

# BGB-11417-101

**Sonrotoclax Plus Zanubrutinib  
R/R CLL**



# Baseline Characteristics and Demographics

## Sonrotoclax + Zanubrutinib in R/R CLL/SLL

Characteristic	Sonro 40 mg + Zanu (n=4)	Sonro 80 mg + Zanu (n=9)	Sonro 160 mg + Zanu (n=6)	Sonro 320 mg + Zanu (n=22)	Sonro 640 mg + Zanu (n=6)	All (N=47)
<b>Study follow-up, median (range), months</b>	46.8 (10.2-48.6)	40.6 (22.9-47.3)	42.0 (41.1-43.6)	19.6 (13.2-39.7)	30.9 (23.8-35.5)	32.2 (10.2-48.6)
<b>Age, median (range), years</b>	60.0 (50-71)	62.0 (55-75)	61.5 (41-76)	67.0 (36-76)	59.5 (53-69)	65.0 (36-76)
<b>Male, n (%)</b>	4 (100)	8 (89)	3 (50)	18 (82)	2 (33)	35 (74)
<b>ECOG PS</b>						
0	4 (100)	5 (56)	4 (67)	11 (50)	4 (67)	28 (60)
1	0	3 (33)	2 (33)	10 (45)	2 (33)	17 (36)
del(17p), n/tested (%)	3/4 (75)	4/8 (50)	1/6 (17)	3/18 (17)	0	11/42 (26)
<b>del(17p) and/or TP53 mutation<sup>a</sup>, n/tested (%)</b>	<b>3/4 (75)</b>	<b>5/8 (63)</b>	<b>1/6 (17)</b>	<b>7/19 (37)</b>	<b>0</b>	<b>16/42 (38)</b>
<b>Unmutated IGHV, n/tested (%)</b>	<b>2/4 (50)</b>	<b>8/9 (89)</b>	<b>3/6 (50)</b>	<b>14/17 (82)</b>	<b>3/5 (60)</b>	<b>30/41 (73)</b>
<b>Prior therapy</b>						
No. of lines of prior therapy, median (range)	1.5 (1-2)	1.0 (1-2)	1.0 (1-2)	1.0 (1-3)	1.0 (1-1)	1.0 (1-3)
<b>Prior BTK inhibitor, n (%)<sup>b</sup></b>	<b>1 (25)</b>	<b>1 (11)</b>	<b>1 (17)</b>	<b>3 (14)</b>	<b>1 (17)</b>	<b>7 (15)</b>
Prior BTK inhibitor duration, median (range), months	86.6 (86.6-86.6)	1.6 (1.6-1.6)	18.5 (18.5-18.5)	38.1 (34.2-49.1)	24.0 (24.0-24.0)	34.2 (1.6-86.6)

Data cutoff: March 1, 2025.

<sup>a</sup>TP53 mutations defined as ≥5% variant allele frequency. <sup>b</sup>BTK inhibitor was the last prior therapy for 7 patients; all discontinued due to toxicity.

BTK=Bruton tyrosine kinase, CLL=chronic lymphocytic leukemia, ECOG PS=Eastern Cooperative Oncology group performance status, sonro=sonrotoclax, zanu=zanubrutinib.

Cheah CY, et al. Oral Presentation at EHA 2025; S159.

# TEAE Summary



## Sonrotoclax + Zanubrutinib in R/R CLL/SLL

- No DLTs occurred and MTD was not reached; the sonrotoclax 320 mg + zanubrutinib cohort was expanded as RP2D
- Sonrotoclax in combination with zanubrutinib was well tolerated, with low rates of treatment discontinuation and dose reductions; no deaths were observed

Patients, n (%)	Sonro 40 mg + Zanu (n=4)	Sonro 80 mg + Zanu (n=9)	Sonro 160 mg + Zanu (n=6)	Sonro 320 mg + Zanu (n=22)	Sonro 640 mg + Zanu (n=6)	All (N=47)
<b>Any TEAEs</b>	4 (100)	9 (100)	6 (100)	22 (100)	5 (83)	46 (98)
Grade ≥3	1 (25)	7 (78)	3 (50)	18 (82)	3 (50)	32 (68)
Serious TEAEs	1 (25)	3 (33)	3 (50)	11 (50)	3 (50)	21 (45)
Led to zanu discontinuation	0	1 (11) <sup>a</sup>	0	2 (9) <sup>b</sup>	1 (17) <sup>c</sup>	4 (8)
Led to zanu dose reduction	0	1 (11) <sup>d</sup>	0	2 (9) <sup>e</sup>	1 (17) <sup>f</sup>	4 (8)
<b>Treated with sonro, n (%)</b>	4 (100)	9 (100)	6 (100)	22 (100)	6 (100)	47 (100)
Led to sonro discontinuation	0	0	0	2 (9) <sup>b</sup>	1 (17) <sup>c</sup>	3 (6)
Led to sonro dose reduction	0	0	0	1 (4) <sup>g</sup>	1 (17) <sup>f</sup>	2 (4)

Data cutoff: March 1, 2025.

<sup>a</sup>Due to intracranial hemorrhage. <sup>b</sup>Discontinued sonro and zanu due to myelodysplastic syndrome and meningococcal sepsis, n=1 each. <sup>c</sup>Discontinued sonro and zanu due to plasma cell myeloma. <sup>d</sup>COVID-19. <sup>e</sup>Reduced zanu during lead-in due to neutropenia, n=1; COVID-19, n=1. <sup>f</sup>Reduced sonro and zanu due to COVID-19, n=1. <sup>g</sup>Due to cellulitis.

CLL=chronic lymphocytic leukemia, DLT=dose-limiting toxicity, MTD=maximum tolerated dose, RP2D=recommended phase 2 dose, sonro=sonrotoclax, TEAE=treatment-emergent adverse event, zanu=zanubrutinib.

Cheah CY, et al. Oral Presentation at EHA 2025; S159.

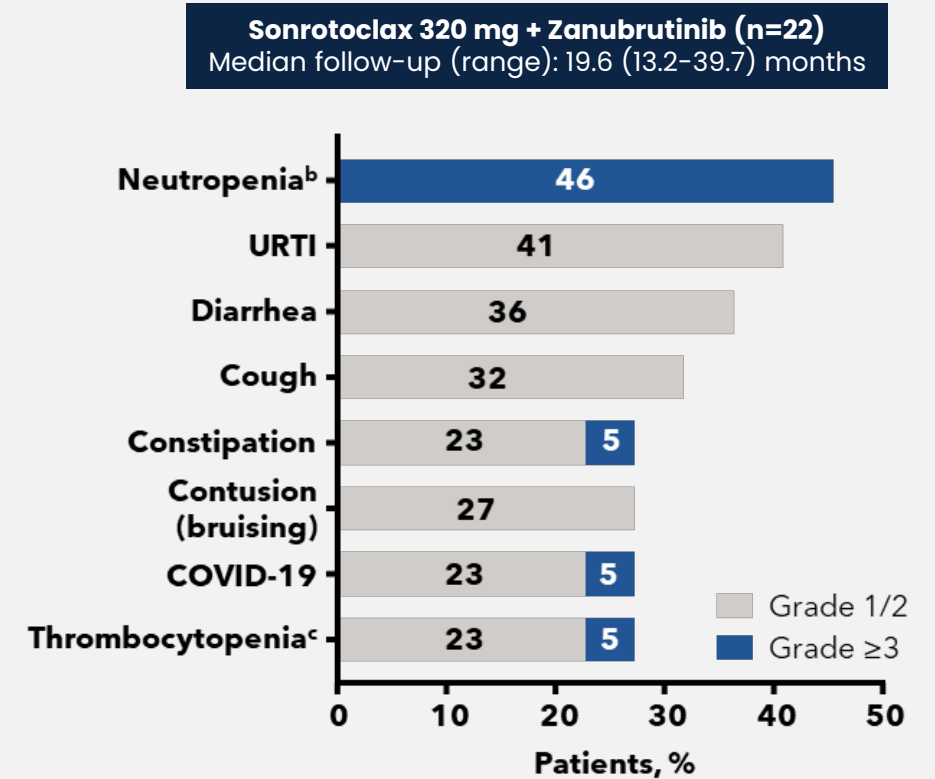
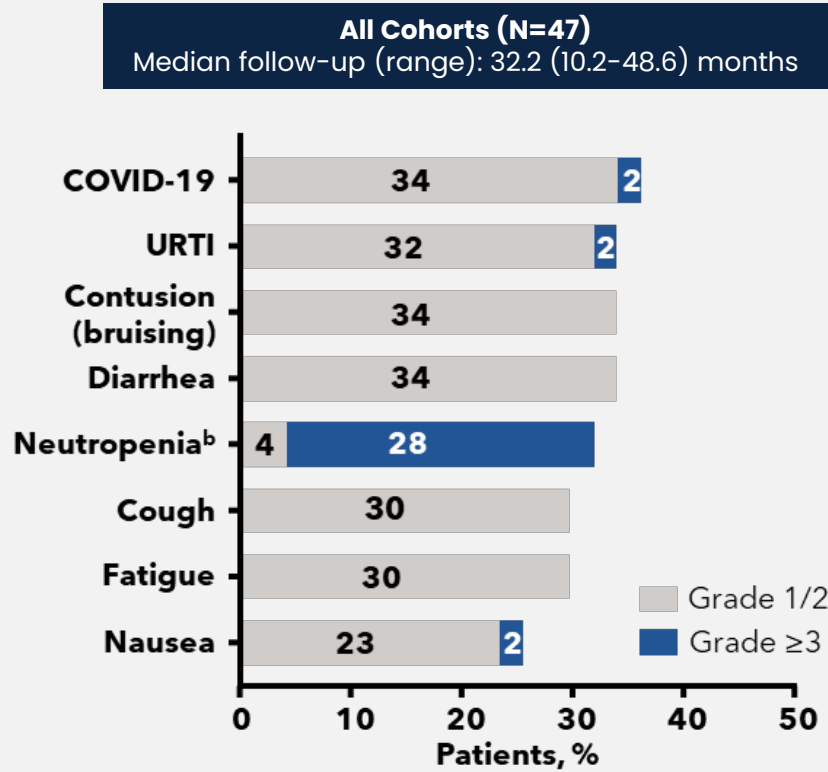
# Most Common TEAEs



## Sonrotoclax + Zanubrutinib in R/R CLL/SLL

- Toxicities were comparable across all dose levels
- No TLS or febrile neutropenia
- No dose reductions occurred due to diarrhea

### TEAEs in ≥25% of all patients and those treated at sonrotoclax RP2D of 320 mg<sup>a</sup>



Data cutoff: March 1, 2025.

<sup>a</sup>Grade is listed as worst grade experienced by patient on any drug. <sup>b</sup>Neutropenia combines preferred terms neutrophil count decreased and neutropenia. <sup>c</sup>Thrombocytopenia combines preferred terms platelet count decreased and thrombocytopenia.

CLL=chronic lymphocytic leukemia, RP2D=recommended phase 2 dose, TEAE=treatment-emergent adverse event, TLS=tumor lysis syndrome, URTI=upper respiratory tract infection.

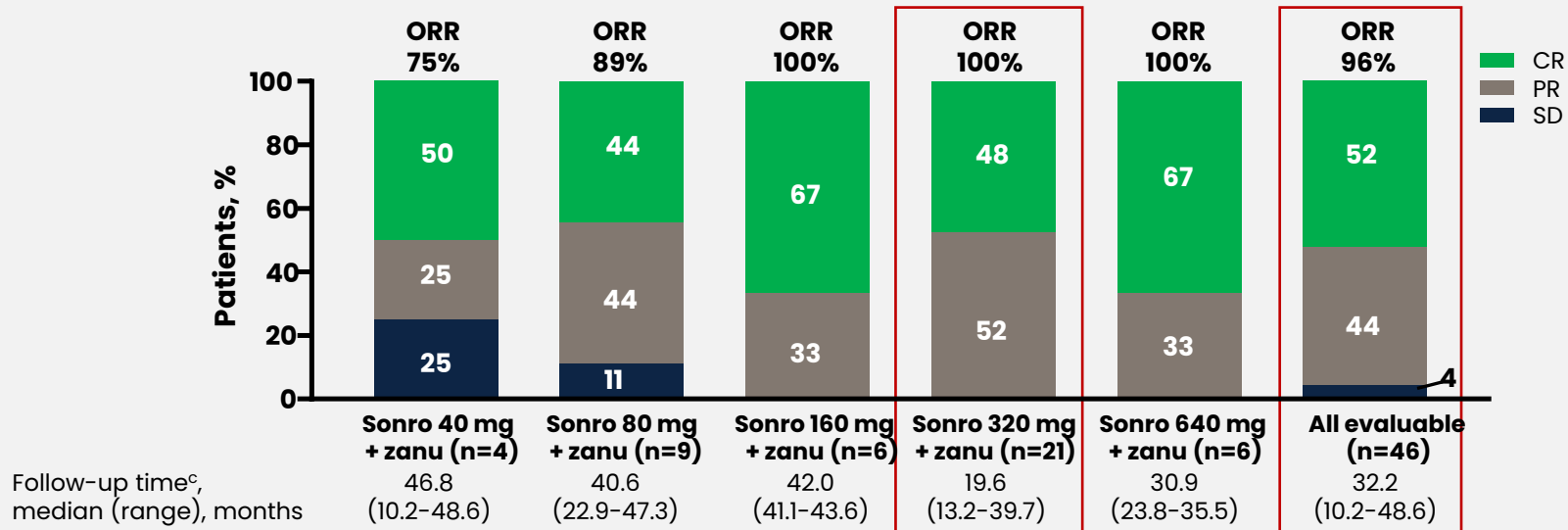
Cheah CY, et al. Oral Presentation at EHA 2025; S159.

# Overall Response Rates



## Sonrotoclax + Zanubrutinib in R/R CLL/SLL

- With a median study follow-up of 32.2 months, the ORR was 96%, with a 52% CR/CRI rate across all doses<sup>a,b</sup>
  - In the 320-mg cohort, the ORR was 100%, with a 48% CR/CRI rate
- The median time to CR or CRI was 10.3 months (range, 5.3-42.4 months)
  - In the 320-mg cohort, the median time to CR was 8.5 months (range, 5.3-22.8 months)
- Of 7 evaluable patients with prior BTK inhibitor therapy, 5 achieved PR and 1 achieved CR



Data cutoff: March 1, 2025.

<sup>a</sup>Responses were assessed per 2008 iwCLL criteria and percentage of response is based on number of patients who had ≥1 post-baseline tumor assessment after sonrotoclax dosing. <sup>b</sup>ORR = PR-L or better. <sup>c</sup>For all patients as treated (n=47).

BTK=Bruton tyrosine kinase, CLL=chronic lymphocytic leukemia, CR=complete response, CRI=complete response with incomplete hematologic recovery, ORR=overall response rate, PR=partial response, PR-L=PR with lymphocytosis, SD=stable disease, sonro=sonrotoclax, zanu=zanubrutinib.

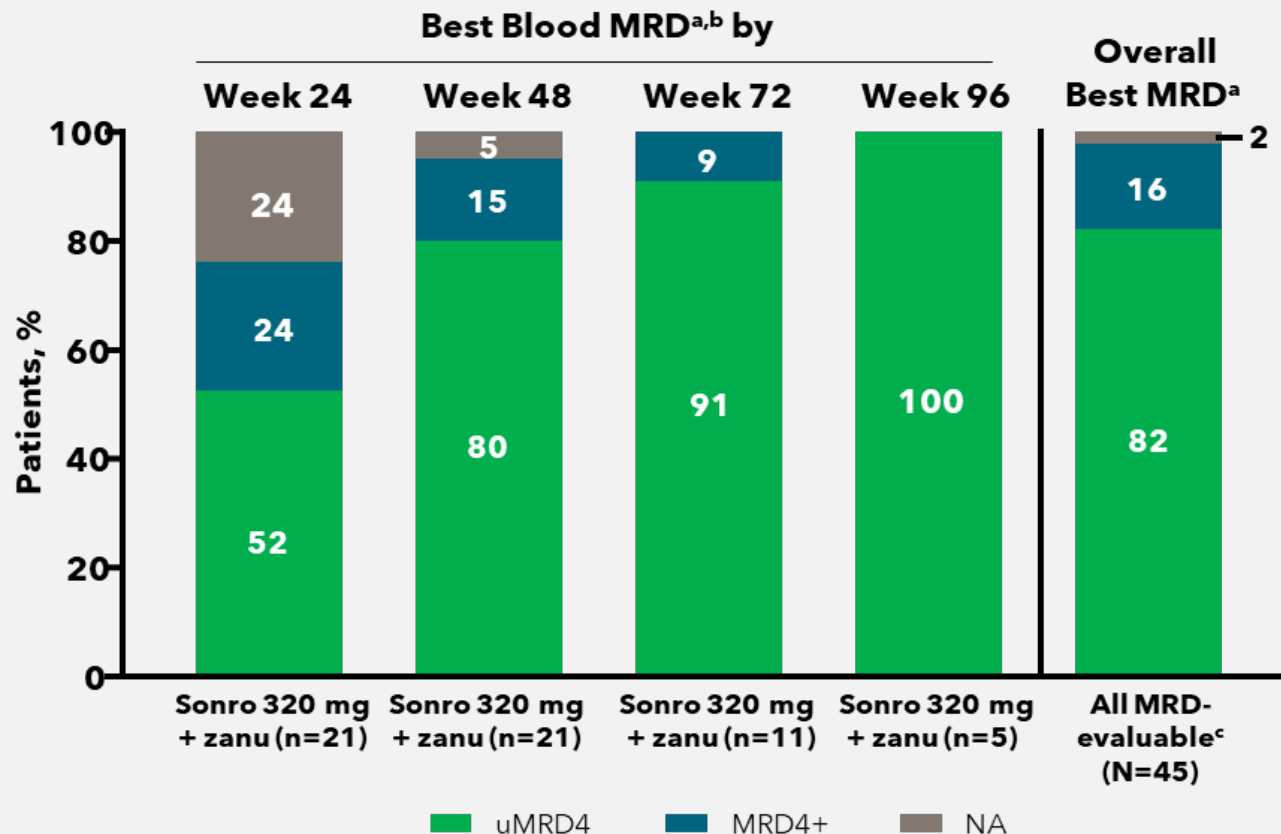
Cheah CY, et al. Oral Presentation at EHA 2025; S159.

# Sonrotoclax + Zanubrutinib: uMRD4 Rates



## Sonrotoclax + Zanubrutinib in R/R CLL/SLL

- Of 45 MRD-evaluable patients, 37 (82%) achieved uMRD4 at the time of data cutoff
- All patients in the 160-mg, 320-mg, and 640-mg cohorts who reached week 96 achieved uMRD4
- In the 320-mg cohort, 4/6 patients with del(17p) or TP53 mutation had uMRD4 by week 48



Data cutoff: March 1, 2025.

<sup>a</sup>Measured by an ERIC-approved flow cytometry method with 10<sup>-4</sup> sensitivity. uMRD4 defined as <10<sup>-4</sup> CLL cells of total WBCs. MRD4+ defined as ≥10<sup>-4</sup> CLL cells of total WBCs. MRD is best reported within a 2-week window following the week 24/week 48/week 72/week 96 day 1 MRD assessments. <sup>b</sup>Weeks 24, 48, 72, and 96 of treatment at target dose, following zanu monotherapy and sonro ramp-up to target dose. <sup>c</sup>All MRD-evaluable set includes patients with ≥1 post-baseline MRD sample or disease progression or death prior to MRD assessment, excluding those with baseline MRD level <10<sup>-4</sup>.

CLL=chronic lymphocytic leukemia, MRD=measurable residual disease, sonro=sonrotoclax, uMRD=undetectable MRD, WBC=white blood cell, zanu=zanubrutinib.

Cheah CY, et al. Oral Presentation at EHA 2025; S159.

# Progression-free Survival



## Sonrotoclax + Zanubrutinib in R/R CLL/SLL

- Thirteen patients electively discontinued treatment after at least 96 weeks of therapy; as of the data cutoff date, all were in remission and had a median time of 4.5 months off treatment (range, 1.8–12.3 months)
- With median study follow-up time of 32.2 months, only 2 PFS events occurred on study:
  - 40 mg: del(17)p+
  - 320 mg: del(17)p+
- The 30-month PFS rate was 94.7% (95% CI, 79.9%–98.7%; median follow-up, 30.5 months)

