BGB-11417-101

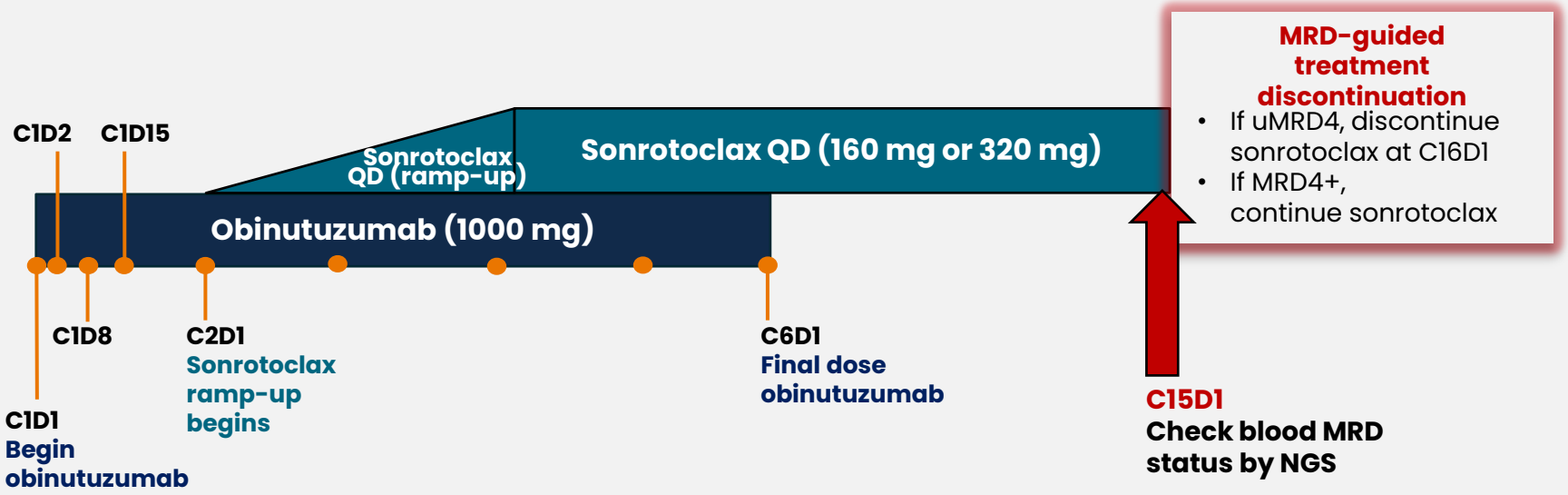
Sonrotoclax Plus Obinutuzumab

TN CLL

BGB-11417-101 Trial Design

Sonrotoclax + Obinutuzumab: TN CLL

- BGB-11417-101 is a global phase 1/1b study evaluating sonrotoclax as monotherapy or in combination with zanubrutinib ± obinutuzumab in patients with B-cell malignancies
- Study endpoints included safety/tolerability, ORR (iwCLL 2018), MRD status by modified ERIC flow cytometry assay or NGS
- Obinutuzumab (IV) monotherapy starts on C1D1 for 6 cycles, then sonrotoclax (oral) is added on C2D1 with ramp-up to the target dose



C=cycle, D=day, IV=intravenous, MRD=minimal residual disease, NGS=next-generation sequencing, ORR=overall response rate, PD=progressive disease, uMRD=undetectable minimal residual disease.

Hoffmann MS, et al. Oral Presentation at ASH 2025; 7489.

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Baseline Characteristics

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Characteristics	Sonrotoclax 160 mg + Obinutuzumab (n=20)	Sonrotoclax 320 mg + Obinutuzumab (n=35)	All Patients (N=137)
Study follow up time, median (range), months	9.8 (0.4-12.5)	19.5 (2.9-28.8)	12.3 (0.4-28.8)
Age, median (range), years	61 (46-81)	63 (42-78)	62 (42-81)
≥65 years, n (%)	7 (35)	16 (46)	23 (42)
Male sex, n (%)	15 (75)	21 (60)	36 (65)
Disease type, n (%)			
CLL	20 (100)	32 (91)	52 (95)
SLL	0	3 (9)	3 (5)
Risk status, n/known status (%)			
del(17p) or TP53 mutation[a]	2/17 (12)	2/28 (7)	4/45 (9)
del(11q)	2/17 (12)	1/31 (3)	3/48 (6)
Unmutated IGHV, n/tested (%)	10/20 (50)	21/33 (63)	31/53 (58)
High tumor bulk[b] at baseline, n/tested (%)	4/19 (21)	4/34 (12)	8/53 (15)

Data cutoff: August 29, 2025.
[a]TP53 mutations were defined as ≥10% VAF. [b]Any LN ≥10 cm or LN ≥5 cm and ALC ≥25×10^9/L.
ALC=absolute lymphocyte count, CLL=chronic lymphocytic leukemia, IGHV=immunoglobulin heavy chain variable region, LN=lymph node, SLL=small lymphocytic lymphoma, VAF=variant allele frequency.
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Safety Summary

Sonrotoclax + Obinutuzumab: TN CLL

Sonrotoclax + obinutuzumab was generally well tolerated across dose levels

	Sonrotoclax 160 mg + Obinutuzumab (n=20)	Sonrotoclax 320 mg + Obinutuzumab (n=35)	All Patients (N=55)
Duration of exposure, median (range), months	9.8 (0-12.5)	13.7 (1.5-17.8)	11.8 (0-17.8)
Any TEAEs, n (%)	20 (100)	35 (100)	55 (100)
Grade ≥3	11 (55)	27 (77)	38 (69)
Serious TEAEs	10 (50)	16 (46)	26 (47)
Leading to death	0	0	0
Leading to discontinuation of obinutuzumab[a]	1 (5)	2 (6)	3 (5)
Leading to discontinuation of sonrotoclax	0	0	0
Relative dose intensity of sonrotoclax, median, %	99.7	99.7	99.7

No treatment discontinuations were attributable to sonrotoclax
No deaths occurred on the study due to adverse events

Data cutoff: August 29, 2025.
[a]Reasons for discontinuation of obinutuzumab treatment were prostate cancer (160 mg; n=1), platelet count decreased (320 mg; n=1), and thrombocytopenia (320 mg; n=1).
TEAE=treatment-emergent adverse event.
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Most Frequent AEs (Incidence ≥15% Patients)

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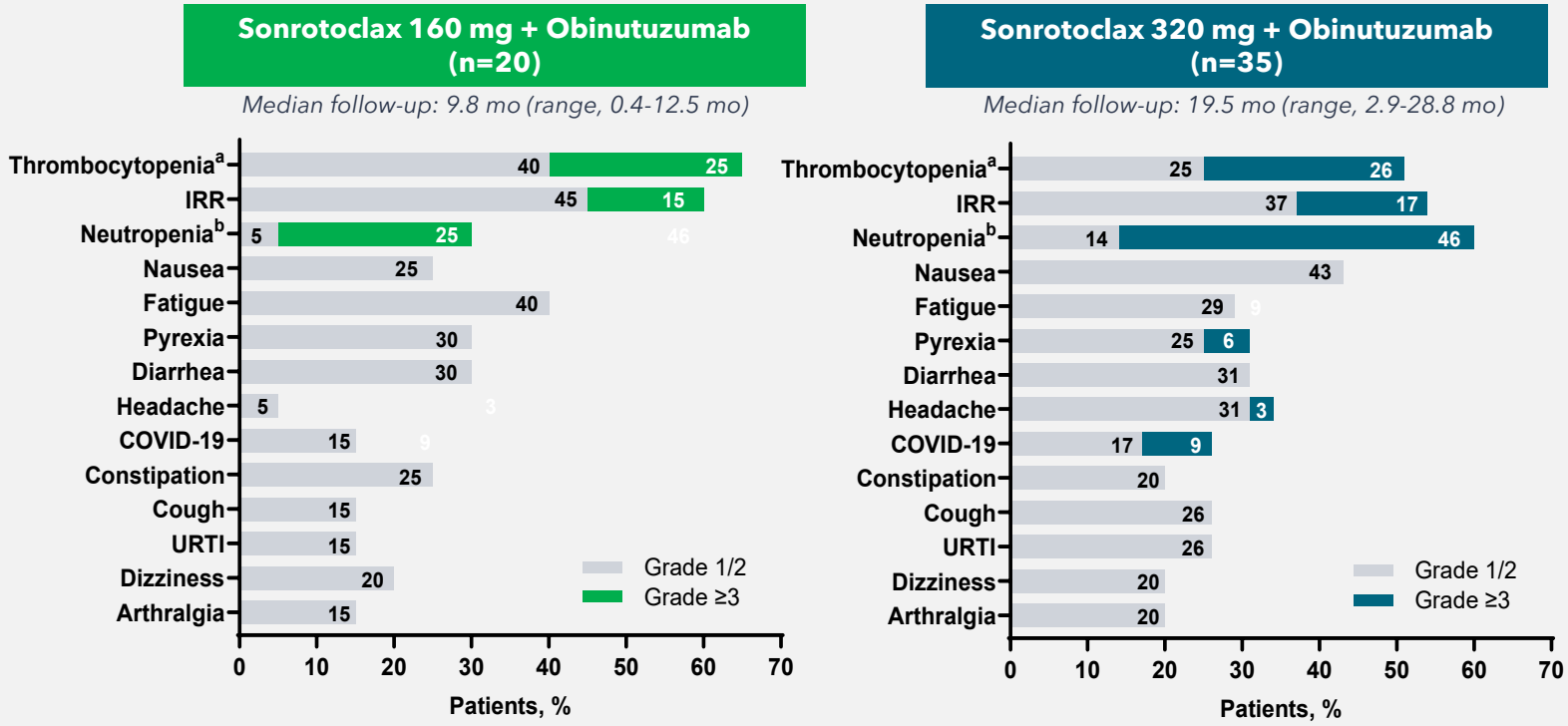
- TEAEs observed with sonrotoclax + obinutuzumab were mostly low grade
- No DLTs
- No TLS was observed during sonrotoclax ramp-up
- Grade 3+ neutropenia did not translate to serious or life-threatening infections



Data cutoff: August 29, 2025.
[a]Includes the combined preferred terms *platelet count decreased* and *thrombocytopenia*. [b]Includes the combined preferred terms *neutrophil count decreased* and *neutropenia*.
DLT=dose-limiting toxicity, IRR=infusion-related reaction, TEAE=treatment-emergent adverse event, TLS=tumor lysis syndrome, URTI=upper respiratory tract infection.
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ORR and MRD in Peripheral Blood

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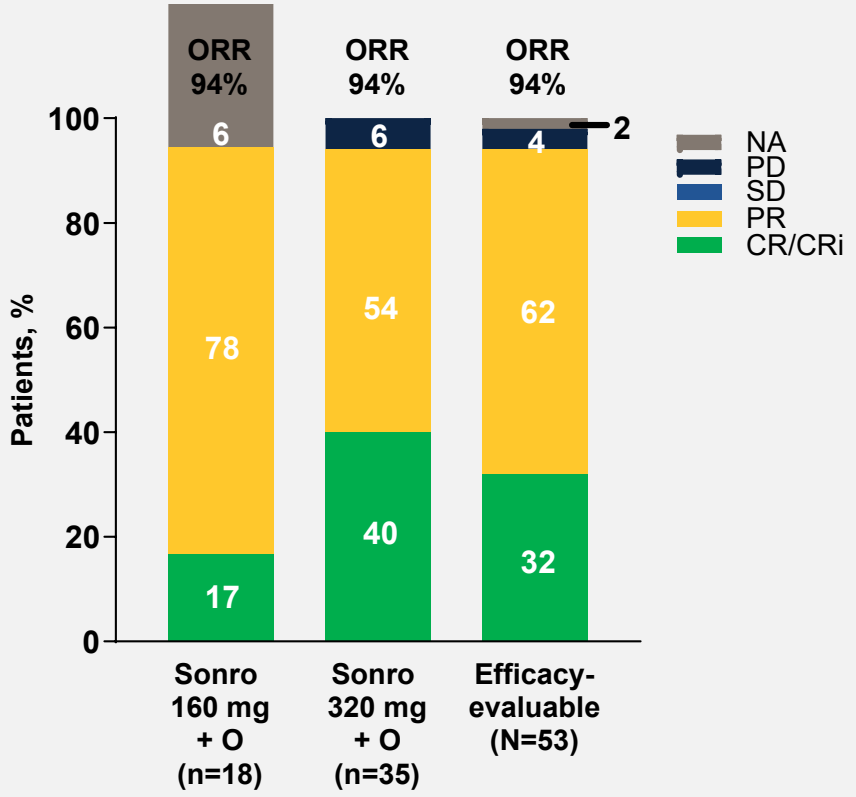
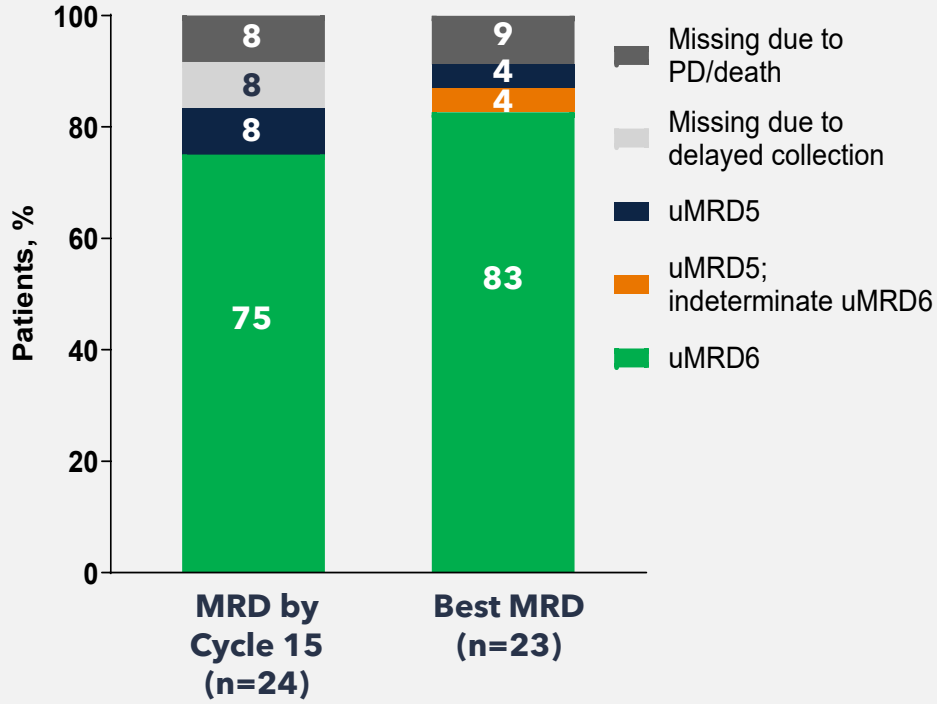


- 94% ORR was achieved across both dose levels and a CR/CRi rate of 40% was observed in the 320-mg cohort

MRD status in sonrotoclax 320-mg cohort by C15 per NGS



- Substantial blood uMRD6 rates were observed by Cycle 15

Data cutoff: August 29, 2025.
C=cycle, CR=complete response, CRi=complete response with incomplete hematopoietic recovery, D=day, EOT=end of treatment, MRD=minimal residual disease, NA=not assessable, NGS=next generation sequencing, O=obinutuzumab, ORR=overall response rate, PD=progressive disease, PFS=progression-free survival, PR=partial response, RT=Richter transformation, SD=stable disease, sonro=sonrotoclax, uMRD=undetectable minimal residual disease.
Hoffmann MS, et al. Oral Presentation at ASH 2025; 7489.