

BGB-11417-102



Sonrotoclax in Adult Patients With Mature B-Cell Malignancies

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Phase 1

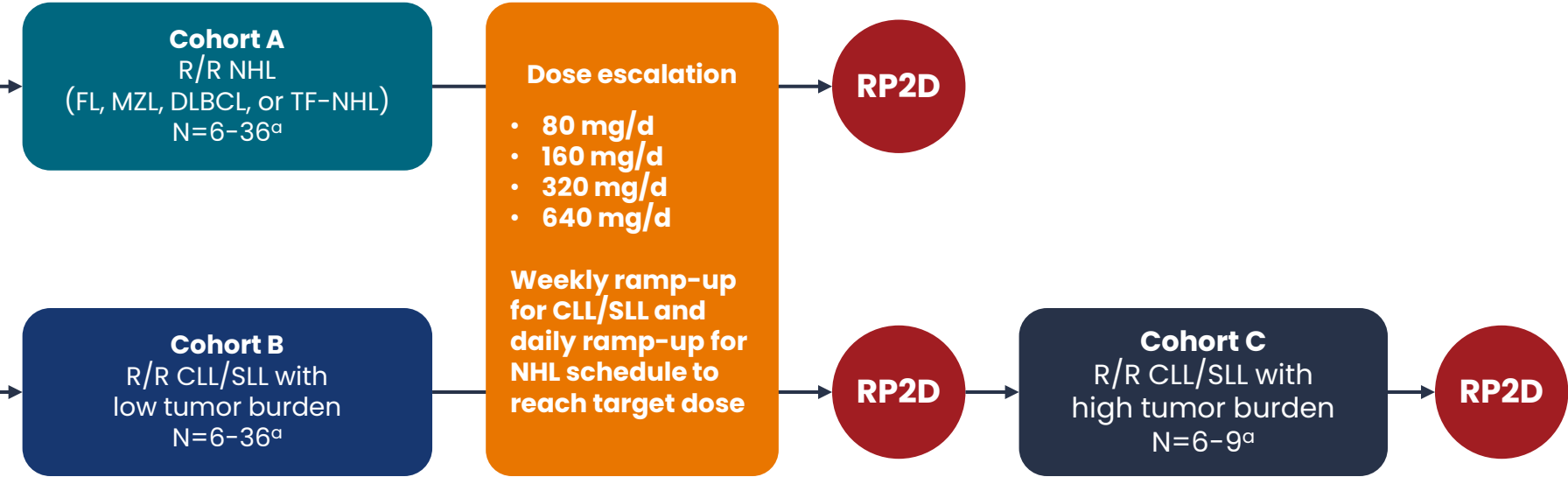
Study Identifier:
BGB-11417-102, NCT04883957

Primary Endpoint: RP2D and/or MTD, safety, tolerability, incidence, and severity of TLS-relevant events
Key Secondary Endpoints: PK parameters, ORR per disease-specific response assessment guidelines per investigator

Key eligibility criteria

- ≥18 years old
- Diagnosed with one of the following diseases
- Cohort A:
 - R/R MZL, FL, DLBCL, or TF-NHL
- Cohorts B & C:
 - R/R CLL/SLL (iwCLL 2008 criteria)
- Measurable disease by CT/MRI
- Adequate organ function

Treatment



^aThe number of patients per cohort is estimated and may vary. CLL=chronic lymphocytic leukemia, CT=computed tomography, DLBCL=diffuse large B-cell lymphoma, FL=follicular lymphoma, iwCLL=International Workshop on Chronic Lymphocytic Leukemia, MRI=magnetic resonance imaging, MTD=maximum tolerated dose, MZL=marginal zone lymphoma, NHL=non-Hodgkin lymphoma, ORR=overall response rate, PK=pharmacokinetics, R/R=relapsed/refractory, RP2D=recommended phase 2 dose, SLL=small lymphocytic lymphoma, TF-NHL=transformed non-Hodgkin lymphoma, TLS=tumor lysis syndrome.
Li C et al. Poster presented at ASCO 2023; Abstract number: 7558.

Demographics and Baseline Characteristics

- As of August 23, 2024, 64 patients (CLL/SLL, n=29; NHL, n=35) had received sonrotoclax, and 16 (25%) remained on study treatment
- Median follow-up was 23.4 months (range, 1.5-35.7 months)
- Overall, 15 patients with CLL/SLL and 33 with NHL discontinued study treatment, primarily due to PD
- Overall, the median age was 61.0 years and the median number of prior lines of therapy was 2

Characteristics	CLL/SLL (n=29)	NHL (n=35)	All (N=64)
Age, median (range), years	61.0 (49-84)	59.0 (31-74)	61.0 (31-84)
Male, n (%)	20 (69.0)	15 (42.9)	35 (54.7)
ECOG PS, n (%)			
0	11 (37.9)	12 (34.3)	23 (35.9)
1	12 (41.4)	19 (54.3)	31 (48.4)
2	6 (20.7)	4 (11.4)	10 (15.6)
Prior therapy			
No. of lines of prior therapy, median (range)	2.0 (1-7)	2.0 (1-7)	2.0 (1-7)
Prior BTK inhibitor, n (%)	15 (51.7)	13 (37.1)	28 (43.8)
Prior BTK inhibitor duration, median (range), months	6.2 (2.4-52.6)	4.5 (0.03-21.4)	4.8 (0.03-52.6)
Disease type, n (%)			
CLL	22 (75.9)	0	22 (34.4)
SLL	7 (24.1)	0	7 (10.9)
DLBCL	0	21 (60.0)	21 (32.8)
FL	0	7 (20.0)	7 (10.9)
MZL	0	4 (11.4)	4 (6.3)
Transformed B-cell NHL	0	3 (8.6)	3 (4.7)
Bulky disease, n (%)^a	6 (20.7)	11 (31.4)	17 (26.6)
CLL/SLL risk characteristic at study entry, n/N (%)			
Binet stage C	7/14 (50.0)	NA	7/14 (50.0)
Unmutated IGHV	14/23 (60.9)	NA	14/23 (60.9)
Del(17p)	2/28 (7.1)	NA	2/28 (7.1)
TP53 mutation	8/24 (33.3)	NA	8/24 (33.3)

Data cutoff: August 23, 2024.

^aAny target lesion with a longest diameter of ≥ 5 cm.

BTK=Bruton tyrosine kinase; CLL=chronic lymphocytic leukemia, DLBCL, diffuse large B-cell lymphoma, ECOG PS=Eastern Cooperative Oncology Group performance status, FL=follicular lymphoma, IGHV=immunoglobulin heavy-chain variable region, MZL=marginal zone lymphoma, NA=not assessed, NHL=non-Hodgkin lymphoma, PD=progressive disease, R/R=relapsed/refractory, SLL=small lymphocytic lymphoma.

Li C, et al. Poster Presentation at EHA 2025; PF574.

TEAE Summary

- Overall, 98.4% of patients experienced a TEAE of any grade, and 62.5% experienced a grade ≥ 3 TEAE
- TEAEs led to treatment discontinuation in three patients (4.7%)
 - CLL: one patient (640 mg) with pneumonia and one patient (160 mg) with nutritional condition abnormal (decreased appetite, fatigue, and vomiting led to significant weight loss)
 - NHL: one patient (640 mg) with pneumonia
- TEAEs led to death in four patients (6.3%)
 - CLL: one patient (640 mg) with pneumonia (related to treatment); one patient (320 mg; related to disease under study) with anemia, platelet count decreased (both related to treatment), and COVID-19 pneumonia (not related to treatment); and one patient (160 mg) with multiple organ failure and hemophagocytic syndrome (both related to treatment)
 - NHL: one patient (640 mg) with pneumonia (not related to treatment)
- No laboratory or clinical TLS was reported
- The MTD was not reached up to 640 mg, and the RP2D was 320 mg once daily

Patients, n (%)	CLL/SLL (n=29)	NHL (n=35)	All (N=64)
Any TEAEs	29 (100)	34 (97.1)	63 (98.4)
Grade ≥ 3	21 (72.4)	19 (54.3)	40 (62.5)
Serious	16 (55.2)	6 (17.1)	22 (34.4)
Leading to dose interruption	15 (51.7)	5 (14.3)	20 (31.3)
Leading to dose reduction	2 (6.9)	1 (2.9)	3 (4.7)
Leading to dose treatment discontinuation	2 (6.9)	1 (2.9)	3 (4.7)
Leading to death	3 (10.3)	1 (2.9)	4 (6.3)

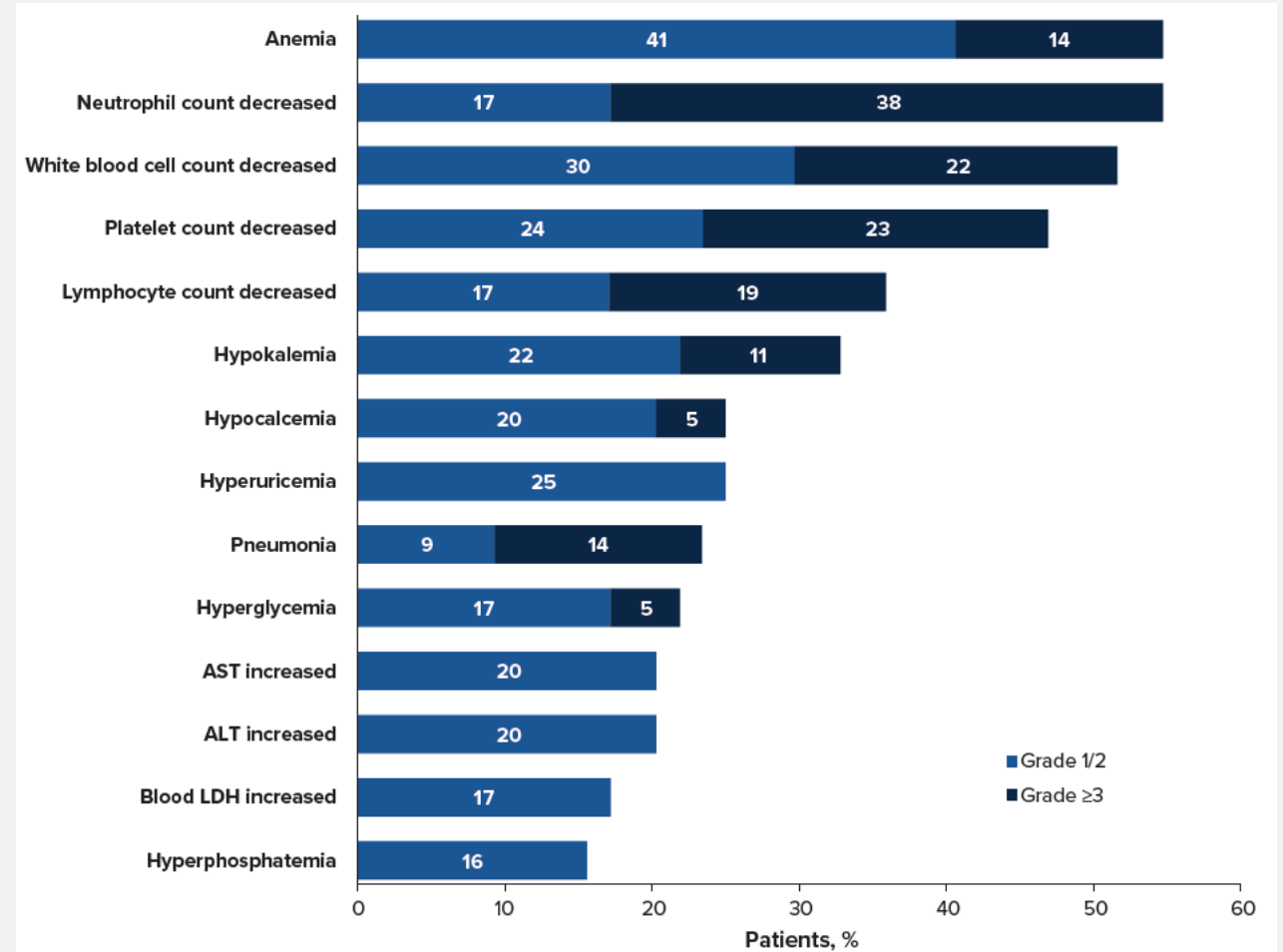
Data cutoff: August 23, 2024.

CLL=chronic lymphocytic leukemia, MTD=maximum tolerated dose, NHL=non-Hodgkin lymphoma, R/R=relapsed/refractory, RP2D=recommended phase 2 dose, SLL=small lymphocytic lymphoma, TEAE=treatment-emergent adverse event, TLS=tumor lysis syndrome.

Li C, et al. Poster Presentation at EHA 2025; PF574.

TEAEs in $\geq 15\%$ of Patients

- The most common all-grade TEAEs were anemia and neutrophil count decreased (54.7% each)
- The most common grade ≥ 3 TEAE was neutrophil count decreased (38%)



Data cutoff: August 23, 2024.

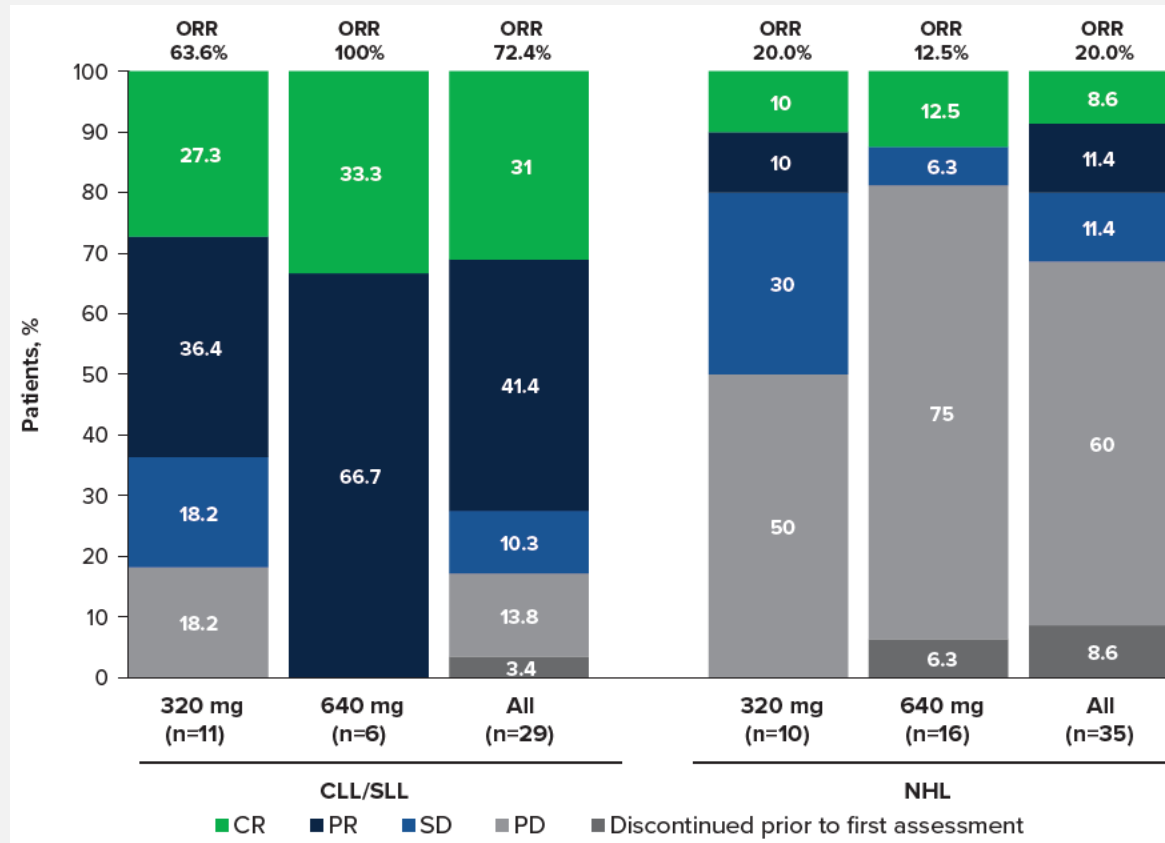
ALT=alanine aminotransferase, AST=aspartate aminotransferase, LDH=lactate dehydrogenase, R/R=relapsed/refractory, TEAE=treatment-emergent adverse event.

Li C, et al. Poster Presentation at EHA 2025; PF574.

Response Rates



- In 29 evaluable patients with CLL/SLL and 35 with NHL, ORRs across dose levels were 72.4% and 20.0%, respectively, and CR rates were 31.0% and 8.6%



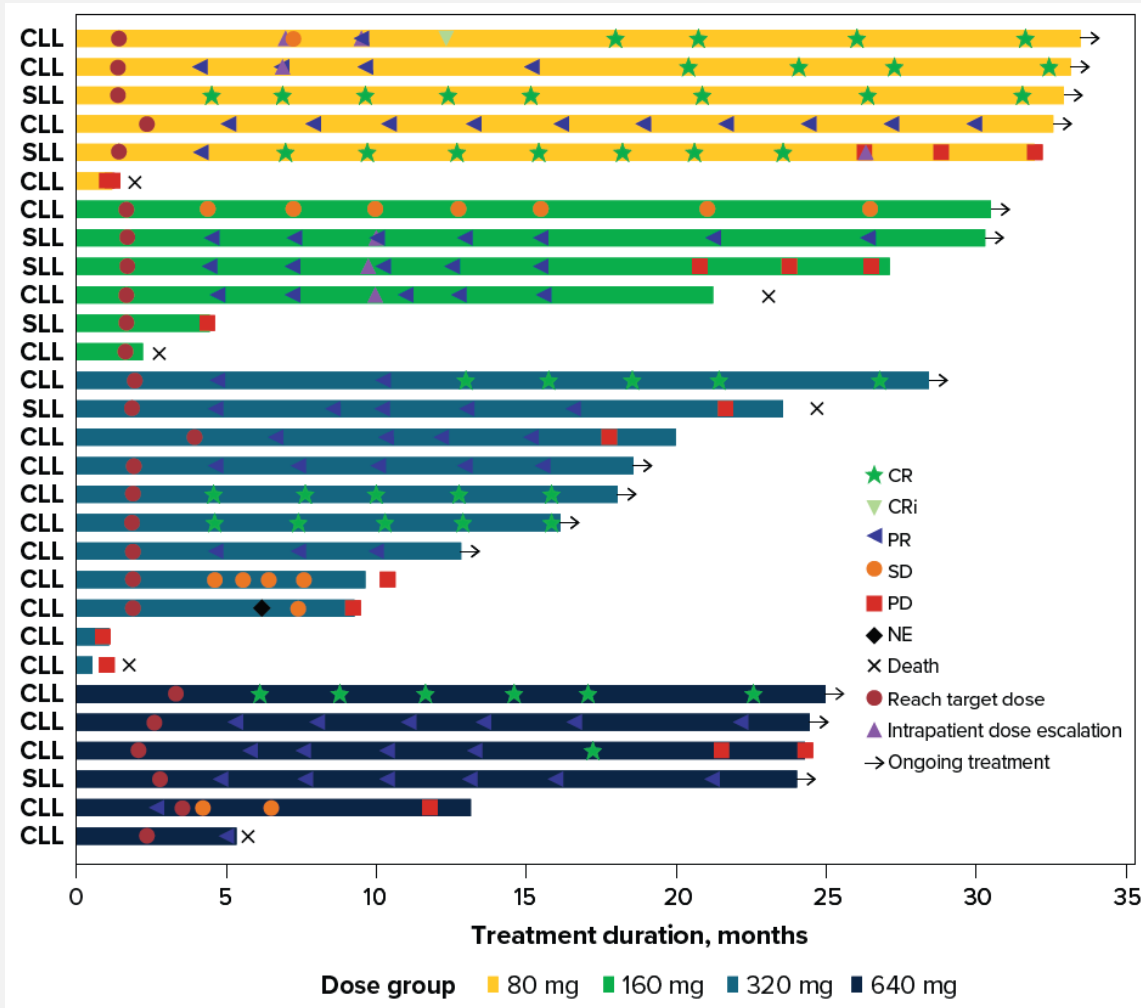
Data cutoff: August 23, 2024.

CLL=chronic lymphocytic leukemia, CR=complete response, NHL=non-Hodgkin lymphoma, ORR=overall response rate, PD=progressive disease, PR=partial response, R/R=relapsed/refractory, SD=stable disease, SLL=small lymphocytic lymphoma.

Li C, et al. Poster Presentation at EHA 2025; PF574.

Treatment Duration and Investigator-Assessed Responses in Patients With R/R CLL/SLL

- Median duration of response was 22.2 months in patients with CLL/SLL and 21.9 months in patients with NHL
- In patients with CLL/SLL, the best rate of uMRD4 in blood was 41.4% (12/29) across doses, with a median time to uMRD of 7.4 months



Data cutoff: August 23, 2024.

CLL=chronic lymphocytic leukemia, CR=complete response, CRi, complete response with incomplete marrow recovery, NE=not evaluable, NHL=non-Hodgkin lymphoma, PD=progressive disease, PR=partial response, R/R=relapsed/refractory, SD=stable disease, SLL=small lymphocytic lymphoma, uMRD=undetectable measurable residual disease.

Li C, et al. Poster Presentation at EHA 2025; PF574.