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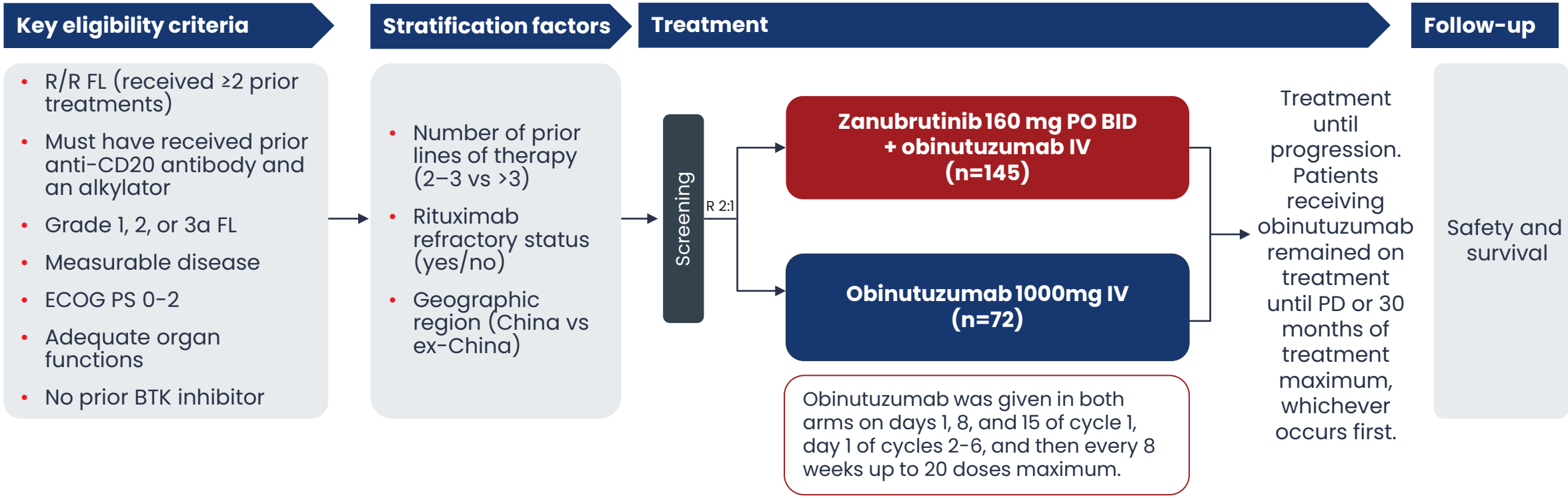
ROSEWOOD Trial Design

Phase 2

Study Identifier:
BGB-3111-212, NCT03332017

Primary Endpoint: ORR by ICR per Lugano Classification[3]
Key Secondary Endpoints: ORR by investigator, DoR and PFS by ICR, OS, CR and CMR rate



[a]Zanubrutinib was given orally at 160 mg twice a day until disease progression confirmed by ICR; [b]Obinutuzumab (1000 mg) was given in both arms on days 1, 8, and 15 of cycle 1, day 1 of cycles 2-6, and then every 8 weeks up to 20 doses maximum. Patients receiving obinutuzumab remained on study treatment until disease progression confirmed by ICR or 30 months of treatment maximum, whichever occurs first.
BID=twice daily, BTK=Bruton tyrosine kinase, CD=cluster of differentiation, CMR=complete metabolic response, CR=complete response, DoR=duration of response, ECOG=Eastern Cooperative Oncology Group performance score, FL=follicular lymphoma, ICR=independent central review, IV=intravenous, ORR=objective response rate, OS=overall survival, PD=progressive disease, PFS=progression-free survival, PO=per oral, R=randomized, R/R=relapsed/refractory.
1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03332017. Accessed October 9, 2025; 2. Zinzani et al. ASCO 2022. Abstract: 7510. 3. Cheson BD. *J Clin Oncol*. 2014;32(27):3059-3068.

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Patient Characteristics at Baseline

Patient Characteristic	Zanubrutinib + Obinutuzumab n=145	Obinutuzumab n= 72	Total N=217
Median age, years (range)	63.0 (31, 84)	65.5 (32, 88)	64.0 (31, 88)
Geographic region			
Mainland China	21 (14)	12 (17)	33 (15)
Rest of the world	124 (86)	60 (83)	184 (85)
Prior lines of therapy			
Median, n (range)	3 (2, 11)	3 (2, 9)	3 (2, 11)
2-3, n (%)	104 (72)	54 (75)	158 (73)
>3, n (%)	41 (28)	18 (25)	59 (27)
ECOG PS 0-1, n (%)	140 (97)	71 (99)	211 (97)
High FLIPI score, n (%)	77 (53)	37 (51)	114 (53)
Ann Arbor stage III-IV, n (%)	119 (82)	60 (83)	179 (82)
Median target lesion SPD by ICR, mm^2 (Q1, Q3)	1614.0 (783.0, 3344.0)	1727.0 (732.0, 3504.0)	1655.0 (756.0, 3351.5)
Bulky disease (≥7 cm), n (%)	23 (16)	12 (17)	35 (16)
High LDH level (>ULN), n (%)	49 (34)	29 (40)	78 (36)
High tumor burden per GELF criteria, n (%)	83 (57)	40 (56)	123 (57)
Refractory to rituximab, n (%)	78 (54)	36 (50)	114 (53)
Refractory to most recent line of therapy, n (%)	47 (32)	29 (40)	76 (35)
PD ≤24 months of starting first line of therapy, n (%)	50 (34)	30 (42)	80 (37)

Data cutoff: June 25, 2022.
ECOG PS=Eastern Cooperative Oncology Group performance status, FLIPI=Follicular Lymphoma International Prognostic Index, GELF=Groupe d'Etude des Lymphomes Folliculaires, ICR=independent central review, LDH=lactate dehydrogenase, PD=progressive disease, SPD=sum of the products of diameters, ULN=upper limit of normal.
Zinzani PL et al. *J Clin Oncol*. 2023;41:5107-5117.

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ORR by ICR: Primary Endpoint

The study met its primary endpoint; ORR per ICR was significantly higher with zanubrutinib plus obinutuzumab with a risk difference of 22%[1]

Response by ICR	Zanubrutinib + Obinutuzumab (n=145)	Obinutuzumab (n=72)
ORR, % (95% CI)	**68.3 (60.0, 75.7)**	**45.8 (34.0, 58.0)**
Risk difference, % (95% CI)	**22.0 (8.3, 35.8)**	
2-sided *P*-value	0.0017	
BOR, n (%)		
CR	54 (37.2)	14 (19.4)
PR	45 (31.0)	19 (26.4)
SD	25 (17.2)	14 (19.4)
Non-progressive disease	3 (2.1)	4 (5.6)
PD	13 (9.0)	15 (20.8)
Discontinued prior to first tumor assessment	4 (2.8)	6 (8.3)
NE	1 (0.7)	0

Median follow-up:
12.5 months

- ORR benefit of zanubrutinib + obinutuzumab over obinutuzumab was generally consistent across subgroups
- A longer follow-up analysis (median follow-up 20.2 months) demonstrated significant complete response rate (39% vs 19%) and a median time to first response of 2.8 months[2]

Data cutoff: October 8, 2021.
BOR=best overall response, CI=confidence interval, CR=complete response, ICR=independent central review, NE=not evaluable, ORR=overall response rate, OS=overall survival, PD=progressive disease, PFS=progression-free survival, PR=partial response, SD, stable disease.
1. Zinzani et al. ASCO 2022. Abstract: 7510; 2. Zinzani PL et al. *J Clin Oncol*. 2023;41:5107-5117.

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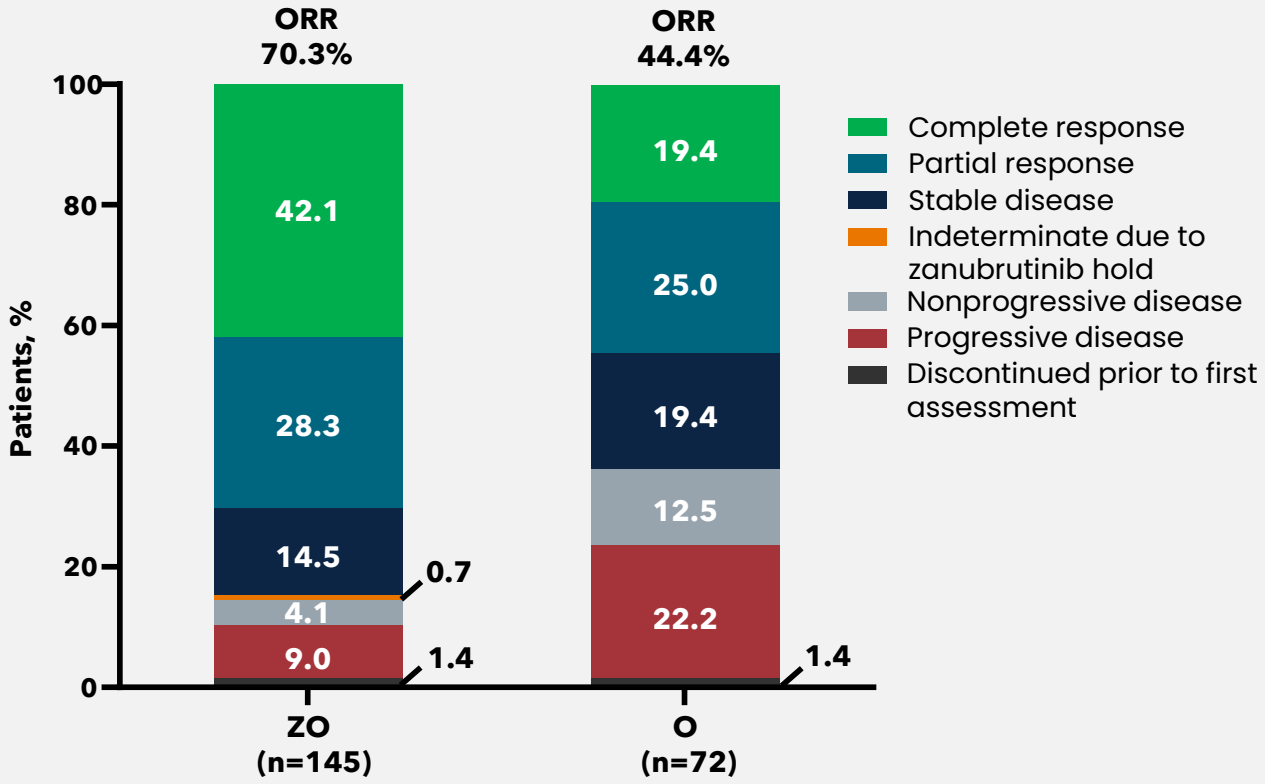
ORR by ICR: Final Analysis

At the final analysis, ORR per ICR with zanubrutinib + obinutuzumab was significantly higher compared with obinutuzumab

Median follow-up: 34.6 months



Response by ICR	Zanubrutinib + Obinutuzumab (n=145)	Obinutuzumab (n=72)
ORR, n (%)	102 (**70.3**)	32 (**44.4**)
95% CI	62.2-77.6	32.7-56.6
Risk difference, % (95% CI)	25.5 (11.8-39.3)	
2-sided *P*-value	.0003	
Complete response rate, n (%)	61 (**42.1**)	14 (**19.4**)
95% CI	33.9-50.5	11.1-30.5
2-sided *P* value	.0009	

Data cutoff: December 31, 2024.
ICR, independent central review; O, obinutuzumab; ORR, overall response rate; ZO, zanubrutinib + obinutuzumab.
Zinzani PL, et al. Oral Presentation at ASH 2025;7171.

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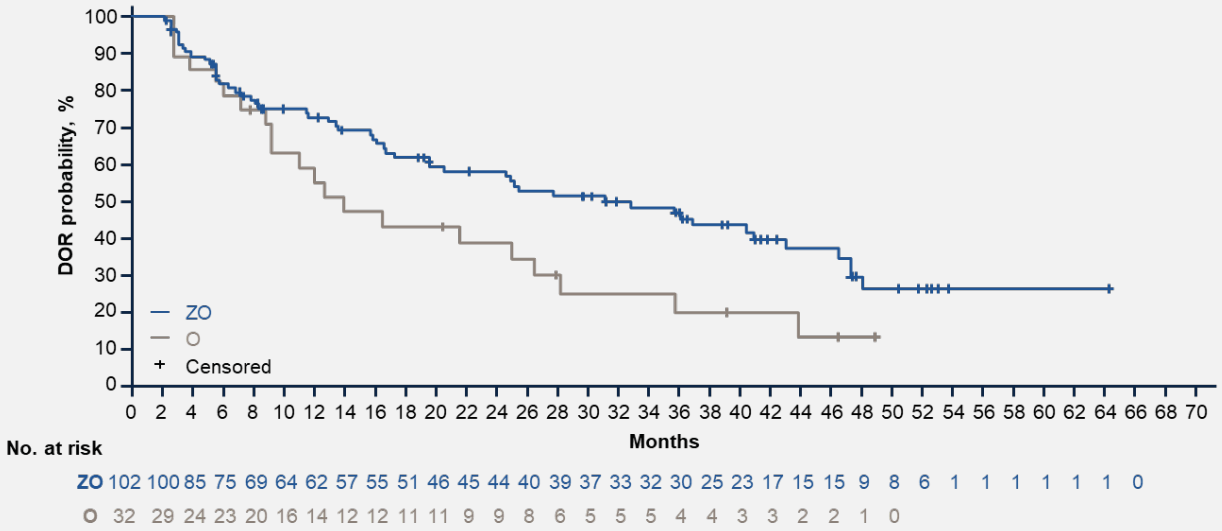
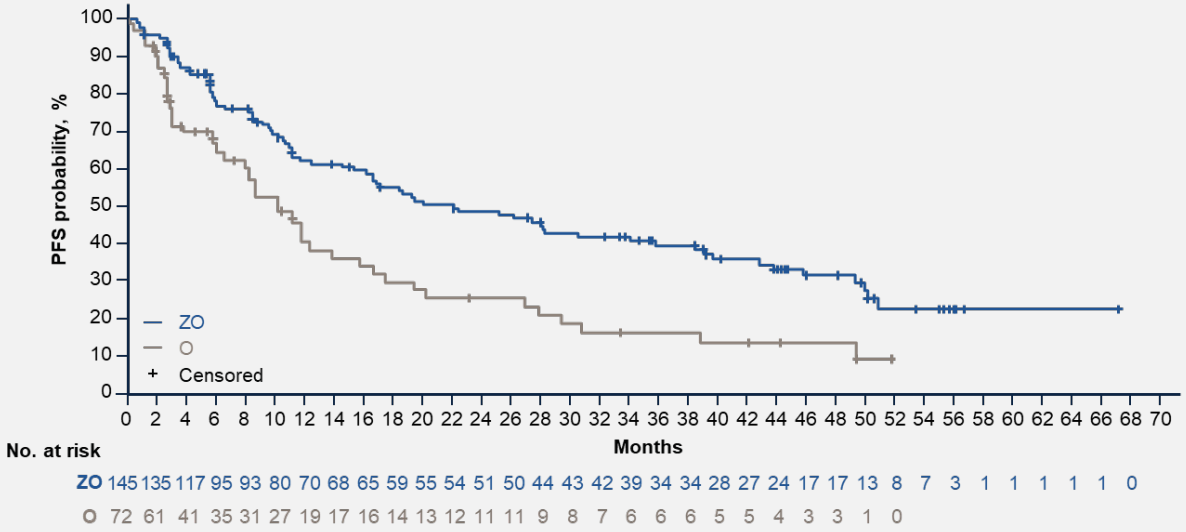
DoR and PFS by ICR: Final Analysis

Median DoR: 32.9 months in the zanubrutinib plus obinutuzumab arm versus 14.0 months with obinutuzumab



Median PFS: 22.1 months with zanubrutinib plus obinutuzumab versus 10.3 months with obinutuzumab (HR 0.54)



Median OS was not reached in the zanubrutinib + obinutuzumab arm and 41.2 months in the obinutuzumab arm

Data cutoff: December 31, 2024.
ICR, independent central review; O, obinutuzumab; ORR, overall response rate; ZO, zanubrutinib + obinutuzumab.
Zinzani PL, et al. Oral Presentation at ASH 2025;7171.

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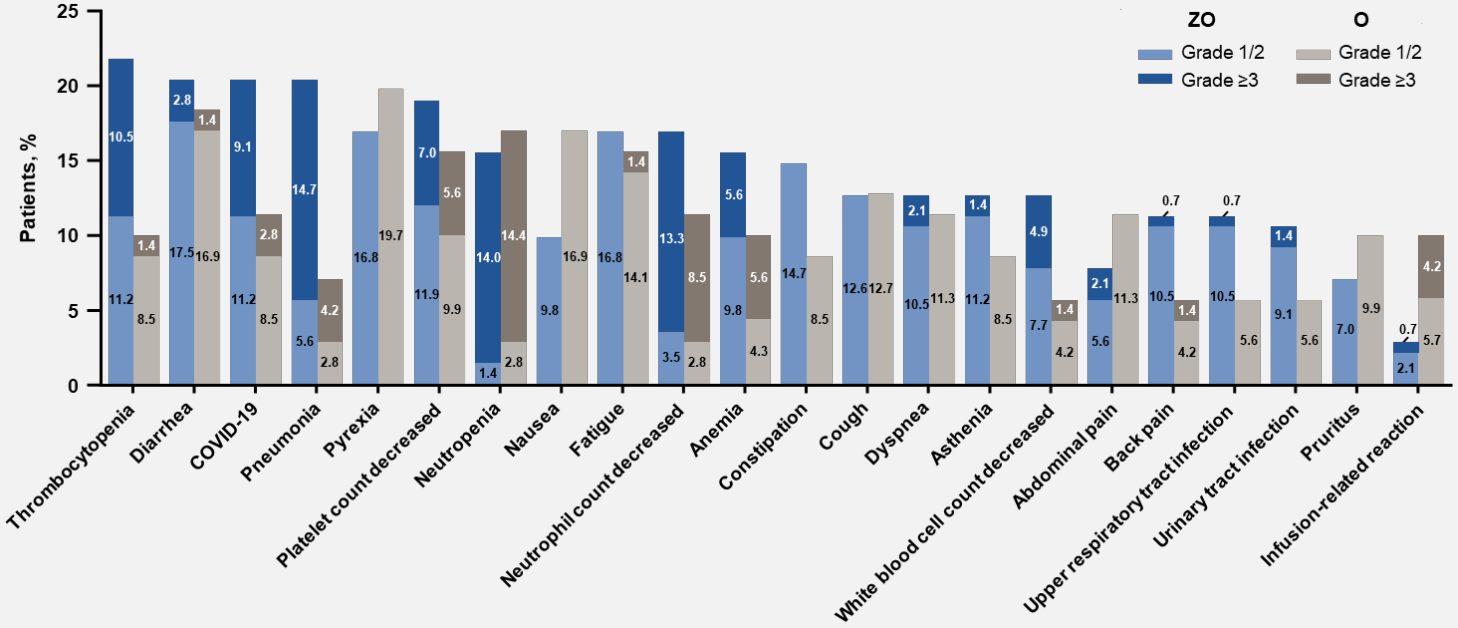
Safety Summary

With a longer median duration of exposure (ZO, 12.4 months; O, 6.5 months), the incidence of TEAEs and treatment-related TEAEs were generally higher in the ZO arm vs the O arm.

n (%)	Zanubrutinib + Obinutuzumab (n=143)	Obinutuzumab (n=71)
Any TEAE	137 (95.8)	65 (91.5)
Any treatment-related TEAE	110 (76.9)	49 (69.0)
Grade ≥3	103 (72.0)	34 (47.9)
Treatment-related grade ≥3	62 (43.4)	19 (26.8)
Serious	75 (52.4)	22 (31.0)
Treatment-related serious	29 (20.3)	8 (11.3)
Leading to death	15 (10.5)	7 (9.9)
Treatment-related leading to death	2 (1.4)	1 (1.4)
Leading to treatment discontinuation	31 (21.7)	9 (12.7)
Treatment-related leading to treatment discontinuation	14 (9.8)	3 (4.2)



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