin (Pola) and glofitamab (Glo) in patients with previously untreated DLBCL ineligible for R-CHOP chemotherapy (R-Pola-Glo)
Sponsor Code	
EudraCT No.	
Investigational medicinal product, dose and mode of application	Trade Name: Glofitamab Substance: Glofitamab Manufacturer: Roche Dose: 2.5mg, 10mg, 30 mg Mode of Application: intravenous Duration of Treatment: 12 times (q3w)
Investigational medicinal product, dose and mode of application	Trade Name: GAZYVARO® Substance: Obinutuzumab Manufacturer: Roche AG Dose: 1000 mg Mode of Application: intravenous Duration of Treatment: once in cycle 1

EUDRACT-NR.
2022-XXXXX-XX

SPONSOR: IKF
A prospective multicenter phase 2 study of the chemotherapy-free combination of intravenous rituximab in combination with the antibody-drug conjugate polatuzumab vedotin and the bispecific antibody glofitamab in patients above 60 years of age with previously untreated DLBCL ineligible for a standard R-CHOP chemotherapy and all patients above 80 years of age.

R-Pola-Glo

STUDY PROTOCOL VERSION XX (XX.XX.XX)

Investigational medicinal product, dose and mode of application	Trade Name: MabThera Substance: Rituximab Manufacturer: Roche AG Dose: 375 mg/m^2 Mode of Application: intravenous Duration of Treatment: 6 cycles (q3w)
Investigational medicinal product, dose and mode of application	Trade Name: Polivy Substance: Polatuzumab Vedotin Manufacturer: Roche AG Dose: 1,8 mg/kg Mode of Application: intravenous Duration of Treatment: 6 cycles (q3w)
Study treatment plan	**Prephase/Debulking Phase** There will be a mandatory prednisolon prephase of 5 days. Prednisolon will be administered p.o. at a dose of 100 mg for 5 days before the start of the study. If p.o. application is not possible intravenous application is considered equivalent. The prephase can have started before enrollment. Vincristine, as used in other prephases, should not been administered. **Step-up cycle (cycle 1)** will comprise of intravenous (i.v.) application of rituximab 375mg/m^2 on d1 followed by i.v. application obinutuzumab 1000 mg on d2, followed by i.v. application polatuzumab 1.8mg/kg on d3 and i.v. application of glofitamab in escalating dose of 2,5 mg on d8 and 10 mg on d15. **Target dose phase (cycle 2-6)** will start 3 weeks after the step up cycle and repeated q3w. Each of the 5 cycle comprise rituximab 375mg/m^2 and polatuzumab 1.8mg/kg both administered i.v. on d1 and i.v. glofitamab 30 mg on d2 **Maintainance phase (cycle 7-12)** will start 3 weeks after the last target dose cycle and will comprise 6 cycles of glofitamab 30 mg administered intravenously on d1. The total duration of the combination of rituximab, obinutuzumab plus polatuzumab and glofitamab will be 6 cycles q3w in 18 weeks (4.5 months) followed by 6 cycles q3w of glofitamab maintenance for 18 weeks (4.5 months). In total, there will be 6 doses of rituximab, 6 doses of polatuzumab vedotin, 1 dose of obinutuzumab and 12 doses of glofitamab. An antiinfective prophylaxis using acciclovir, cotrimoxaxol, ciprofloxacin will be mandatory.

EudraCT-Nr.
2022-XXXXX-XX

Sponsor: IKF
A prospective multicenter phase 2 study of the chemotherapy-free combination of intravenous rituximab in combination with the antibody-drug conjugate polatuzumab vedotin and the bispecific antibody glofitamab in patients above 60 years of age with previously untreated DLBCL ineligible for a standard R-CHOP chemotherapy and all patients above 80 years of age.

R-Pola-Glo

Study Protocol Version XX (XX.XX.XX)

Study population (or indication)	All previously not treated patients diagnosed with a histologically confirmed CD20 positive aggressive lymphoma above ≥ 80 years of age (cohorte 1) and non-fit patients not eligible for full dosed R-CHOP-like therapies between 61-80 years of age (cohort 2).
Study design	Prospective, multicenter, bi-national (Germany and Austria) one arm phase-II-study.
Study objectives	The primary objective of this study is: (1) The 1-year PFS of the chemotherapy-free combination of rituximab, glofitamab, polatuzumab in patients with previously untreated CD20 positive aggressive lymphoma ≥ 80 years of age (cohort 1), and; (2) The 1-year PFS patients of unfit patients not eligible for R-CHOP-like therapies between 61-79 years of age (cohort 2). The secondary objectives are to evaluate feasibility, safety and efficacy, treatment compliance, and patient-reported symptoms of the chemotherapy free new combination therapy in the first line treatment of patients with CD20 positive aggressive lymphoma.

EudraCT-Nr.
2022-XXXXX-XX

Sponsor: IKF
A prospective multicenter phase 2 study of the chemotherapy-free combination of intravenous rituximab in combination with the antibody-drug conjugate polatuzumab vedotin and the bispecific antibody glofitamab in patients above 60 years of age with previously untreated DLBCL ineligible for a standard R-CHOP chemotherapy and all patients above 80 years of age.

R-Pola-Glo

Study Protocol Version XX (XX.XX.XX)

Study endpoints	**Primary endpoint:** 1.) PFS at 1 year for patients ≥80 years (cohort 1) 2.) PFS at 1 year for non-fit patients 61-79 years (cohort 2) **Secondary endpoints:** All secondary end points will be evaluated in both cohorts separately. • Rate of complete metabolic remission (CR) after 6 cycles and at end of treatment (12 cycles) • Rate of partial remission (PR) after 6 cycles and at end of treatment (12 cycles) • Overall response rate (ORR; CR+PR) • Rate of progressive disease (PD) • Relapse rate • Conversion rate of PRs to CRs during maintenance • Rate of treatment-related mortality • Rate and type of AEs and SAEs as secondary toxicity endpoints. • Event-free and overall survival at 1 year (EFS and OS; next lymphoma therapy as an event; non mCR as event) • Duration of response • Patient characteristics of recruited population (Ratio: >80/60-79) • Protocol adherence • Patient reported outcome analysis for quality of life • As determined by imaging and liquid biopsy: - Percentage of MRD-negative patients at the end of cycle 6 and end of glofitamab maintainance cycle 12 - Duration of molecular remission as determined by liquid biopsy for MRD negative patients from end target dose cycles - Molecular and imaging based predictors of response and sensitivity - Molecular and imaging based predictors of PR to CR conversion.
Subject number	n=70 analyzable patients will be included into the trial. It is assumed that 50 patients are recruited in cohort 1 (≥80 years) and 20 patients are recruited in cohort 2 (non-fit patients 61-79 years). The numbers might be subject to changes according to clinical routine. To accomplish allocation of 70 analyzable patients, a total number of n=100 subjects will be assessed for eligibility allowing to compensate for screening failures and drop-outs.

Inclusion criteria	Subjects will only be included in the study, if they meet all of the following criteria: **Informed consent** ● Able and willing to provide written informed consent and to comply with the study protocol and protocol mandated hospitalizations according to ICH and local regulations **Age** ● a) Age ≥ 80 years, medical fit to receive the combination therapy b) Age 61-79 years, medical non-fit and not eligible for R-CHOP-like therapies **Type of Patients and Disease Characteristics** ● Histologically-confirmed CD20 positive aggressive lymphoma with a biopsy performed before study entry and with material available for central review. *Note: transformed follicular lymphoma and composite lymphoma can be included as long as the low grade component had not obtained treatment.* ● Any gender (male, female, non-binary) ● The contraception and abstinence requirements are intended to prevent exposure of an embryo to the study treatment. The reliability of sexual abstinence for male and/or female enrollment eligibility needs to be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or post-ovulation methods) and withdrawal are not acceptable methods of contraception: ○ Female patients: A female patient is eligible to participate if she is not pregnant (see appendix x), not breastfeeding, and at least one of the following conditions applies: i. Women of non-childbearing potential (WONCBP, as defined in Section y of appendix x); or ii. Women of childbearing potential (WOCBP), as defined in appendix x who: – Have a negative serum pregnancy test

	within 7 days prior to study treatment. Women who are not of childbearing potential, i.e., who are considered to be post-menopausal (12 months of non-therapy amenorrhea) or surgically sterile (absence of ovaries and/or uterus) are not required to have a pregnancy test. – Agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of 1% per year during the treatment period and for at least: o 18 months after pretreatment with obinutuzumab o 2 months after the last dose of glofitamab o 9 months after the last dose of polatuzumab vedotin o 3 months after the last dose of tocilizumab (if applicable), whichever islonger Examples of contraceptive methods with a failure rate of 1% per year include bilateral tubal occlusion, male sterilization, established proper use of hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices and copper intrauterine devices (see appendix x). – Refrain from donating ova during the same period described above b) Male Patients During the treatment period and for at least: o 3 months after pretreatment with obinutuzumab o 2 months after the last dose of glofitamab o 6 months after the last dose of polatuzumab vedotin o 2 months after the last dose of tocilizumab (if applicable), whichever is longer Remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures such as

	a condom plus an additional contraceptive method that together result in a failure rate of 1% per year, with partners who are women of childbearing potential (WOCBP, as defined in Section y of appendix x). With pregnant female partners, remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures such as a condom to avoid exposing the embryo. Refrain from donating sperm during this same period. ● No prior lymphoma therapy ● ECOG performance status 0, 1, 2 *Note: Participants with an initial ECOG performance status of 3 may be considered during screening if the performance status is DLBCL-related and if pre-phase treatment (not more than 100 mg steroids/day up to 7 days prior to Cycle 1 Day 1) during the screening phase results in an improvement of ECOG performance status to </= 2 prior to enrollment* ● Life expectancy (in the opinion of the Investigator) of 12 weeks ● Adequate liver function: ● Total bilirubin ≤1.5 x ULN (≤3 x ULN in patients with Gilbert's syndrome) ● AST (aspartate aminotransferase)/ALT (alanine aminotransferase), ALP (alkaline phosphatase) ≤3 x ULN ○ Patients with bone marrow or liver involvement: ALP ≤5 x ULN ○ Patients with documented liver involvement: AST and/or ALT ≤5 x ULN ● Albumin ≥ 2.5 g/dL ● Adequate hematological function: ● Neutrophil count of ≥1.5 x 10^9 cells/L (1.500/µL) ● Platelet count of ≥75 x 10^9 cells/L (75,000/µL) ● Hemoglobin (Hb) ≥9.0 g/dL ● Note: In case screening procedures are leading to situations that would exclude the patient from study

	participation (such as Hb value below entry criteria), the patient may still be enrolled into the trial after consultation with the Medical Monitor. ● For patients not receiving therapeutic anti-coagulation: INR or aPTT ≤ 1.5 x ULN ● Adequate renal function: ● Creatinine ≤ 1.5 x ULN, or; ● Creatinine clearance (CrCl) calculated by Cockroft-Gault formula of ≥ 40 mL/min for patients in whom, in the Investigator's judgment, serum creatinine levels do not adequately reflect renal function ● Negative serologic and/or polymerase chain reaction (PCR) test results for ● acute or chronic hepatitis B virus (HBV) infection. (Note: Patients whose HBV infection status cannot be determined by serologic test results [https://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf] must be negative for HBV by PCR to be eligible for study participation). ● Negative test results for hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Note: Patients who are positive for HCV antibody must be negative for HCV by PCR to be eligible for study participation.

Exclusion criteria	Subjects will not be included in the study if any of the following criteria apply: **Medical Conditions** 1. Patients with CLL, ALL (including CD20+ ALL), lymphoblastic lymphoma, Richter`s transformation, Burkitt lymphoma 2. Patients with known active infection, or reactivation of a latent infection, whether bacterial (e.g., tuberculosis), viral (including, but not limited to severe pneumonia, COVID-19, Epstein-Barr virus [EBV], cytomegalovirus [CMV], hepatitis B, hepatitis C, and HIV], fungal, mycobacterial, or other pathogens (excluding fungal infections of nail beds) or any major episode of infection requiring hospitalization or treatment with IV antibiotics (for IV antibiotics this pertains to completion of last course of antibiotic treatment) within 4 weeks prior to study enrollment. *Note:* Patients receiving prophylactic antibiotics (e.g., to prevent a urinary tract infection or chronic obstructive pulmonary disease exacerbation) are eligible for the Study. 3. Current > Grade 1 peripheral neuropathy 4. Patient with history of confirmed progressive multifocal leukoencephalopathy (PML) 5. History of leptomeningeal disease 6. Current or past history of CNS lymphoma 7. Current or past history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease *Note: Patients with a history of stroke who have not experienced a stroke or transient ischemic attack in the past 2 years and have no residual neurologic deficits, as judged by the Investigator, are allowed.* 8. Patients with another invasive malignancy in the last 2 years (with the exception of basal cell carcinoma and tumors deemed by the Investigator to be of low likelihood for recurrence), with the exception of malignancies with a negligible risk of metastasis or death (e.g., 5-year OS rate 90%), such as adequately-treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer. 9. Significant or extensive history of cardiovascular disease (such as New York Heart Association (NYHA) Class ≥ II cardiac disease, congestive heart failure, myocardial

	infarction or cerebrovascular accident within the past 3 months, unstable arrhythmias, or unstable angina or history of multiple cardiovascular events) or significant pulmonary disease (including obstructive pulmonary disease and history of bronchospasm). *Note: Congestive heart failure NYHA II patients can be included if they provide an LVEF >40%* 10. Active or history of autoimmune disease or immune deficiency, including, but not limited to, myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, antiphospholipid antibody syndrome, Wegener granulomatosis, Sjögren syndrome, Guillain-Barré syndrome, or multiple sclerosis (see addendum for a more comprehensive list of autoimmune diseases and immune deficiencies), with the following exceptions: ● Patients with a history of autoimmune-related hypothyroidism who are on thyroid-replacement hormone are eligible for the study. ● Patients with controlled Type 1 diabetes mellitus who are on an insulin regimen are eligible for the study ● Patients with eczema, psoriasis, lichen simplex chronicus, or vitiligo with dermatologic manifestations only (e.g., patients with psoriatic arthritis are excluded) are eligible for the study provided all of following conditions are met: – Rash must cover 10% of body surface area. – Disease is well controlled at baseline and requires only low-potency topical corticosteroids. – No occurrence of acute exacerbations of the underlying condition requiring psoralen plus ultraviolet A radiation, methotrexate, retinoids, biologic agents, oral calcineurin inhibitors, or high-potency or oral corticosteroids within the previous 12 months. 11. Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently). *Note:* Patients with indwelling catheters (e.g., PleurX) are allowed. 12. History of idiopathic pulmonary fibrosis, organizing

	pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic. **Prior/Concomitant Therapy** 13. Treatment with any other standard anti-cancer radiotherapy/chemotherapy including investigational therapy (defined as treatment for which there is currently no regulatory authority approved indication) within 4 weeks prior to study enrollment. 14. Prior solid organ transplantation 15. Prior allogeneic SCT 16. Prior treatment with targeted therapies (e.g., tyrosine kinase inhibitors, systemic immunotherapeutic/immunostimulating agents, including, but not limited to, CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies, radio-immunoconjugates, ADCs, immune/cytokines and monoclonal antibodies) within 4 weeks or five half-lives of the drug, whichever is shorter, prior to study enrollment. 17. Toxicities from prior anti-cancer therapy including immunotherapy that did not resolve to ≤ Grade 1 with the exception of alopecia, endocrinopathy managed with replacement therapy and stable vitiligo. 18. Any history of immune related ≥ Grade 3 AE with the exception of endocrinopathy managed with replacement therapy. 19. Ongoing corticosteroid use 25 mg/day of prednisone or equivalent within 4 weeks prior and during study treatment ● Patients who received corticosteroid treatment with 25 mg/day of prednisone or equivalent must be documented to be on a stable dose of at least 4-week duration prior to Day 1 of Cycle 1. ● Patients may have received a brief (max. 7 days) course of systemic steroids (100 mg prednisone equivalent per day) prior to initiation of study therapy for control of lymphoma-related symptoms as a prephase. 20. Treatment with systemic immunosuppressive medication (including, but not limited to, cyclophosphamide,

	azathioprine, methotrexate, thalidomide, and antiTNF-agents) within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during study treatment, with the following exceptions: ● Patients who received mineralocorticoids (e.g., fludrocortisone), corticosteroids for chronic obstructive pulmonary disease (COPD) or asthma, or low-dose corticosteroids for orthostatic hypotension or adrenal insufficiency are eligible for the study. 21. Administration of a live, attenuated vaccine within 4 weeks prior to study enrollment infusion or anticipation that such a live, attenuated vaccine will be required during the study or within 5 months after the last dose of study treatment. *Note: Influenza vaccination should be given during influenza season only. Patients must not receive live, attenuated influenza vaccine (e.g., Flumist®) at any Time during the study treatment period.* **Other Exclusions** 22. History of illicit drug or alcohol abuse within 12 months prior to screening, in the Investigator's judgment 23. History of severe allergic anaphylactic reactions to chimeric or humanized monoclonal antibodies or recombinant antibody-related fusion proteins. Please consult Medical Monitor if the patient has documented history of CRS or HLH at previous treatments. *Note:* Patients with IRRs are in general not excluded, only in case if IRR was accompanied by documented tryptase elevation. 24. Known hypersensitivity to Chinese hamster ovary cell products or to any component of the rituximab, obinutuzumab, polatuzumab vedotin and/or glofitamab formulation and/or to the contrast agents used in the study.

Efficacy evaluations	Assessment of tumor response and progression will be conducted via clinical examination (physical examination, including lymphoma's B symptoms), defined blood work (see appendix) and imaging studies (PET-CT) after 3, 6 and 12 cycles or at any sign of clinical progression. Metabolic response rate will be evaluated following the Lugano criteria following investigators assessment. Efficacy evaluations include, PET-CT, and if medical needed/applicable magnetic resonance imaging, bone marrow aspirate and biopsy, or other procedures as necessary. For all subjects, survival and subsequent antineoplastic therapy data will be collected until lost to follow-up, withdrawal of consent, or study end. Subjects who discontinue treatment prior to disease progression will have regularly scheduled disease evaluations until disease progression, death, or study end, whichever occurs first. In addition to longitudinal dynamic response assessment of MRD is performed via liquid biopsy within the correlative science program before and after each cycle and as f/u and correlation to PET/CT-based imaging. At baseline proteogenomic molecular studies will be performed incl. COO transcriptional subtypes, MYC/BCL2 translocation status, genetic subtypes, TME characterization (see separate program).
Investigational study sites	The study will be conducted in approximately 30 centers in Germany and Austria, which must meet the structural and personnel requirements for performing the planned regular study-related investigations. In particular they need to be able to have an inpatient service that allows admitting patients with CRS or ICANs. All investigators agree to supervise the conduct of this study in their affiliation and to ensure its conduct in compliance with the protocol, informed consent, IRB/EC procedures, the Declaration of Helsinki, ICH Good Clinical Practices guideline, the EU directive Good Clinical Practice (2001-20-EG), and local regulations governing the conduct of clinical studies.

Statistical rationale	The analyzable study population will consist of 70 subjects (allocated from a screen population of n=100 to compensate for screening failures and drop outs; It is assumed that 50 patients are recruited in cohort 1 and 20 patients are recruited in cohort 2.) based on the following considerations: It is assumed that the PFS at 1 year with R-Pola-Glo is at least as it has been reported for a R-miniCHOP treated patients >80 years (Peyrade et al.; 1-year PFS-rate = 59%). With a sample size of 70 patients in total and 50 patients expected to be over 80 years, the 95% confidence interval would range about from 45% to 74%. In case the R-Pola-Glo regimen is more effective than R-miniCHOP with a 1-year PFS-rate of 74% (95% confidence interval: 60%-87%), then this trial allows excluding a historical value of PFS at 1-year below 59%. With an expected number of 20 non-fit patients between 61 and 80 years and a 1-year PFS-rate as in B-R-ENDA trial of 37% for this collective (Braulke et al, submitted) the 95% confidence interval would range from 14% to 60%. In case the R-Pola-Glo therapy leads to a remarkably better 1 year PFS-rate of greater than 60% the 95% confidence interval would range from 38% to 84% and would therefore allow to exclude a historical value of PFS at 1 year below 37%. Progression-free survival will be analyzed according to the Kaplan-Meier method. 95%-confidence intervals will be determined.

Safety analysis / Safety run in - phase	The first 6 cycles will be obligatory administered as an inpatient to closely monitor CRS. Cycles 7-12 are planned as outpatient. In case there was a CRS ≥ 2 in the prior cycle (inpatient or outpatient) the patients must be hospitalized for 24h. Safety evaluations include: adverse event monitoring, physical examinations, evaluation of changes to concomitant medications, and clinical laboratory parameters. All adverse events that occur between the date of subject registration through 28 days after subjects have completed study treatment will be collected. Infections and secondary malignancies will be reported during the whole duration of the study. The severity of adverse events will be assessed using National Cancer Institute Common

	Terminology Criteria for Adverse Events, Version 5.0. Serious adverse events will be reported according to the GCP regulations. Due to the not previously tested combination of rituximab in combination with the previously tested polatuzumab and glofitamab (triple vs. dual antibody combination) that all target the B-cell compartment, we will perform a safety run in of 10 patients with a recruitment stop for 3 cycles. We will assess the frequency of infectious related SAEs despite the use of mandatory anti-infectious prophylaxis. Given the small sample size and the aprox. 10-20% TRM due to infectious complications in the R-mini-CHOP population, we intentionally do not define metric parameters, but require the immediate evaluation of safety and continuation of rituximab in addition to the Pola-Glo combination (triple vs. dual antibody combination) if there are more than 3 treatment-related death, a significant increase of grade 3 and higher SAEs due to infectious complications and/or significant increased hospitalization rate in this safety run in phase by the independent data safety board. In addition, we will closely monitor (without any recruitment stopp) the performance of the first 5 patients that presentend before the pre-phase with an ECOG 3 and improved during pre-phase for additional safety signals, including increased toxicity, mortality. In case of an increase of grade 3 and higher SAEs due to infectious complications and/or significant increased hospitalization rate in this safety run in phase data will be assessed and evaluated by the independent data safety board.
Time schedule	We anticipate first patient in the 2. quartal 2023. With an expected recruitment of approximately 2 patients per year/center, recruitment for the R-Pola-Glo combination should be finished within 1.5 years (last patient in 4Q 2024). The follow up phase of 3 year starts for the last patient in at randomization in 1Q2025 and ends 1Q2028; hence the study is expected to be closed 4.5 years after start of recruitment.

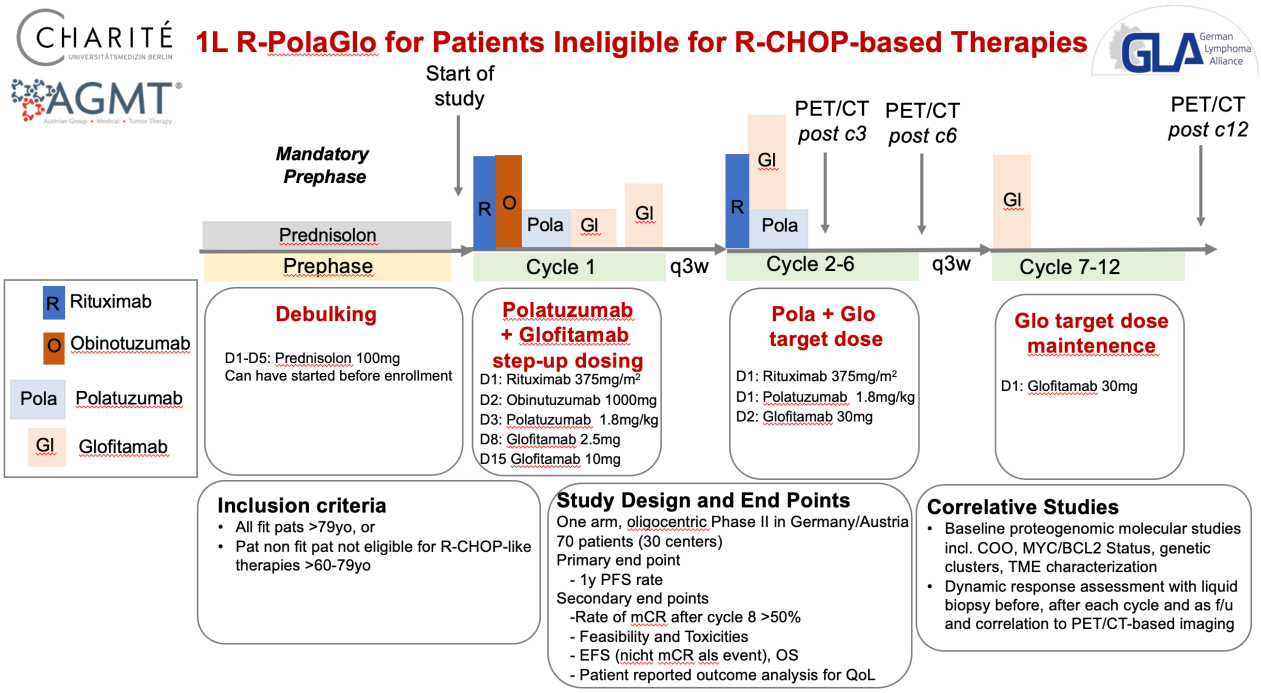
EudraCT-Nr.
2022-XXXXX-XX

Sponsor: IKF
A prospective multicenter phase 2 study of the chemotherapy-free combination of intravenous rituximab in combination with the antibody-drug conjugate polatuzumab vedotin and the bispecific antibody glofitamab in patients above 60 years of age with previously untreated DLBCL ineligible for a standard R-CHOP chemotherapy and all patients above 80 years of age.

R-Pola-Glo

Study Protocol Version XX (XX.XX.XX)

Reports	An interim report for efficacy will be performed following recruitment of all 70 patients and first follow-up visit of the last patient in. A final report will be performed after all patients are recruited and the last patient in has at least 3 year observation time after inclusion and the documentation is completed.



Responsible PIs/contact: B. Chapuy on behalf of the GLA and R. Greil for the AGMT