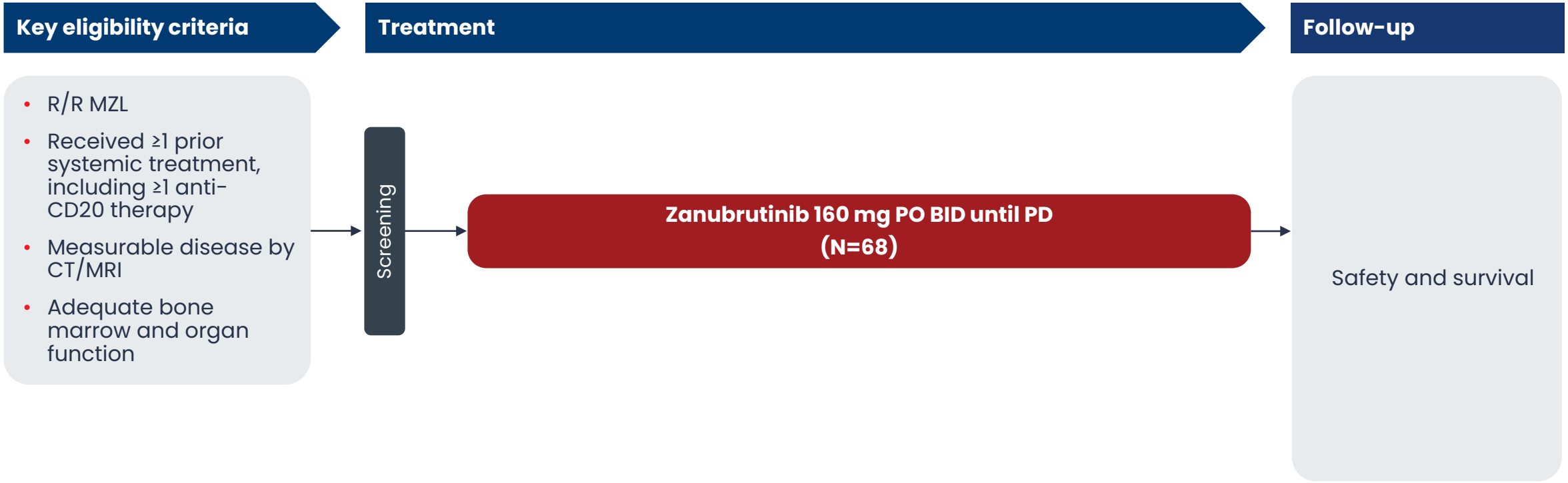
MAGNOLIA

MAGNOLIA Trial Design

Phase 2

Study Identifier:
BGB-3111-214, NCT03846427

Primary Endpoint: ORR by IRC
Key Secondary Endpoints: ORR by investigator, DoR, PFS, OS, TTR



BID=twice daily, CT=computed tomography, DoR=duration of response, IRC=independent review committee, MRI=magnetic resonance imaging, MZL=marginal zone lymphoma, ORR=objective response rate, OS=overall survival, PD=progressive disease, PFS=progression-free survival, PO=per oral, R/R=relapsed/refractory, TTR=time to response.
ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03846427. Accessed October 9, 2025.

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Baseline Demographics and Disease History

	Patients (N=68)
Age, years, median (range)	70.0 (37-95)
Age category, n (%)	
<65 years	27 (39.7)
≥65 and <75 years	22 (32.4)
≥75 years	19 (27.9)
Sex, n (%)	
Male	36 (52.9)
Female	32 (47.1)
Baseline ECOG score, n (%)	
0	39 (57.4)
1	24 (35.3)
2	5 (7.4)
Disease stage, n (%)	
Stage I/II	9 (13.2)
Stage III/IV	59 (86.8)
Bulky disease	
LDi > 5 cm	25 (36.8)
Bone marrow involvement, n (%)[a]	29 (42.6)
Extranodal disease, n (%)[b]	53 (77.9)
Refractory disease, n (%)[c]	22 (32.4)
FDG avid by IRC assessment, n (%)	
FDG-avid	61 (89.7)
Non-FDG-avid	7 (10.3)

	Patients (N=68)
MZL subtype, n (%)	
Extranodal (MALT)	26 (38.2)
Nodal	26 (38.2)
Splenic	12 (17.6)
Unknown[d]	4 (5.9)
Site of disease (MALT subtype), n (%)	
Gastric	2 (7.7)
Cutaneous	4 (15.4)
Non-gastric/non-cutaneous	19 (73.1)
Unknown	1 (3.8)
LDH, n (%)	
Above normal	16 (23.5)
Number of previous therapies, median (range)	2 (1-6)
Time since end of last therapy, months, median (range)	20·6 (1-176.6)
Previous therapy, n (%)	
Rituximab-based chemotherapy	60 (88.2)
R-CVP	25 (36.8)
BR	22 (32.4)
R-CHOP	17 (25.0)
Rituximab monotherapy	7 (10.0)
Rituximab + lenalidomide	2 (2.9)
Radiation therapy	15 (22.1)
Splenectomy	7 (10.3)
ASCT	4 (5.9)

Data cutoff date: May 4, 2022.
[a]Derived from baseline bone marrow biopsy/aspiration per investigator assessment. [b]Extranodal disease is defined as patients with extranodal baseline target or nontarget lesions, or bone marrow involvement, as per investigator assessment. [c]Refractory disease is defined as best overall response of stable disease or PD from last prior anticancer regimen. [d]Four patients presented with both nodal and extranodal lesions; investigators were unable to classify the primary MZL subtype.
ECOG=Eastern Cooperative Oncology Group, FDG=fluorodeoxyglucose, IRC=independent review committee, LDH=lactate dehydrogenase, LDi=longest transverse diameter of a lesion, MALT=mucosa-associated lymphoid tissue, MZL=marginal zone lymphoma, PS=performance status,
Opat S et al. *Blood Adv*. 2023;7:6801-6811.

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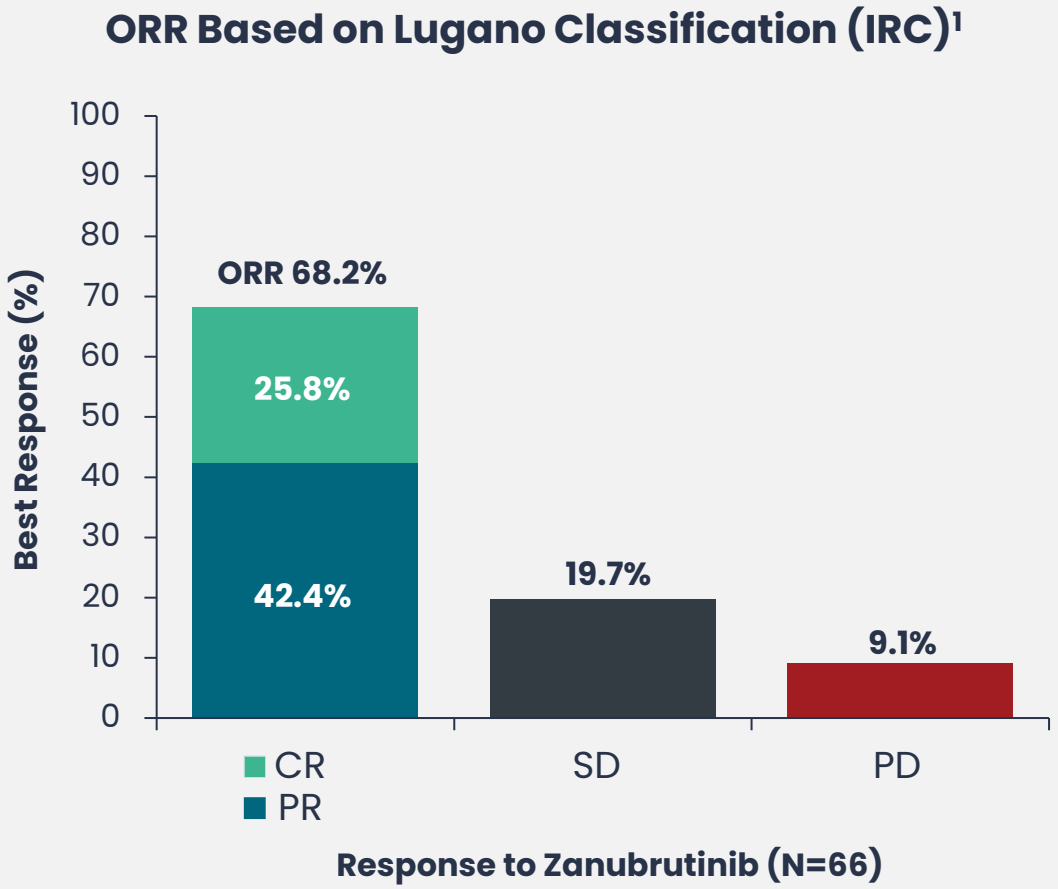
Best Overall Response by Investigator Assessment: Primary Endpoint



Median follow-up:
15.7 months

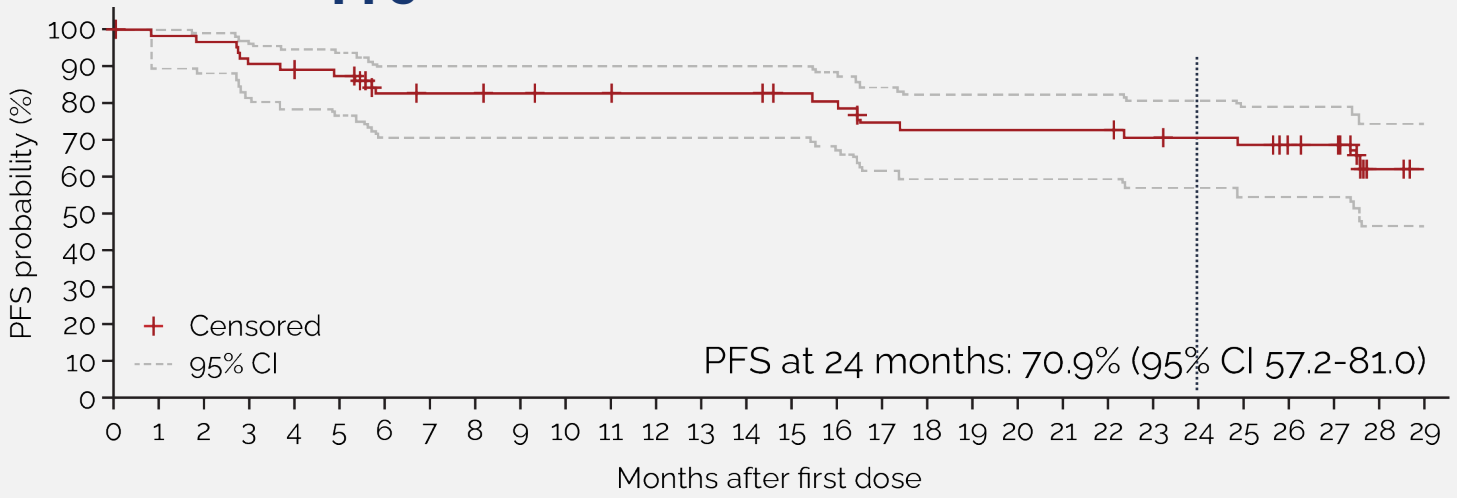
Efficacy was observed across all MZL subtypes, including nodal MZL, splenic MZL, and extranodal mucosa-associated lymphoid tissue

In the final analysis (median follow-up 28 months), ORR was 68.2% (by PET and/or CT) and 66.7% (by CT only) with a CR of ~25% by IRC[2]

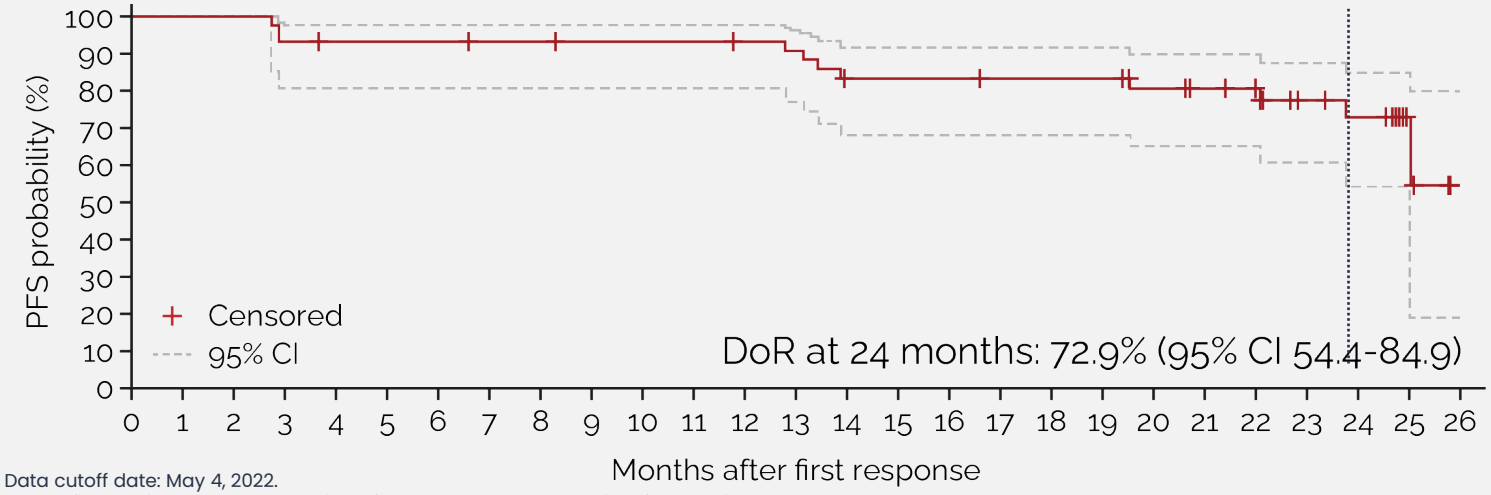
Data cutoff: January 18, 2021; Final analysis data cutoff: May 4, 2022.
CR=complete response, CT=computed tomography, IRC=independent review committee, ORR=overall response rate, PD=progressive disease, PR=partial response, PET=positron emission tomography, SD=stable disease.
1. Opat S et al. *Clin Cancer Res.* 2021;27(23):6323-6332; 2. Opat S et al. *Blood Adv.* 2023;7:6801-6811.

PFS and DoR: Secondary Endpoints

PFS



DoR



Median PFS and DoR were not reached

Data cutoff date: May 4, 2022.
CI=confidence interval, DoR=duration of response, PFS=progression-free survival.
Opat S et al. *Blood Adv*. 2023;7:6801-6811.

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Safety Summary

The zanubrutinib safety profile was consistent with the primary analysis, with no new safety signals observed

TEAEs, n (%)	N=68
Patients with ≥1 TEAE	68 (100)
Grade ≥3	33 (48)
Serious	30 (44)
Leading to death	5 (7)
Leading to dose interruption	25 (37)
Leading to study drug discontinuation	5 (7)
Leading to dose reduction	0

Most common TEAEs: Contusion, diarrhea, constipation, neutropenia, thrombocytopenia

AE of special interest	Any Grade AE	Grade ≥3 AE
Any AE of special interest	54 (79.4)	23 (33.8)
Infections	38 (55.9)	15 (22.1)
Opportunistic infections	3 (4.4)	2 (2.9)
Bleeding	28 (41.2)	1 (1.5)
Major hemorrhage[a]	1 (1.5)	1 (1.5)
Second primary malignancies	5 (7.4)	3 (4.4)
Skin cancers	2 (2.9)	0
Neutropenia[b]	11 (16.2)	8 (11.8)
Thrombocytopenia[c]	11 (16.2)	3 (4.4)
Anemia	4 (5.9)	2 (2.9)
Hypertension	3 (4.4)	2 (2.9)
Atrial fibrillation/flutter	2 (2.9)	1 (1.5)
Ventricular arrhythmia	1 (1.5)	0

Atrial fibrillation/flutter and hypertension were uncommon

Data cutoff date: May 4, 2022.
[a]Defined as any serious or grade ≥3 bleed at any site, or central nervous system bleed of any grade. [b]"Neutropenia" included the terms "neutropenia" and "neutrophil count decreased." [c]"Thrombocytopenia" included the terms "thrombocytopenia" and "platelet count decreased."
AE=adverse event, TEAE=treatment emergent adverse event.
Opat S et al. *Blood Adv*. 2023;7:6801-6811.