Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML KONGRESSE

Expert:innen berichten zu Lymphomen & Leukämien

EHA2024 HYBRID

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Expert:innen berichten zu Lymphomen & Leukämien

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CCCU | Universitätsklinikum Ulm

Morbus Waldenström (WM) & Marginalzonen-Lymphom (MZL)

Offenlegung potentieller Interessenskonflikte

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Anstellungsverhältnis, Führungsposition	Universitätsklinikum Ulm, Institut für Experimentelle Tumorforschung
Beratungs-/ Gutachtertätigkeit	Gilead Sciences, Janssen, Roche, Pfizer, BeiGene, Celltrion, AbbVie, Incyte, Regeneron, MorphoSys, Novartis, Sobi, Lilly
Besitz von Geschäftsanteilen, Aktien oder Fonds	-
Patent, Urheberrecht, Verkaufslizenz	-
Honorare	Roche/Genentech, Janssen, BeiGene, Novartis, Pfizer, Incyte, AbbVie, Gilead Sciences, Celltrion, MorphoSys, Regeneron, Sobi, Lilly
Finanzierung wissenschaftlicher Untersuchungen	Roche/Genentech, Janssen, Celltrion, MSD, Pfizer, Amgen, Bayer
Andere finanzielle Beziehungen	-
Immaterielle Interessenkonflikte	-

Morbus Waldenström

Dosisreduktionen Ibrutinib möglich ohne Wirkverlust?

Abstract: P2070

Title: DOSE ADJUSTMENT OUTCOMES IN PATIENTS WITH WALDENSTRÖM MACROGLOBULINEMIA TREATED WITH IBRUTINIB

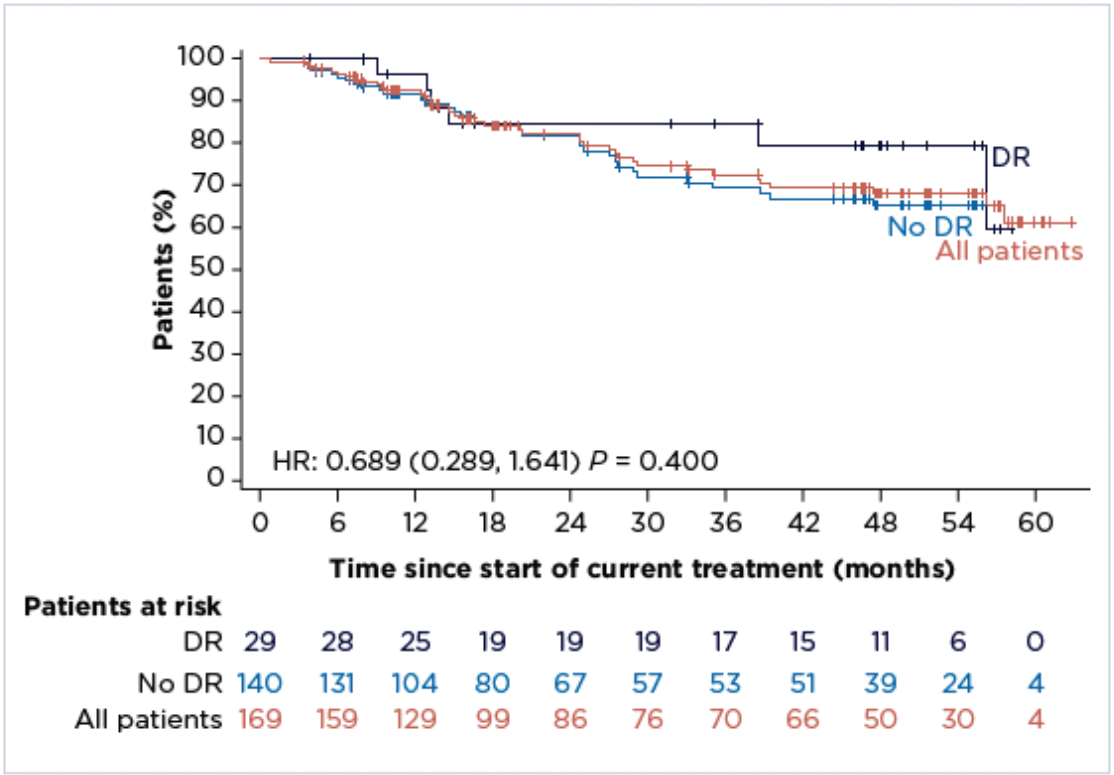
Sarosiek et al.

Methoden

- This analysis pooled data from
  - PCYC-1118 (NCT01614821) was an open-label, single arm, phase 2 trial of patients with (R/R) WM who received single-agent ibrutinib
  - iNNOVATE (NCT02165397) was a randomized, doubleblind, placebo-controlled, phase 3 trial of patients with previously treated and untreated WM who received ibrutinib+ rituximab (Arm A) versus placebo + rituximab (Arm B) and patients who received single-agent ibrutinib after failure of prior rituximab-containing therapy (Arm C)
- This post hoc analysis included patients from 2 ibrutinib arms of the iNNOVATE study and PCYC-1118
- The median follow-up for data used in this analysis was 14.8 months for PCYC-1118 (primary analysis) and 49.7 months for iNNOVATE (final analysis)

Ergebnisse

Estimated 48-Month PFS Rates Were Similar Among Patients With and Without DR in the Pooled Analysis



AEs Leading to Dose Modification in Pooled Ibrutinib-Treated Patients

AEs Leading to Dose Modification[a]	Pooled Ibrutinib-Treated Patients[b] N=169
Any AE leading to dose modification, n (%)	29 (17)
Initial DR, n (%)	
420 mg to 280 mg	27 (93)
420 mg to 140 mg	2 (7)
AEs leading to dose modification, n (%)[c]	
Hematologic	8 (5)
Gastrointestinal	6 (4)
Musculoskeletal	6 (4)
Dermatologic	5 (3)
Other	5 (3)
Cardiac	2 (1)
Infection	2 (1)
Grade of AE leading to dose modification, n (%)[c]	
Grades 1 and 2	15 (9)
Grades 3 and 4	18 (11)
Outcome of first AE leading to dose modification, n/N (%)[d]	
Initial AE resolved	27/29 (93)
No recurrence or recurred at lower grade	22/29 (76)
Recurred at same or higher grade	7/29 (24)

[a]Dose modification inclusive of dose hold and DR.
[b]Pool includes patients from long-term analysis of iNNOVATE and preliminary analysis of PCYC-1118.
[c]The same patient may be counted in more than 1 category due to multiple events.
[d]Denominator is patients with any AEs leading to dose modifications.

Morbus Waldenström

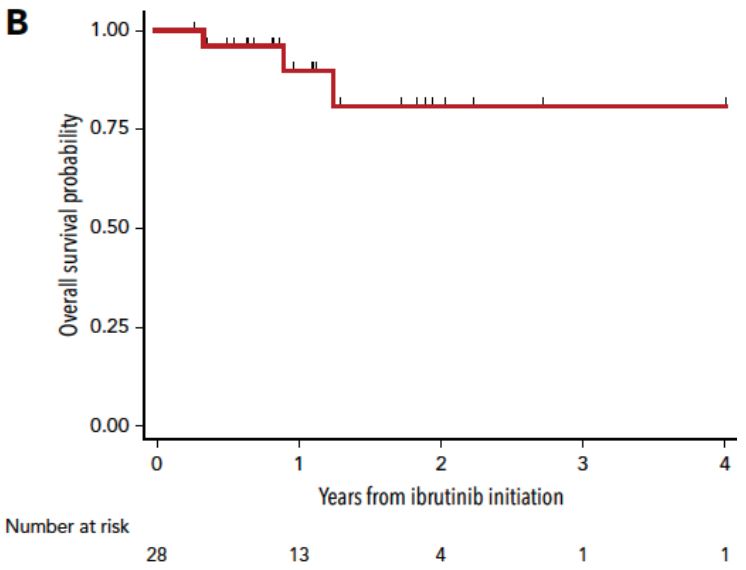
Welche Behandlungsmöglichkeiten haben wir beim Bing-Neel Syndrom?

Ibrutinib for the treatment of Bing-Neel syndrome

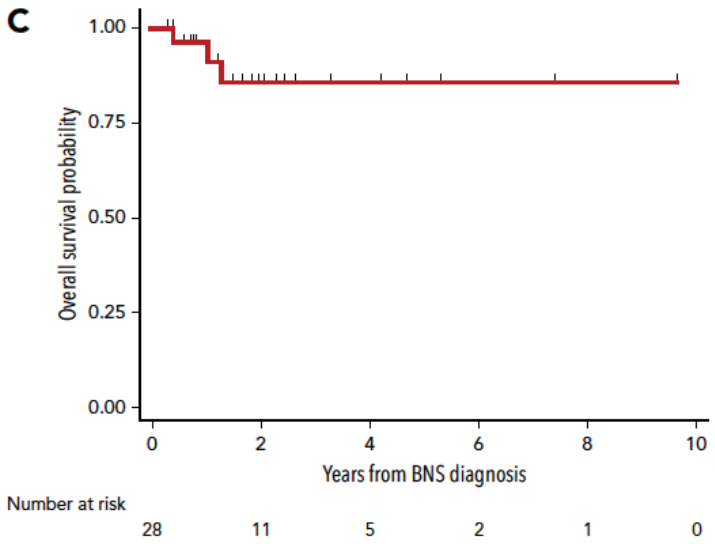
Responses in 28 pts with BNS treated with single agent ibrutinib

	n/N (%)			
	3 mo	6 mo	12 mo	Best response
Symptomatic				
Resolved	1/26 (4)	3/20 (15)	2/10 (20)	5/28 (18)
Improved	21/26 (81)	15/20 (75)	7/10 (70)	19/28 (68)
Unchanged	4/26 (15)	2/20 (10)	1/10 (10)	4/28 (14)
Radiologic				
Resolved	0/15 (0)	1/9 (11)	2/8 (25)	2/18 (11)
Improved	9/15 (60)	7/9 (78)	6/8 (75)	13/18 (72)
Unchanged	6/15 (40)	1/9 (11)	0/8 (0)	3/18 (17)
Cytologic				
Cleared	7/12 (58)	2/7 (29)	0/1 (0)	8/17 (47)
Persistent	5/12 (42)	5/7 (71)	1/1 (100)	9/17 (53)

Survival from start of ibrutinib



Survival from diagnosis Bing-Neel



Castillo et al., Blood 2019

Title: ZANUBRUTINIB IN BING-NEEL SYNDROME: EFFICACY AND TOLERABILITY

Abstract: P1145

Becking et al.

AIM

To assess the efficacy of zanubrutinib treatment on neurological symptoms, radiological abnormalities, and cerebrospinal fluid (CSF) involvement in BNS patients, as well as tolerability.

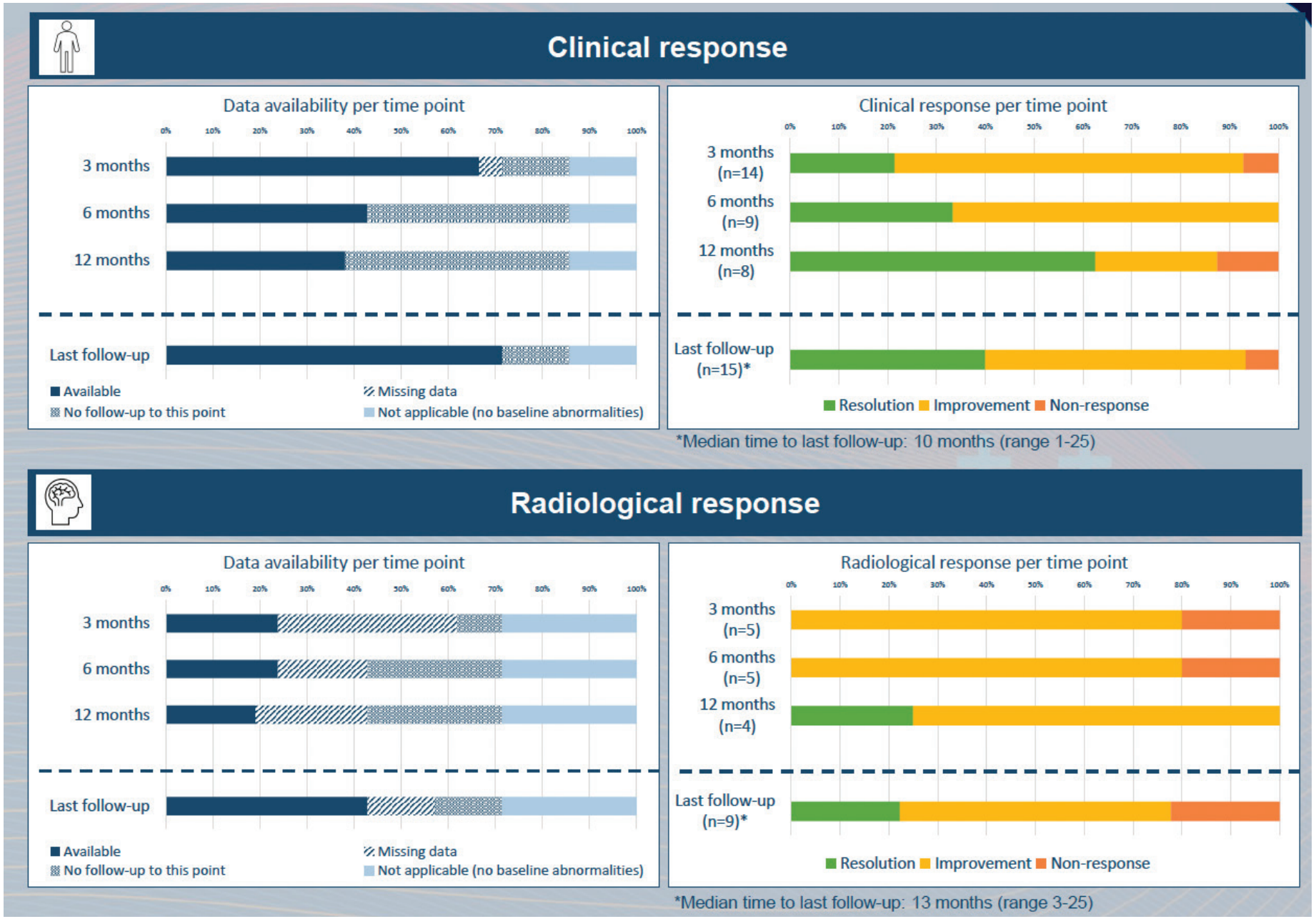
METHOD

International retrospective study including BNS patients who received ≥1 dose of zanubrutinib, with clinical, radiological and/or cytological BNS signs at start. Patients treated with concurrent chemotherapy were excluded. Response data and AEs were collected until last follow-up:

- Symptomatic and radiological response were categorized into non-response, improvement, and resolution.
- Cytological response was defined as absence of LPL cells in CSF, and absence of MYD88 mutation if assessed.
- AEs were graded according to the CTCAE, v5.0.

Baseline characteristics (N=21)	
Sex, male	17 (81%)
Details on LPL	
Age at LPL diagnosis, median (IQR)	60 (57-68)
$MYD88^{L265P}$ found in bone marrow	11/11 (100%)
CXCR4 mutation found in bone marrow	1/5 (20%)
Previously treated for LPL	14 (67%)
Details on BNS	
Setting of BNS diagnosis	
As first diagnosis of LPL	5 (24%)
As feature of relapsing/progressive LPL	16 (76%)
Age at BNS diagnosis, median (IQR)	67 (61-74)
Previously treated for BNS	11 (52%)
Previously treated with ibrutinib for BNS	2 (10%)
$MYD88^{L265P}$ found in CSF	12/12 (100%)
CXCR4 mutation found in CSF	0/2
Details on zanubrutinib treatment	
Age at start zanubrutinib, median (IQR)	67 (62-74)
Abnormalities at start zanubrutinib	
Neurological symptoms	18 (91%)
Radiological CNS involvement	15 (71%)
Positive CSF*	17/19 (89%)

Ergebnisse


Clinical response
Data availability per time point
3 months
6 months
12 months
Last follow-up
Available
No follow-up to this point
Missing data
Not applicable (no baseline abnormalities)
Clinical response per time point
3 months (n=14)
6 months (n=9)
12 months (n=8)
Last follow-up (n=15)*
Resolution
Improvement
Non-response
*Median time to last follow-up: 10 months (range 1-25)
Radiological response
Data availability per time point
3 months
6 months
12 months
Last follow-up
Available
No follow-up to this point
Missing data
Not applicable (no baseline abnormalities)
Radiological response per time point
3 months (n=5)
6 months (n=5)
12 months (n=4)
Last follow-up (n=9)*
Resolution
Improvement
Non-response
*Median time to last follow-up: 13 months (range 3-25)

Schlussfolgerungen der Autoren

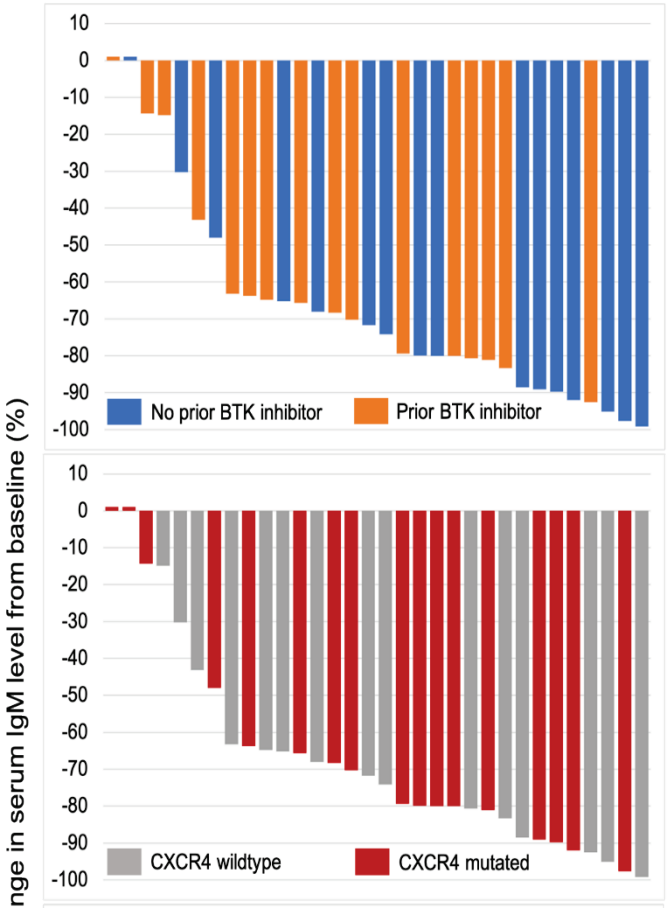
CONCLUSIONS

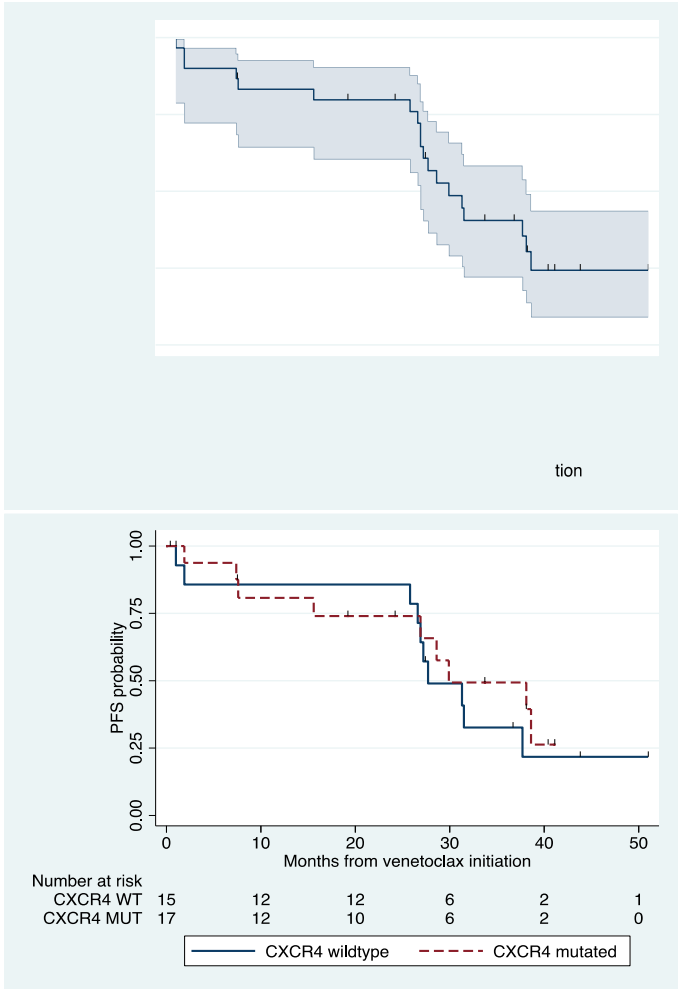
- Zanubrutinib yields a quick clinical response in BNS patients (>90% after 3 months), eventually leading to complete resolution in the majority.
- Clinical responses are typically accompanied by a decrease of radiological abnormalities.
- A negative CSF does not seem necessary to achieve clinical improvement.
- Zanubrutinib for BNS is associated with a low incidence of high grade AEs and high tolerability.

Morbus Waldenström

BCL-2 Inhibition – der neue Weg in der Behandlung?

Phase II study of venetoclax in previously treated WM





ORR: 84%; Major RR: 81%
Median PFS: 30 months

Clinical trials.gov: NCT02677324
Castillo et al., J Clin Oncol 2022; 40(1): 63-71

Abstract: P1113

Title: WAVE STUDY, A RETROSPECTIVE OF FILO TRIAL: PATIENTS WITH RELAPSE WALDENSTRÖM'S MACROGLOBULINEMIA TREATED BY VENETOCLAX IN REAL LIFE

Vonfeld et al.

Ziel der Studie und Methoden

Aims:

- to evaluate the efficacy and safety of Venetoclax in real-life WM within the French population

Methods:

- French multicenter retrospective cohort study within FILO-LLC/MW group, in patients with WM treated with Venetoclax from January 2018 to December 2023.
- Eligible patients: diagnosis of WM and had received a treatment with Venetoclax.
- Adverse events (AE) were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0
- responses were evaluated according to the IWWM6.
- The ORR, progression free survival (PFS) and overall survival (OS) were analyzed at 6 months.
- Descriptive statistics, including proportions, medians, and ranges, were calculated. Responses were assessed using the Chi2 test or the Fisher exact test in low effective and survival using Kaplan-Meier method with comparison with Cox model.

Results

- data for a total of 41 patients from 16 different centers, having received a median prior therapy of 3 [0-7] including 37 (90%) with BTKi and 40 (98%) with immuno-chemotherapy.
- The genotypic profile was: 25/28 pts (89%) MYD88 mutated, 11/21 pts (52%) CXCR4 mutated, 4/16 pts (25%) with p53 mutations, and results unavailable for 14 pts (33%).
- Median age at diagnosis of WM and at Venetoclax initiation were respectively 63 [34-82] et 72 years old [46-89].
- Modality of Venetoclax administration was: 20 pts in monotherapy and 21 pts in association with anti-CD20 monoclonal antibody (Rituximab: n=10, including 1 patient in association with Bortezomib, and Obinutuzumab: n=11).
- The doses of Venetoclax went from 100 to 800 mg daily and the majority (64%, n=27) received 400 mg daily. The median follow-up (FU) time was at time of analysis 8,3 months.
- At 6 months, the ORR was of 74% (23/31) including 1 CR, 9 VGPR, 9 PR and 4 minor responses.
- The OS and PFS at 6 months were of 97% [95% CI 81-99] and of 94% [95% CI 79-99], respectively.
- No significant difference was found regarding ORR, OS and PFS dependent on BTKi-refractory status, presence of CXCR4 or p53 mutations.

Nebenwirkungen – Schlussfolgerungen der Autoren

- Among AE, no tumor lysis syndrome was reported. Seven pts developed at least one infection (6 bacterial, 5 viral including 3 COVID-19, no fungus infection), including 4 grade 3 infections and 2 febrile neutropenia. No grade 4 infections were reported.
- 11 patients showed at least 1 cytopenia grade ≥ 3 (anemia n=6, thrombopenia n=8, neutropenia n=9).
- A dose reduction of Venetoclax was necessary for nine patients due to AE: 2 for digestive disorder, 7 for cytopenia. Two patients had a temporary Venetoclax hold due to infection.

Summary/Conclusion:

In this French cohort, despite a still limited median follow-up of 8 months, Venetoclax showed efficacy and a fair safety profile in patients treated multiple times for relapsed WM.

Abstract: P1110

Title: SAFETY AND EFFICACY RESULTS OF A PHASE 1 STUDY OF THE NOVEL BCL2 INHIBITOR SONROTOCLAX (BGB-11417) FOR RELAPSED/REFRACTORY WALDENSTRÖM'S MACROGLOBULINEMIA

Cheah et al.

Ziele und Methoden

Aims:

To report updated safety and efficacy data for patients with relapsed/refractory (R/R) WM treated with sonrotoclax in BGB-11417-101.

Methods:

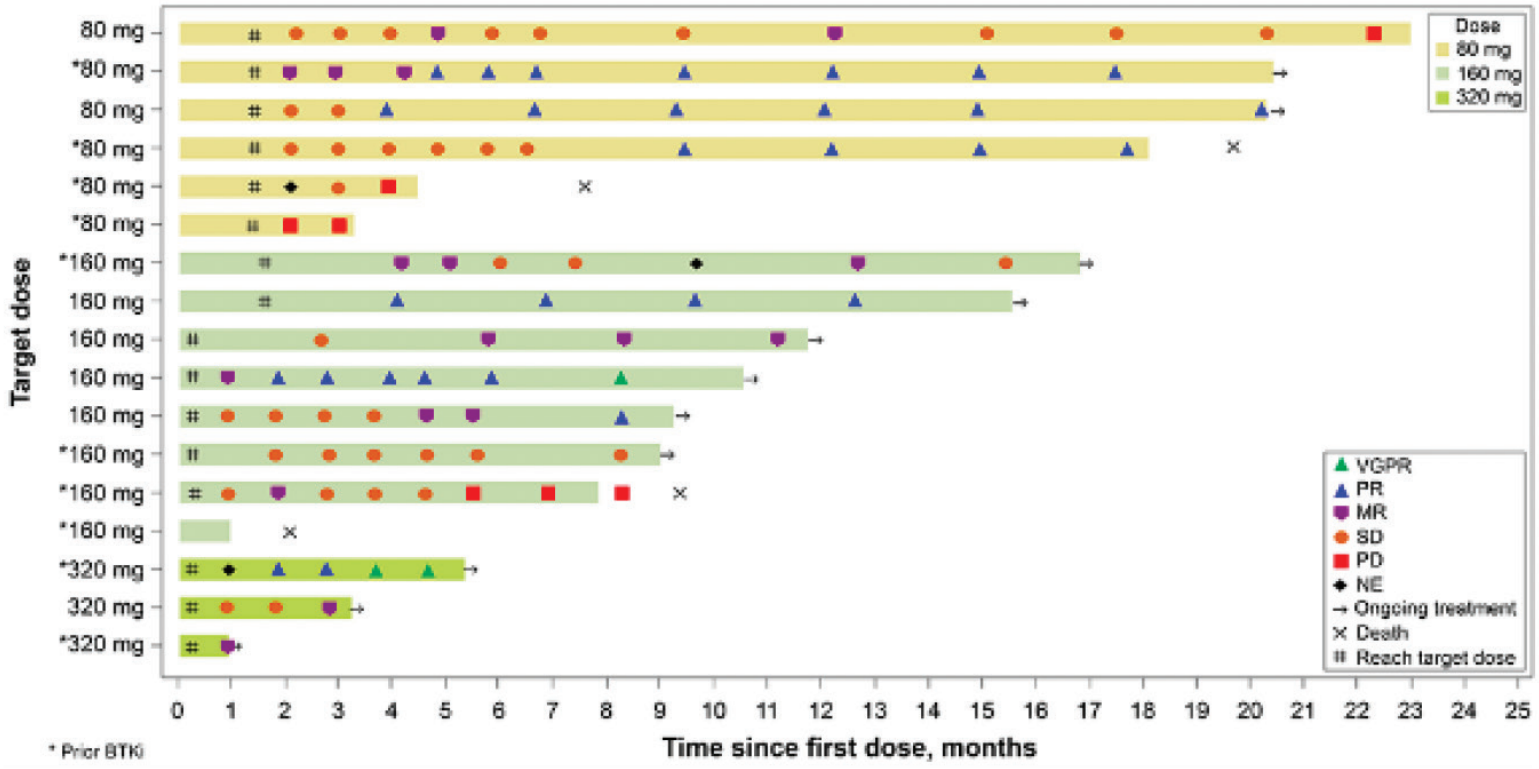
- Patients with R/R WM (≥1 prior therapy) received sonrotoclax (planned dose escalation: 80, 160, 320, or 640 mg QD) with a ramp-up schedule to the intended dose to mitigate potential risk of tumor lysis syndrome (TLS).
- Patients were treated until progression or unacceptable toxicity.
- The primary endpoint is safety reported per CTCAE v5.0 and the secondary endpoint is ORR (minor response [MR] or better per Modified Owens 2013 criteria). TLS was assessed per Howard 2011 criteria.

Patientencharakteristika/Nebenwirkungen

- 17 patients with R/R WM have been enrolled in 3 dose-escalation cohorts (80 mg, n=6; 160 mg, n=8; 320 mg, n=3);
- median age (range) 68 (48-87) years.
- median number of prior treatments (range) was 2 (1-9);
- 10 patients were previously treated with a BTK inhibitor (1 noncovalent, 9 covalent) and 14 were previously treated with anti-CD20.
- Median follow-up (range) was 10.6 (1-24) months.
- Six patients discontinued treatment: 4 due to progressive disease (PD) and 2 due to adverse events (AEs; multifocal neurological syndrome and COVID-19).
- Four patients died while on study: 2 due to PD, 1 due to COVID-19 pneumonia, and 1 due to pneumonia.
- Treatment-emergent AEs (TEAEs) that occurred in ≥20% of patients who received sonrotoclax were anemia (n=6, 35%), COVID-19 (n=6, 35%), pyrexia (n=5, 29%), neutropenia (n=4, 24%), and pruritus (n=4, 24%).
- No DLTs or cases of TLS occurred up to the highest dose tested (320 mg). No cases of atrial or ventricular fibrillation were reported.

Ergebnisse

- All 17 patients were evaluable for response assessments.
- The overall, major, and very good partial response (VGPR) rates were 76% (13/17), 41% (7/17), and 12% (2/17), respectively.
- Seven patients had a BTK inhibitor as their last therapy and achieved an ORR of 70% (MR, n=2; PR, n=1; VGPR, n=2).

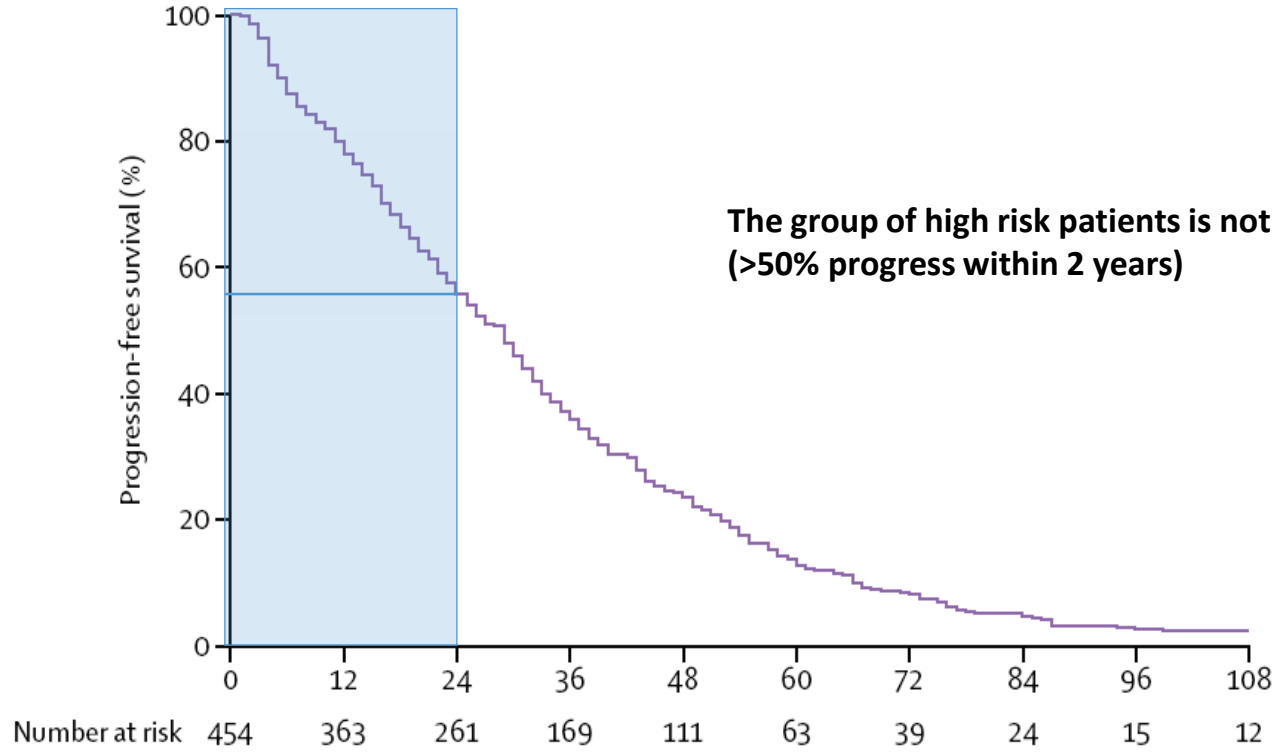


Morbus Waldenström

Irgendeine Rolle für CAR-T Zellen beim Morbus Waldenström?

What do we know……., there is a high risk population in WM

PFS



The group of high risk patients is not that small!
(>50% progress within 2 years)

Lancet Haematol 2018;
5: e299-309

Abstract: P1461

Title: HIGH EFFICACY AND FAVORABLE SAFETY OF CD20-TARGETED CAR-T THERAPY FOR BTK INHIBITOR-REFRACTORY WALDENSTRÖM MACROGLOBULINEMIA (WM)/ LYMPHOPLASMACYTIC LYMPHOMA (LPL)

Till et al.

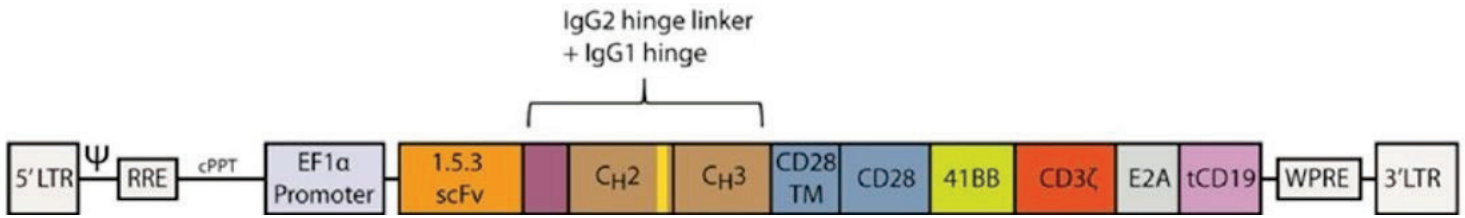
Ziele und Methoden

Aims:

To assess the safety and efficacy of MB-106 for the cohort of WM/LPL patients (pts) in our Phase I study.

Methods:

- single-institution study in which pts with relapsed/refractory B-NHLs including WM/LPL were eligible after confirmation of CD20 expression.
- Lymphodepletion (LD) consisted of cyclophosphamide + fludarabine.
- CAR-T cells were administered at one of 4 dose levels (DL): DL1: 3.3x105, DL2: 1x106, DL3: 3.3x106, DL4: 1x107 CAR T cells/kg.
- Initial treatment response was assessed on day 28 after CAR-T infusion and best response was assessed by IWWM-11. CRS and ICANS were graded per ASTCT criteria.



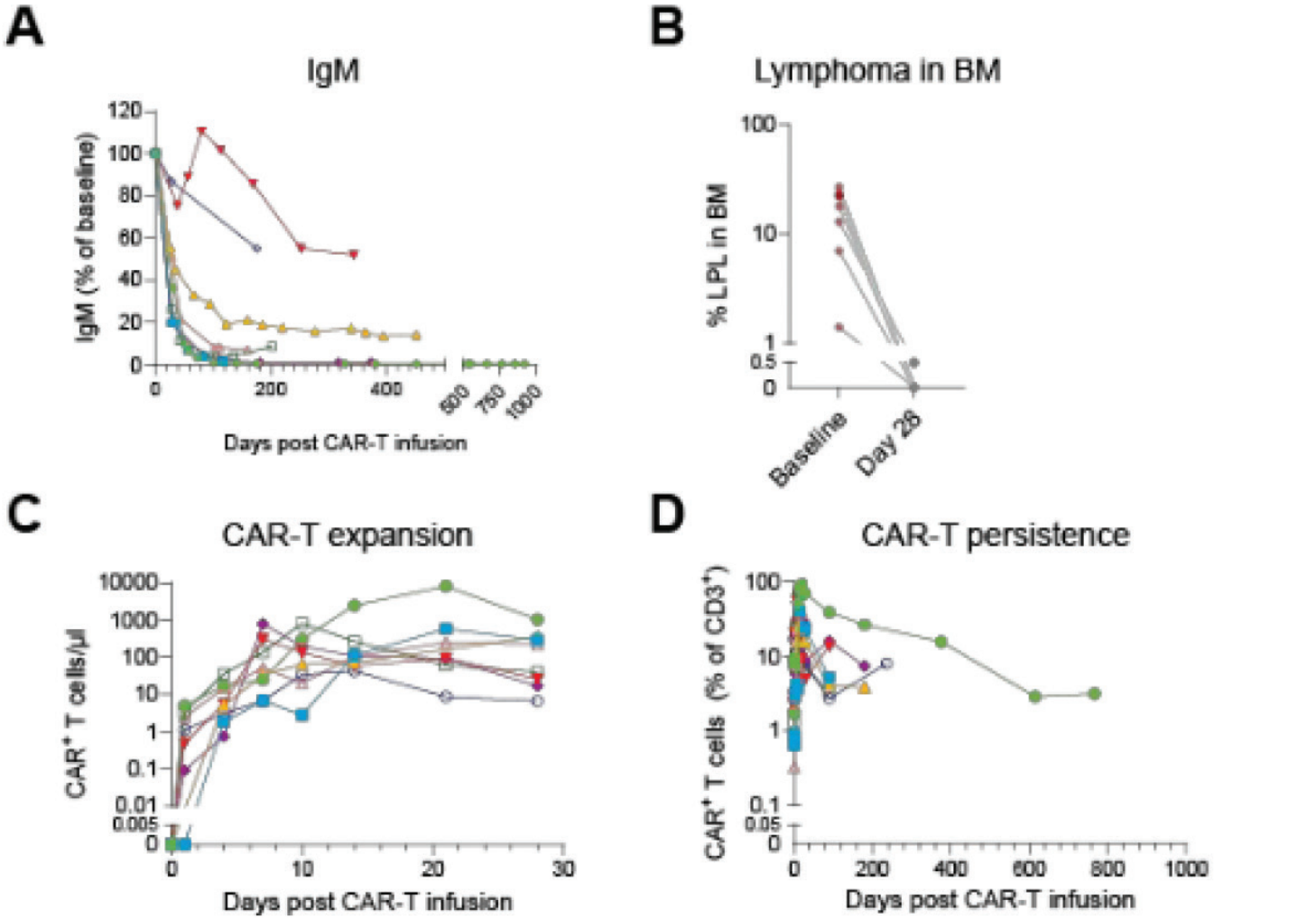
FDA granted orphan drug designation
WM is one of the priority disease for MB-106

Patientencharakteristika und Nebenwirkungen:

- Between 7/2021-2/2024, 10 pts with WM were enrolled and 9 treated with MB-106 (1 DL4, 4 DL3 and 4 DL2, 1 pending infusion),
- 8 were evaluable for response and toxicity at the data cut-off. The median age was 69.5 yrs (range 51-79), with 7 of 10 male.
- median prior treatment lines was 9 (range 1-12). All 10 pts had BTKi refractory disease (9 ibrutinib, 2 acalabrutinib, 5 zanubrutinib, 1 pirtobrutinib).
- MYD88L265P was present in 9/10 pts and 1 of 6 tested pts had a CXCR4 mutation.
- Bridging therapy was continuation of BTKi (n=5), bendamustine (n=1), dexamethasone (n=1), or none (n=3).
- Of 8 evaluable pts, 7 developed CRS (4 grade 1, 3 grade 2), and 2 pts received tocilizumab; no pts had grade 3 or 4 CRS. One pt had grade 1 ICANS.

Ergebnisse

- all 8 pts responded to treatment (2 CR, 3 VGPR, 1 PR, and 2 MR) (Fig. A).
- Of the 5 pts with FDG-avid adenopathy, all had a complete metabolic remission at day 28.
- Abnormal B cells in the marrow were absent by day 28 in 7 of 8 pts (Fig. B), and all pts experienced B cell aplasia.
- CAR-T expansion and persistence were robust (Fig. C-D).
- One pt died from complications of COVID-19 while in remission 7 months after treatment.
- One pt had PD at day 80 after CAR-T but subsequently had a PR without additional treatment. The other 6 pts are free of progression at a median of 9.6 months (range 1.3 to 31.6).



A) IgM % change from baseline over time. B) Change in % lymphoma (by flow cytometry) in the marrow from baseline to day 28. C) CAR T cell expansion in 1st month. D) CAR-T persistence over time.

Marginalzonenlymphom

Vergleich Zanubrutinib – R-Chemotherapie in der Behandlung des MZL?

Real-World Daten?

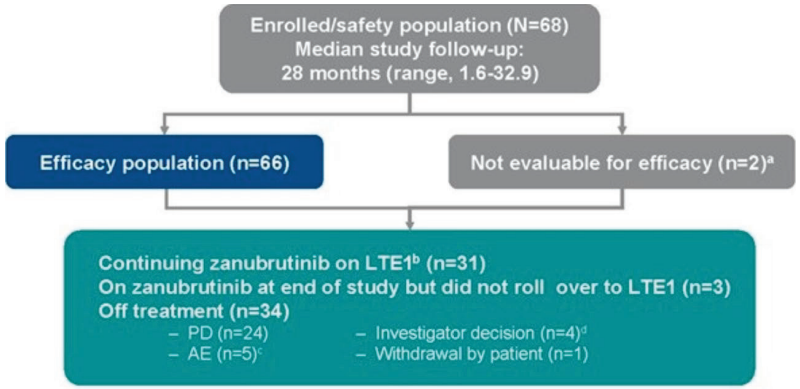
Abstract: P1123

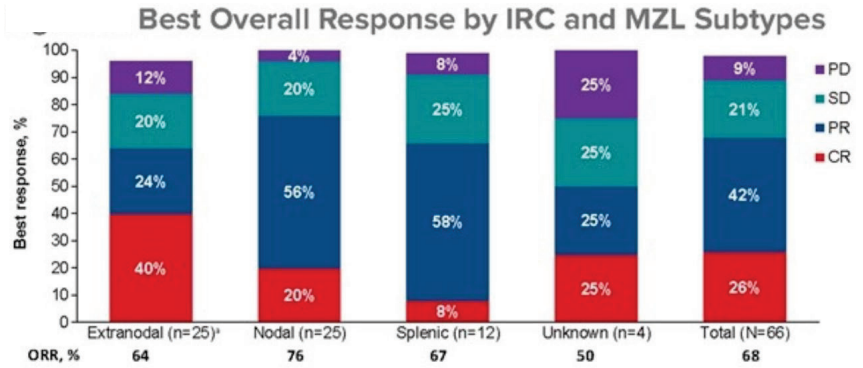
Title: MATCHING-ADJUSTED INDIRECT COMPARISON (MAIC) OF ZANUBRUTINIB VERSUS REAL-WORLD CHEMOIMMUNOTHERAPY (CIT) OR CHEMOTHERAPY (CHEMO) IN RELAPSED/REFRACTORY MARGINAL ZONE LYMPHOMA (R/R MZL)

Walewska et al.

FINAL ANALYSIS OF THE MAGNOLIA (BGB-3111-214) TRIAL

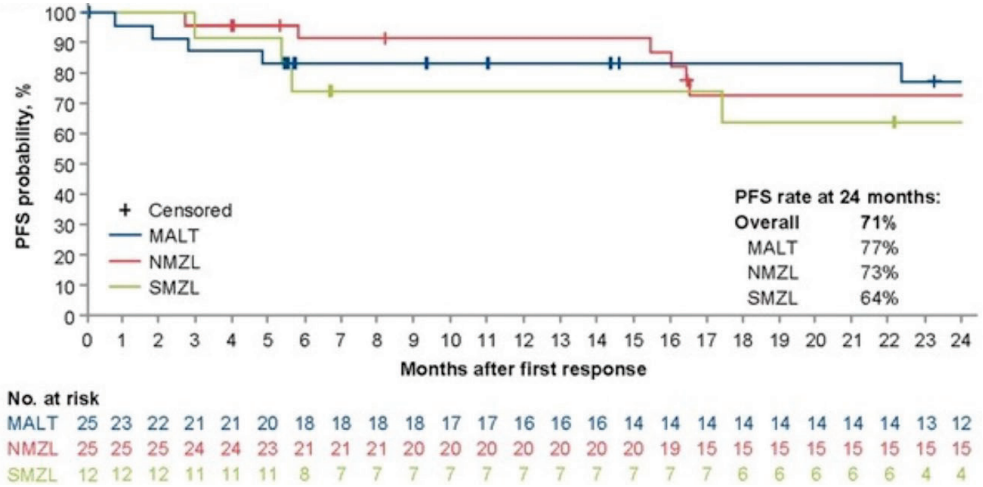
ZANUBRUTINIB in R/R MZL





TEAEs of clinical interest, n (%)	All grade	Grade ≥3
Infections	38 (56)	15 (22)[d]
Hemorrhage	28 (41)	1 (1.5)[e]
Cardiac		
Hypertension	3 (4)[f]	2 (3)
Atrial fibrillation/flutter	2 (3)[g]	1 (1.5)
Ventricular extrasystole	1 (1.5)[h]	0
Second primary malignancy	5 (7)[i]	3 (4)

Characteristics	Total (N=68)
Age, median (range), years	70 (37-95)
≥65 years, n (%)	41 (60)
≥75 years, n (%)	19 (28)
Male, n (%)	36 (53)
ECOG PS 0 or 1, n (%)[a]	63 (93)
MZL subtypes, n (%)	
Extranodal	26 (38)
Nodal	26 (38)
Splenic	12 (18)
Unknown	4 (6)
Disease status, n (%)	
Relapsed	44 (65)
Refractory	22 (32)
Stage III/IV, n (%)	59 (87)
FDG avid (by IRC), n (%)	61 (90)
Extranodal site involvement, n (%)	53 (78)
Bone marrow infiltration, n (%)	29 (43)
Prior lines of systemic therapy, median (range)[b]	2 (1-6)
Immunochemotherapy, n (%)	61 (90)[b]
Rituximab monotherapy, n (%)	7 (10)



- Median Follow-Up 28 months
- ORR 68%
- 24mo-PFS 71%
- Well tolerated

Ziele und Methoden

Aims:

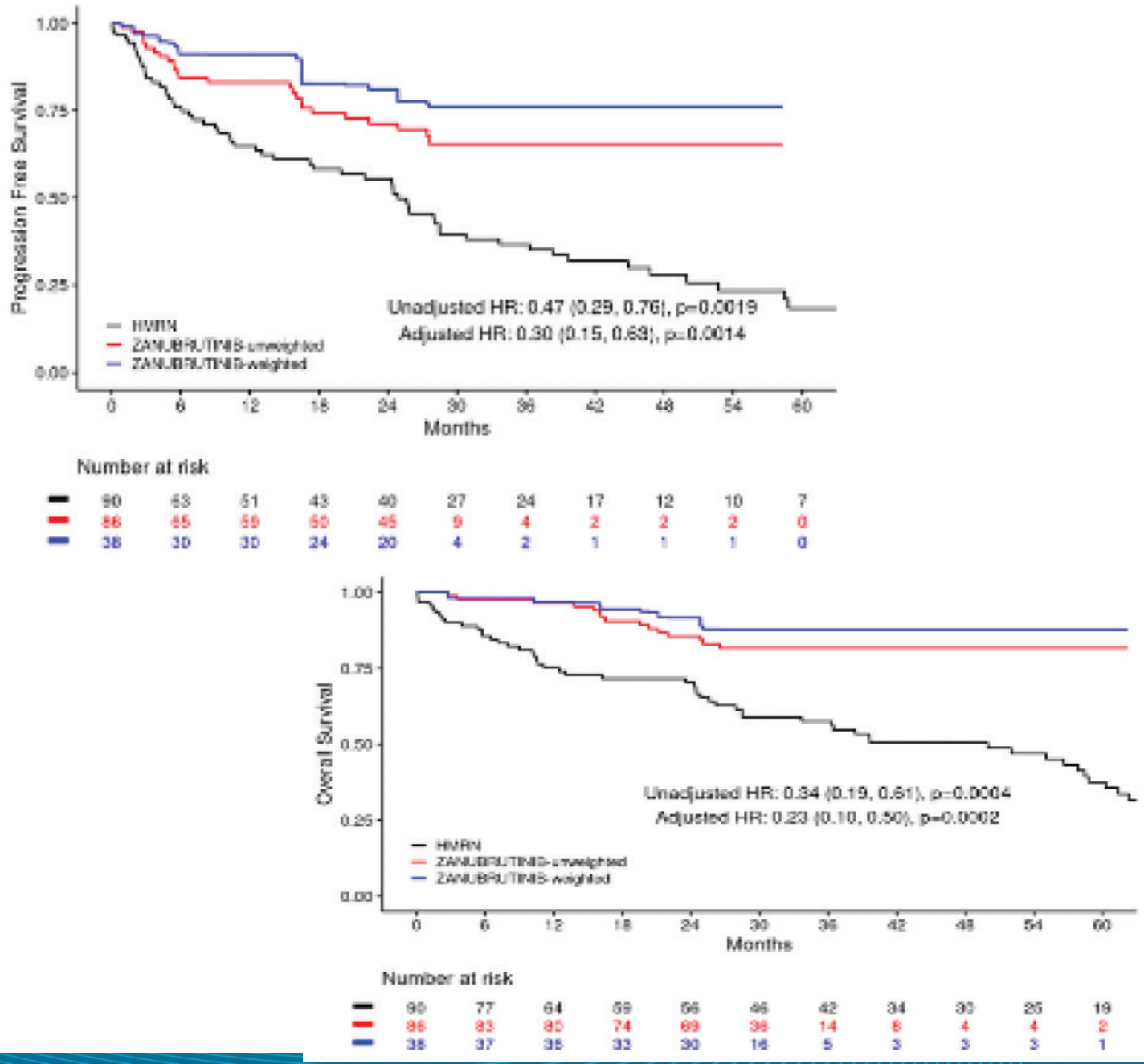
An unanchored MAIC was conducted to estimate the comparative effectiveness of zanubrutinib versus CIT or chemo in R/R MZL.

Methods:

- The MAIC utilized aggregate data from HMRN registry and pooled individual patient-level data from MAGNOLIA and BGB-3111-AU-003 (MAGNOLIA-003 hereafter). Overall, the HMRN cohort selected for analysis consisted of 90 patients who were enrolled from 2014 onwards
- A logistic propensity score model was applied to estimate weights for patients in MAGNOLIA-003 such that weighted mean baseline characteristics matched those in the HMRN dataset.
- The following characteristics were pre-specified as key prognostic factors and considered for adjustment in the base case model: number of prior lines of therapy, refractory to prior therapy, age, progression of disease within 24 months of initiation of systemic therapy, and median time since diagnosis.
- Comparisons were conducted for PFS and OS.

Ergebnisse

- Compared with CIT or chemo, zanubrutinib significantly reduced the risk of progression (HR 0.30; 95% CI 0.15–0.63, p=0.001) and death (HR 0.23; 95% CI 0.10–0.50, p<0.001) (Figure).
- The sensitivity analysis comparison of zanubrutinib (ESS=40) to CIT also demonstrated significantly reduced risk of progression (HR: 0.28; 95% CI 0.14-0.57, p<0.001) and death (HR: 0.23, 95% CI 0.10-0.49, p<0.001).



Marginalzonenlymphom

Erste Daten bi-spezische Antikörper beim MZL?

Abstract: P1127

Title: RESPONSE-ADAPTED TREATMENT WITH MOSUNETUZUMAB WITH OR WITHOUT OBINUTUZUMAB AND POLATUZUMAB VEDOTIN IN TREATMENT NAÏVE FOLLICULAR AND MARGINAL ZONE LYMPHOMA: INTERIM RESULTS AND PHASED-SEQ MRD ANALYSIS

Lynch et al.

Ziele und Methoden

Aims:

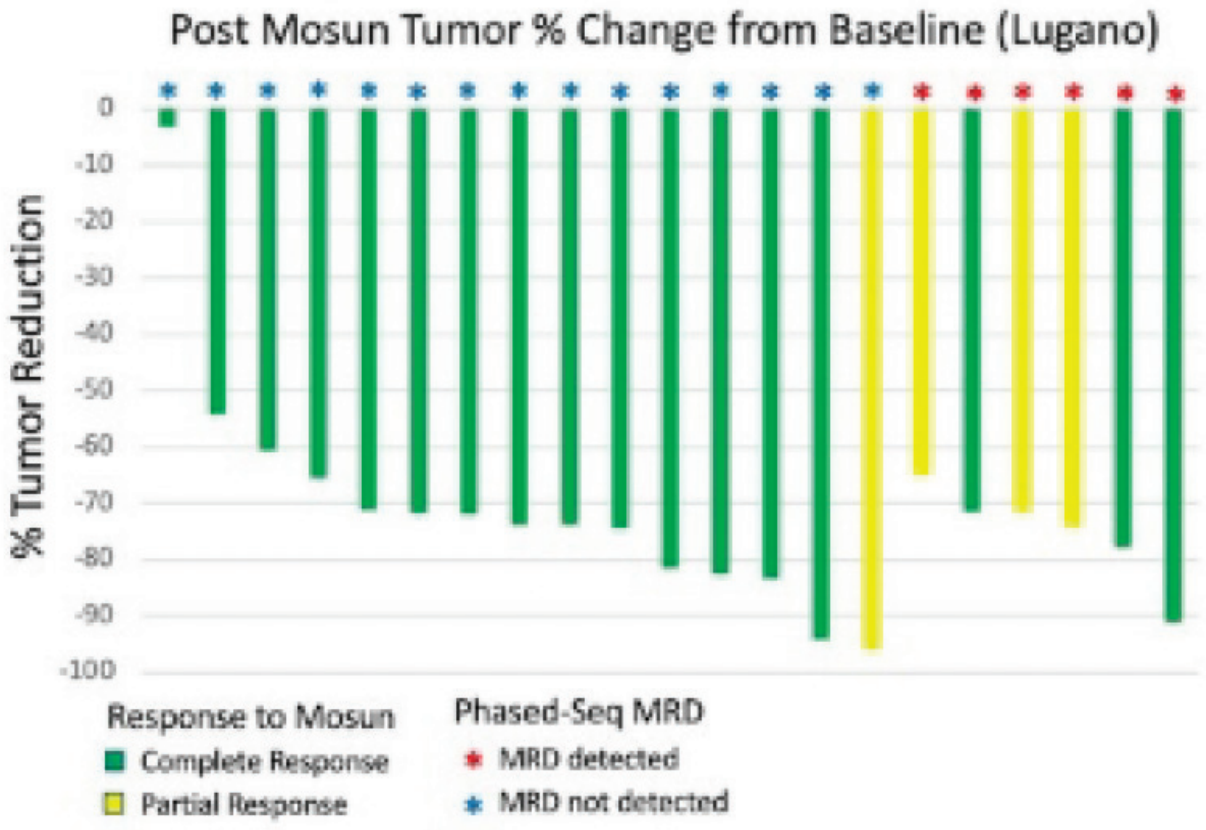
We present interim safety, efficacy, and MRD analyses from an ongoing response-adapted study of mosunetuzumab in untreated FL/MZL (NCT05169658).

Methods:

- single center, open label, investigator-initiated response-adapted clinical trial in untreated pts with FL or MZL with indication for treatment.
- Pts received subcutaneous mosunetuzumab monotherapy for 8 cycles employing step up dosing in cycle 1 (5/45/45 mg).
- A PET/CT was performed after 8 cycles, and pts in CR were observed without further treatment. Pts with SD or PR could receive 6 cycles of polatuzumab vedotin and obinutuzumab, followed by an end of treatment (EOT) PET/CT. Total planned accrual is 42 pts.
- The primary endpoint is complete response (CR) rate.
- PhasED-Seq (Kurtz et al. Nature Biotech 2021) was performed on baseline plasma specimens as well as MRD analyses at C3D1, after all mosun treatment, and after obinutuzumab and polatuzumab vedotin for those in PR.

Ergebnisse

- 35 pts enrolled on study between March 24, 2022, and January 25, 2024, with 35 pts evaluable for safety, and 31 pts evaluable for efficacy.
- Four pts experienced a serious adverse event, (one pt with G3 lung infection followed by G3 shingles, one pt observed inpatient overnight with G1 cytokine release syndrome, and one pt with a G2 URI, and one patient with G3 abdominal pain/malabsorption).
- Twenty-seven patients have completed all mosun therapy, with an ORR and CR rate of 100% and 77%, respectively.
- All pts remain alive, and one patient in PR after mosun had a biopsy which demonstrated highgrade transformation.
- After 2 cycles of mosun, 8/20 (40%) of patients had undetectable ctDNA (Figure 1). After 8 cycles of mosun, 15/21 (71%) of patients had undetectable MRD.



Zusammenfassung | Take-Home-Messages

- Dosisreduktionen des cBTKi Ibrutinib beim Morbus Waldenström bedeuten nicht Wirkungsverlust und können Nebenwirkungen reduzieren
- Neben Ibrutinib zeigt auch Zanubrutinib eine hohe Wirksamkeit beim Bing-Neel Syndrom
- Venetoclax ist eine wirksame Substanz beim Morbus Waldenström, nicht nur in prospektiven Studien sondern auch unter Real-World Bedingungen
- Neue Entwicklungen beim Morbus Waldenström sind die Weiterentwicklung von BCL-2 Inhibitoren und CAR-T Zellen
- Beim MZL bestätigen Real-World Daten die hohe Effektivität von BTKi
- Erste Daten des bi-spezifischen Antikörpers Mosunetuzumab beim MZL zeigen eine exzellente Wirksamkeit

Die Kurzpräsentationen sind online unter

www.lymphome.de/eha2024

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