CLINICAL STUDY REPORT

Title:	Pembrolizumab in Marginalzone Lymphoma A Multicentre Open Label Single-Arm Phase II Study
Study number:	POLE-1
EudraCT number:	2018-000187-28
Test drug:	Pembrolizumab (Keytruda®) Rituximab (Truxima®)
Development phase:	Phase II
Sponsor's name and address:	University Hospital Ulm, Ulm, Germany; represented by the Chairman of the board
Co-ordinating Investigator:	Prof. Dr. Christian Buske University Hospital of Ulm Department of Internal Medicine III Albert-Einstein-Allee 23 D-89081 Ulm Phone: +49 / 731 / 500-65801 E-Mail: christian.buske@uni-ulm.de
Responsible Statistician:	Dr. Jens Dreyhaupt Institute of Epidemiology and Medical Biometry Ulm University Schwabstrasse 13 D-89075 Ulm E-Mail: jens.dreyhaupt@uni-ulm.de
Study dates:	Study initiation date (first patient enrolled): 02-MAR-2022 Date of recruitment interruption: 28-JUN-2024 Date of early study termination: 06-DEC-2024
Version/date:	Version: 1.0, date: 02-DEC-2025

2 SIGNATURE PAGE

PRINCIPAL OR COORDINATING INVESTIGATOR'S SIGNATURE OR SPONSOR'S RESPONSIBLE MEDICAL OFFICER

STUDY TITLE: Pembrolizumab in Marginalzone Lymphoma
A Multicentre Open Label Single-Arm Phase II Study

STUDY AUTHORS: Prof. Dr. Christian Buske; Principal Coordinating Investigator

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

INVESTIGATOR/SPONSOR: Prof. Dr. Christian Buske

AFFILIATON: University Hospital of Ulm
Department of Internal Medicine III
Albert-Einstein-Allee 23
D-89081 Ulm

DATE: 2.12.2025 SIGNATURE: C. Buske

3 LIST OF ABBREVIATIONS

AE	Adverse Event
aPTT	Activated Partial Thromboplastin Time
ALAT (SGPT)	Alanine Aminotransferase
ASAT (SGOT)	Aspartate Aminotransferase
BM	Bone Marrow
BTK	Bruton Tyrosine Kinase
CI	Confidence Interval
CR	Complete Response
CRR	Complete Response Rate
CT	Computed Tomography
CTCAE	Common Terminology Criteria for Adverse Events
DSMC	Data Safety Monitoring Committee
EOT	End of Treatment
FACT-LYM	Functional Assessment of Cancer Therapy – Lymphoma
GCP	Good Clinical Practice
GELA	Groupe d'Etude des Lymphomes de l'Adulte (French Lymphoma Study Group)
GFR	Glomerular Filtration Rate
Hb	Haemoglobin
HCV	Hepatitis C Virus
HE	Haematoxylin Eosin
HBV	Hepatitis B Virus
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
INR	International Normalized Ratio
ITT	Intent-to-Treat
MALT	Mucosa-Associated Lymphoid Tissue
MZL	Marginal Zone Lymphoma
NE	Not Evaluable
OS	Overall Survival
PFS	Progression-Free Survival
pRBC	Packed Red Blood Cells
PR	Partial Response
PT	Prothrombin Time
QoL	Quality of Life
RNA	Ribonucleic Acid
SD	Stable Disease
SMZL	Splenic Marginal Zone Lymphoma
SOC	System Organ Class
TTF	Time to Treatment Failure
ULN	Upper Limit of Normal

4 STUDY SYNOPSIS

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Title of the study:	Pembrolizumab in Marginalzone Lymphoma A Multicentre Open Label Single-Arm Phase II Study V 2.0 valid from initial authorization on 20-OCT-2020 until 13-JUN-2021 V 3.0 valid from 14-JUN-2021 until end of trial on 06-DEC-2024
Investigator(s):	Coordinating Investigator, *Leiter der klinischen Prüfung* according to German law: Prof. Dr. Christian Buske University Hospital of Ulm Department of Internal Medicine III Albert-Einstein-Allee 23 D-89081 Ulm Co-coordinating Investigator: ao Univ. Prof. Dr. Markus Raderer (Austria)
Study centre(s):	Number of centers recruiting in the study: Germany: 12 (see Appendix 1 for a listing of sites and investigators) Austria: 0
Publications (references):	Not applicable
Period of study:	Study initiation date (first patient enrolled): 01-MAR-2022 Date of recruitment interruption: 28-JUN-2024 Date of early study termination: 06-DEC-2024 Reason for early study termination: The estimated duration of recruitment had been exceeded significantly and recruitment could not be increased despite major efforts. The slow recruitment was due to the COVID-19 pandemic and the associated restrictions. Another important factor was most likely the authorization of the well tolerated orally available covalent BTK inhibitor Zanubrutinib in October 2022. Approval was based on its excellent safety profile and its high activity as single agent in this lymphoma subtype. In this situation and due to the rapidly changing treatment landscape continuation of the recruitment into this trial was not feasible any longer. In addition, many competing clinical trials in MZL had been started, testing drugs such as CD20xCD3 bi-specific antibodies, which promised substantially higher efficacy as the regimen tested in our trial. Additionally, data from this trial analysed before discontinuation had demonstrated that the treatment was safe and did not put the patients at any unforeseen risk, but at the same time only showed modest activity, indicating that stop of this trial would not withhold any highly efficient treatment option from patients. Taken all this together, it was considered justified to stop the trial early.
Clinical phase:	Phase II
Objectives:	The objective of this trial was to test the efficacy and toxicity of the treatment of Pembrolizumab/Rituximab in patients with MZL in need of treatment, who have failed or are not eligible for local therapy or relapsed after local or systemic therapy. For efficacy the rate of complete remissions (according to the GELA criteria for

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	gastric MALT or to the Cheson 2007 criteria for non-gastric extranodal, nodal and splenic MZL) after therapy were planned to be primarily analysed. Secondary study objectives: Response rates (CR, PR, CR or PR) four weeks after the end of therapy, best response, time to best response, time to first response, progression free survival (PFS), time to treatment failure (TTF), duration of response (DR), cause specific survival (CSS), overall survival (OS), quality of life (QoL) during therapy
Methodology (design of study):	European phase II trial, multicenter, single–arm, open label **Treatment phase:** • MZL patients in need of treatment. <u>Treatment:</u> Cycle 1 (21 days cycle): • Rituximab 375 mg/m^2 i.v. Day 1, 8, 15 • Pembrolizumab 200mg i.v. Day 2 Cycle 2-18 (21 days cycle) or until progression or non-tolerable toxicity • Rituximab 375 mg/m^2 i.v. Day 1 every second cycle • Pembrolizumab 200mg i.v. Day 1 **Follow-up Phase** All subjects who entered the trial were planned to be followed every 3 months for disease progression, subsequent treatment, and survival for two years after completion/ discontinuation of the treatment. Subsequently, patients were planned be monitored every 6 months for three additional years. The follow-up phase was planned be shorter than 5 years if End of Study is reached before this time period. **Data Safety Monitoring Committee** A Data Safety Monitoring Committee (DSMC) was installed and composed of 3 members, including a statistician, who were not involved in the execution of the trial. The DSMC reviewed data regarding safety including the safety analyses as planned according to the DSMC Charter after 6 patients had completed nine treatment cycles. No further data review was conducted by the DSMC as the further planned review timepoints were not reached due to study cancellation. **Path Reference** Biopsy material from an excisional or core biopsy were submitted for retrospective central confirmation to the national reference pathology for confirmation of MZL including specification of MZL subtype.
Number of patients:	56 patients were planned. Recruitment was interrupted when 22 patients had been enrolled and afterwards, the study was terminated previously. The 22 patients included until this timepoint were analysed.
Diagnosis and main criteria for inclusion:	• Proven pathological diagnosis of MZL, confirmed by a reference pathology center: o Confirmed CD20 positive de novo or relapsed MALT Lymphoma in need of treatment following or being not eligible for local therapy (including surgery, radiotherapy and antibiotics e.g. for H. pylori-positive gastric lymphoma arisen at any extranodal site)

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OR

- Confirmed CD20 positive de novo or relapsed splenic MZL in need of treatment following or not being eligible for local therapy (including surgery and antiviral therapy for Hepatitis C Virus)

OR

- Confirmed CD20 positive de novo or relapsed nodal MZL in need of treatment following or not being eligible for local therapy (radiotherapy). The need of treatment is applicable in the case of B symptoms, deterioration of peripheral blood counts due to lymphoma infiltration of the bone marrow, rapid enlargement of lymph nodes or compression of vital organs by bulky disease.

- For nodal MZL and extragastric MALT lymphoma:
  - At least one bi-dimensionally measurable lesion (≥ 1.5 cm in its largest dimension by CT/ PET-CT scan or MRI).
- For splenic MZL (SMZL):
  - An enlarged spleen on CT scan and lymphoma cell infiltration has to be seen in bone marrow and/or peripheral blood.
  - At least one of the following criteria must be fulfilled:
    - Bulky progressive or painful splenomegaly
    - one of the following symptomatic/progressive cytopenias: Hb < 10 g/dL, or Platelet count < 80.000 /µL, or neutropenia < 1000 /µL, whatever the reason (autoimmune or hypersplenism or bone marrow infiltration)
    - splenectomised patients with rapidly raising lymphocyte counts, development of lymphadenopathy or involvement of extranodal sites if not being eligible for local therapy
    - SMZL with concomitant hepatitis C infection which has not responded to or has relapsed after Interferon and/or Ribavirin and/or direct antiviral agents (patients positive for HCV antibody are eligible only if PCR is negative for HCV RNA)
- For gastric MALT Lymphoma:
  - Clinical evidence of the MZL as seen by gastroendoscopy is sufficient. There is no need to show a measurable lesion by CT scan or MRI.
  - Inclusion is possible for patients with:
    - H. pylori-negative disease de novo or following or being not eligible for local therapy (i.e., surgery, radiotherapy or antibiotics) or after systemic therapy
    - H. pylori-positive disease that has remained stable, progressed, or relapsed following antibiotic therapy
- Other criteria:
  - Others:
  - Age ≥ 18 years
  - Life expectancy >3 months.
  - Meet the following pretreatment laboratory criteria at the Screening visit conducted within 28 days of study enrollment (unless due to underlying lymphoma):
    - Baseline platelet count ≥ 75 x 10^9/L (if not due to BM infiltration by the lymphoma), absolute neutrophil count ≥ 1.5 x 10^9/L
    - Hemoglobin ≥ 9.0 g/dL or ≥ 5.6 mmol/L (Criteria must be met without erythropoietin dependency and without packed red blood cell (pRBC) transfusion within last 2 weeks)

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- International Normalized Ratio (INR) or Prothrombin Time (PT): ≤ 1.5 × ULN unless subject is receiving anticoagulant therapy as long as PT or PTT is within therapeutic range of intended use of anticoagulants
- Activated Partial Thromboplastin Time (aPTT): ≤ 1.5 × ULN unless subject is receiving anticoagulant therapy as long as PT or PTT is within therapeutic range of intended use of anticoagulants
- ASAT (SGOT): ≤ 2,5 times the upper limit of institutional laboratory normal value or ≤ 5 times the upper limit of institutional laboratory normal value in subjects with lymphoma in the liver
- ALAT (SGPT): ≤ 2,5 times the upper limit of institutional laboratory normal value or ≤ 5 times the upper limit of institutional laboratory normal value in subjects with lymphoma in the liver
- Serum total bilirubin: ≤ 1.5 × ULN OR Direct bilirubin ≤ ULN for subjects with total bilirubin levels > 1.5 ULN (unless clearly related to the disease)
- Serum creatinine ≤1.5 × ULN OR ≥60 mL/min GFR or CrCl for subjects with creatinine levels > 1.5 × institutional ULN
- Negative HIV antibody
- Patients with occult or prior HBV infection (defined as negative HBsAg and positive total HBcAb) may be included if HBV DNA is undetectable, provided that they are willing to undergo monthly DNA testing. Patients who have protective titers of HBSAb after vaccination or prior but cured hepatitis B are eligible
- Patients positive for HCV antibody are eligible only if PCR is negative for HCV RNA
- For women of child-bearing potential only: Serum or urine β-HCG must be negative during screening and at study enrolment visit.

o Premenopausal fertile females must agree to use a highly effective method of birth control for the duration of the therapy up to 12 months after the last dose of Rituximab and through 4 months after the last dose of pembrolizumab. A highly effective method of birth control is defined as those which results in a low failure rate (i.e. less than 1% per year) when used consistently and correctly such as combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable or implantable), intrauterine device (IUD), intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomised partner or sexual abstinence. Contraception and pregnancy testing are required according the CTFG recommendations.

o Men must agree not to father a child for the duration of therapy and 6 months after and must agree to advice a female partner to use a highly effective method of birth control. According to CTFG recommendations, men must use condoms.

o Willingness and ability to comply with scheduled visits, drug administration plan, imaging studies, laboratory tests, other study procedures, and study restrictions.

o Evidence of a personally signed informed consent indicating that the subject is aware of the neoplastic nature of the disease and has been informed of the procedures to be followed, the experimental nature of the therapy,

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	alternatives, potential benefits, possible side effects, potential risks and discomforts, and other pertinent aspects of study participation.
Test product, dose and mode of administration, batch number:	Treatment: Cycle 1 (21 days cycle): Rituximab 375 mg/m2 i.v. Day 1, 8, 15 Pembrolizumab 200mg i.v. Day 2 Cycle 2-18 (21 days cycle) or until progression or non-tolerable toxicity Rituximab 375 mg/m2 i.v. Day 1 every second cycle Pembrolizumab 200mg i.v. Day 1
Duration of treatment:	Per protocol, each patient should receive treatment over a period of 18 21-day-cycles, i.e. treatment duration 54 weeks. Of the 22 patients treated in the study, 14 completed this treatment, eight stopped treatment prematurely. The reasons for premature treatment discontinuation were: Adverse Event: 4 Progressive Disease: 1 Physician's Decision: 3
Reference therapy, dose and mode of administration, batch number:	Not applicable
Criteria for evaluation: Efficacy, Safety	The aim of this trial was to test the efficacy and toxicity of the treatment of Pembrolizumab/Rituximab in patients with MZL. For efficacy, the rate of complete remissions (according to the GELA criteria for gastric MALT or to the Cheson 2007 criteria for non-gastric extranodal, nodal and splenic MZL) after therapy was planned to be primarily analysed. For toxicity assessment, treatment associated adverse events and quality of life were documented. **Primary parameter for efficacy evaluation:** Complete response rate after end of treatment (18 cycles) **Expected improvement** So far Rituximab single agent is the most frequent chemotherapy-free approach used in this entity. Thus, a novel chemotherapy – free treatment approach should be at least as efficient as Rituximab monotherapy. In a large randomized study Rituximab single agent therapy induced a CRR of 55.8% in de novo MZL of the MALT type. CR rates in splenic MZL are comparable high at about 60%, whereas patients with nodal MZL achieve a CRR of around 20%. As the distribution of subtypes is about 70% MALT, 20% splenic, and 10% nodal MZL, a CRR which is better than 56% for the total population with MZL should at least be achieved by a new chemotherapy – free approach after end of treatment (18 cycles after start of therapy) for such a mixture of the population.

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Statistical methods:

Efficacy:

Summary statistics are provided for all relevant efficacy endpoints.

The efficacy analyses are based on the modified intent-to-treat population (ITT) which includes all randomized subjects who have received at least one cycle of treatment (Core-Analysis Population).

The one sample exact binomial test was used for the analysis of the primary endpoint to test the CRR against the fixed value 56% at the 2.5% significance level (one-sided).

For secondary endpoint, partially two-sided 95% confidence intervals or Kaplan-Meier estimates were used to further assess treatment.

Safety:

Data from all subjects who received at least one dose of study drug are included in the descriptive safety analyses.

Summary and conclusions:

Efficacy: The combination of Pembrolizumab/Rituximab is able to induce a response in a proportion of MZL patients. Refer to Table 1 for the summary of efficacy results.

Table 1: Summary of Efficacy – Core-Analysis Population

	N=22
Primary endpoint	
COMPLETE RESPONSE RATE (CRR)	
All subtypes, n (%, 95% CI)	3 (13.6, 2.9 – 100.0)
Splenic MZL (n=8), n (%, 95% CI)	2 (25.0, 3.2 – 100.0)
Nodal MZL (n=7), n (%, 95% CI)	1 (14.3, 0.4 – 100.0)
Extranodal MZL (n=7), n (%, 95% CI)	0 (0.0, 0.0-100.0)
Secondary endpoints	
RESPONSE AT EOT	
Overall Response (OR), n (%; 95% CI)	13 (59.1, 36.4 – 79.3)
Complete Response (CR), n (%)	3 (13.6)
Partial Response (PR), n (%)	10 (45.5)
Stable Disease (SD), n (%)	7 (31.8)
Progressive Disease (PD), n (%)	2 (9.1)
BEST RESPONSE	
CR, n (%)	3 (13.6)
PR, n (%)	11 (50.0)
TIME TO BEST RESPONSE, median months (range)	7.6 (2.3 – 13.5)
TIME TO FIRST RESPONSE, median months (range)	6.90 (2.3 – 13.5)

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PROGRESSION-FREE SURVIVAL (PFS)	
Median months (95% CI)[a]	25.1 (16.4 – not evaluable (NE))
12-months PFS, % (95% CI)	94.1 (65.0 – 99.2)
OVERALL SURVIVAL (OS)	
Median months (95% CI)[a]	Not reached (NR)
CAUSE-SPECIFIC SURVIVAL (CSS)	
Median months (95% CI)[a]	NR
DURATION OF RESPONSE (DR)[a]	
Median months (95% CI)[a]	15.9 (6.4 – NE)
12-months DR, % (95% CI)	81.5 (43.5 – 95.1)
TIME TO TREATMENT FAILURE (TTF)	
Median months (95% CI)[a]	18.5 (11.6 – 25.1)
12-months TTF, % (95% CI)	63.6 (40.3 – 79.9)
QUALITY OF LIFE BY FACT-LYM (FACT-Lymphoma total score)	
Before treatment, median total score (range), n=20	130.0 (85.0 – 164.8)
Cycle 4, median total score (range), n=14	138.9 (70.0 – 164.0)
Cycle 7, median total score (range), n=14	138.9 (108.8 – 164.0)
Cycle 10, median total score (range), n=14	124.7 (92.7 – 165.0)
Cycle 13, median total score (range), n=15	124.2 (95.0 – 167.0)
Cycle 16, median total score (range), n=15	144.0 (78.5 – 166.0)
EOT, median total score (range), n=19	125.0 (88.0 – 166.0)

Median observation period was 22.5 months (range: 2.1 – 33.2)
a: Based on Kaplan-Meier Estimates

Safety: The observed toxicities were within the expected range according to the previously reported toxicity profiles for the combination and with regard to the general condition of the patients. No new safety signals or toxicities were identified. Refer to Table 2 for the summary of safety results.

Table 2: **Summary of Safety – Core-Analysis Population**

	N=22
Number of participants who died	3
Primary reason for death:	
Disease progression	**0**
Study drug toxicity	**0**
Unknown	**0**
Other:	**3**
• Cardiac Failure	2
• Pneumonia	1

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	Any Grade	≥Grade 3	Serious
Adverse Events (AEs)	206	37	35
Related to Pembrolizumab	58	15	14
Related to Rituximab	48	12	8
AEs leading to permanent discontinuation of Pembrolizumab	9	5	7
Related to Pembrolizumab	7	4	5
AEs leading to permanent discontinuation of Rituximab	9	5	7
Related to Rituximab	3	2	3

AEs by System Organ Class (SOC)	Any Grade	≥Grade 3*	Serious	Pembroli-zumab-related	Rituximab-related
Infections and Infestations	37	5	6	4	5
Gastrointestinal Disorders	35	7	7	11	5
General Disorders and Administration Site Conditions	24	2	5	10	14
Metabolism and Nutrition Disorders	13	4	2	2	3
Skin and Subcutaneous Tissue Disorders	13	2	1	9	5
Nervous System Disorders	11	1	1	2	2
Blood and Lymphatic System Disorders	9	6	1	5	5
Endocrine Disorders	8	2	1	7	1
Cardiac Disorders	7	3	3	3	0
Respiratory, Thoracic and Mediastinal Disorders	7	1	2	1	1
Vascular Disorders	7	1	0	1	0
Renal and Urinary Disorders	6	0	0	1	0
Injury, Poisoning and Procedural Complications	5	1	0	0	5
Investigations	5	0	0	1	1
Psychiatric Disorders	5	0	0	0	0
Immune System Disorders	4	1	3	1	1
Musculoskeletal and Connective Tissue Disorders	4	1	1	0	0
Eye Disorders	3	0	0	0	0
Neoplasms Benign, Malignant and Unspecified (incl. Cysts and Polyps)	2	0*	1	0	0
Hepatobiliary Disorders	1	0	1	0	0

*For one event no CTCAE-grading was available. The respective event is not included in the counts for ≥Grade 3

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Conclusions: The results of all efficacy analyses have to be interpreted carefully due to early stop of the study and with this small number of participants. However, data indicate that the tested combination regimen seems not to be of any major superiority compared to standard Rituximab single agent. Safety data demonstrate that treatment with Pembrolizumab/Rituximab was safe and well tolerated. No unexpected safety signals have been observed during the trial.

5 APPENDIX 1: LIST OF INVESTIGATORS

Germany:

First Name	Last Name	Institution	Department	Street	Post code	City
Christian	Buske	Universitätsklinikum Ulm	Klinik für Innere Medizin III	Albert-Einstein-Allee 23	89081	Ulm
Ullrich	Graeven	Kliniken Maria Hilf GmbH Akademisches Lehrkrankenhaus der Uniklinik RWTH Aachen	Klinik für Hämatologie, Onkologie und Gastroenterologie	Viersener Straße 450	41063	Mönchengladbach
Gabriele	Prange-Krex	Gemeinschaftspraxis Mohm & Prange-Krex	FÄ f. innere Medizin Hämatologie/Onkologie	Canaletto Str. 10	01307	Dresden
Lena	Illert	Klinikum rechts der Isar der TU München	Klinik und Poliklinik für Innere Medizin III	Ismaninger Str. 22	81675	München
Tobias	Gaska	Brüderkrankenhaus St. Josef Paderborn	Klinik für Hämatologie und Onkologie	Husener Str. 46	33098	Paderborn
Mathias	Hänel	Klinikum Chemnitz gGmbH	Klinik f. Innere Medizin III	Flemmingstr. 2	09116	Chemnitz
Corinna	Leng	Charité Universitätsmedizin Berlin	Hämatologie – Onkologie – Tumorimmunologie Campus Benjamin Franklin, CC14	Hindenburgdamm 30	12200	Berlin
Rüdiger	Liersch	Gemeinschaftspraxis für Hämatologie und Onkologie	---	Steinfurter Str. 60b	48149	Münster
Andreas	Voss	Klinikum Oldenburg AöR	Universitätsklinik für Innere Medizin Onkologie und Hämatologie	Rahel-Straus-Str. 10	26133	Oldenburg
Alexander	Stehle	Robert-Bosch-Krankenhaus	Hämatologie, Onkologie und Palliativmedizin	Auerbachstraße 110	70376	Stuttgart
Thomas	Südhoff	Klinikum Passau	II. Medizinische Klinik Hämatologie, Onkologie und Palliativmedizin	Innstr. 76	94032	Passau
Gerhard	Puchtler	RoMed Klinikum Rosenheim	Med. Klinik II / OTK	Ellmaierstraße 23	83022	Rosenheim