CaDAnCe-101

R/R CLL/SLL

BGB-16673 in Patients With Relapsed or Refractory B-Cell Malignancies

BGB-16673-101 – CADANCE-101 (R/R CLL/SLL)

Phase 1

Study Identifier:
BGB-16673-101, CaDAnCe-101, NCT05006716

Primary Endpoint: Safety[a] and tolerability, define MTD and RP2D
Key Secondary Endpoints: Characterize PK, pharmacodynamics, and preliminary antitumor activity[b]

Key eligibility criteria (CLL/SLL)

- Meets iwCLL 2018 criteria for treatment
- ≥2 prior therapies, including covalent BTK inhibitor if approved for disease
- ECOG PS 0-2
- Adequate end-organ function

Part 1: Monotherapy Dose Finding

Part 1a: Dose escalation
Selected R/R B-cell malignancies
(MZL, FL, MCL, CLL/SLL, WM, DLBCL, RT)
n≤72
Oral, QD, 28-day cycle[c]
Doses: 50mg, 100mg, 200mg, 350mg, 500mg, 600mg

Part 1b: Safety expansion
Selected R/R B-cell malignancies
(MZL, MCL, CLL/SLL, WM)
n≤120

Part 1c: Additional safety expansion
Selected R/R B-cell malignancies
(MZL, WM, RT, DLBCL, FL)
n≤100

Part 1d: Additional safety expansion
R/R CLL/SLL
n≤30

Part 1e: Additional safety expansion
Selected R/R B-cell malignancies (Japan only)
(MZL, FL, MCL, CLL/SLL, WM)
n=6-9

Part 1e: Monotherapy safety expansion
Selected BTK inhibitor-naïve B-cell malignancies
(MZL, MCL, CLL/SLL, WM, RT)
n≤40

Part 2: Dose Expansion

Determination of BGB-16673 RP2D

- **Cohort 1:** Post-BTK inhibitor, R/R CLL/SLL
- **Cohort 2:** Post-BTK inhibitor, R/R MCL
- **Cohort 3:** Post-BTK inhibitor, R/R WM
- **Cohort 4:** Post-BTK inhibitor, R/R MZL
- **Cohort 5:** R/R FL
- **Cohort 6:** R/R non-GCB DLBCL
- **Cohort 7:** Post-BTK inhibitor, R/R RT

[a]Safety was assessed according to CTCAE v5.0 in all patients and iwCLL hematologic toxicity criteria in patients with CLL. [b]Response was assessed per iwCLL 2018 criteria after 12 weeks in patients with CLL. [c]Treatment was administered until progression, intolerance, or other criteria were met for treatment discontinuation.
BTK=Bruton tyrosine kinase, cBTKi=covalent Bruton tyrosine kinase inhibitor, CLL=chronic lymphocytic leukemia, DLCBL=diffuse large B-cell lymphoma, ECOG PS=Eastern Cooperative Oncology Group performance status, FL=follicular lymphoma, GCB=germinal center B-cell type, IGHV=immunoglobulin heavy chain variable region, MCL=mantle cell lymphoma, MTD=maximum tolerated dose, MZL=marginal zone lymphoma, PK=pharmacokinetics, QD=once daily, RP2D=recommended phase 2 dose, R/R=relapsed/refractory, RT=Richter transformation, SLL=small lymphocytic leukemia, TP53=tumor protein 53, WM=Waldenström macroglobulinemia.
1. Scarfò L, et al. Oral Presentation at EHA 2025; S158. 2. https://clinicaltrials.gov/study/NCT05006716?term=NCT05006716&rank=1. Accessed October 9, 2025.

CaDAnCe-101

Baseline Patient Characteristics

CaDAnCe-101: CLL/SLL

- Heavily pretreated, with high-risk CLL features

	Total (N=68)
Age, median (range), years	70 (47-91)
Male, n (%)	47 (69.1)
ECOG PS, n (%)	
0	38 (55.9)
1	29 (42.6)
2	1 (1.5)
CLL/SLL risk characteristics at study entry, n/N with known status (%)	
Binet stage C	29/64 (45.3)
Unmutated IGHV	38/49 (77.6)
del(17p) and/or *TP53* mutation	46/68 (67.6)
Complex karyotype (≥3 abnormalities)	22/44 (50.0)

	Total (N=66)
Mutation status, n/N (%)	
BTK mutation present	26/66 (39.4)
PLCG2 mutation present	10/66 (15.2)
BTK and *PLCG2* mutation present	5/66 (7.6)
No. of prior lines of therapy, median (range)	4 (2-10)
Prior therapy, n (%)	
Chemotherapy	49 (71.2)
cBTK inhibitor	64 (94.1)
ncBTK inhibitor	14 (20.6)
BCL2 inhibitor	56 (82.4)
cBTK + BCL2 inhibitors	44 (64.7)
cBTK + ncBTK + BCL2 inhibitors	12 (17.6)
Discontinued prior BTK inhibitor due to PD, n/N (%)[a]	57/64 (89.1)

Data cutoff: August 22, 2025.
[a]The remaining 7 patients discontinued prior BTK inhibitor due to toxicity (n=4), and other (n=3).
BCL2, B-cell lymphoma 2; BTK, Bruton tyrosine kinase; cBTK, covalent Bruton tyrosine kinase; CLL, chronic lymphocytic leukemia; ECOG PS, Eastern Cooperative Oncology Group performance status; IGHV, immunoglobulin heavy chain variable region; ncBTK, noncovalent Bruton tyrosine kinase; PD, progressive disease; SLL, small lymphocytic lymphoma.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

Overall Safety Summary

CaDAnCe-101: CLL/SLL

- Tolerable safety profile, with no treatment-related TEAEs leading to death

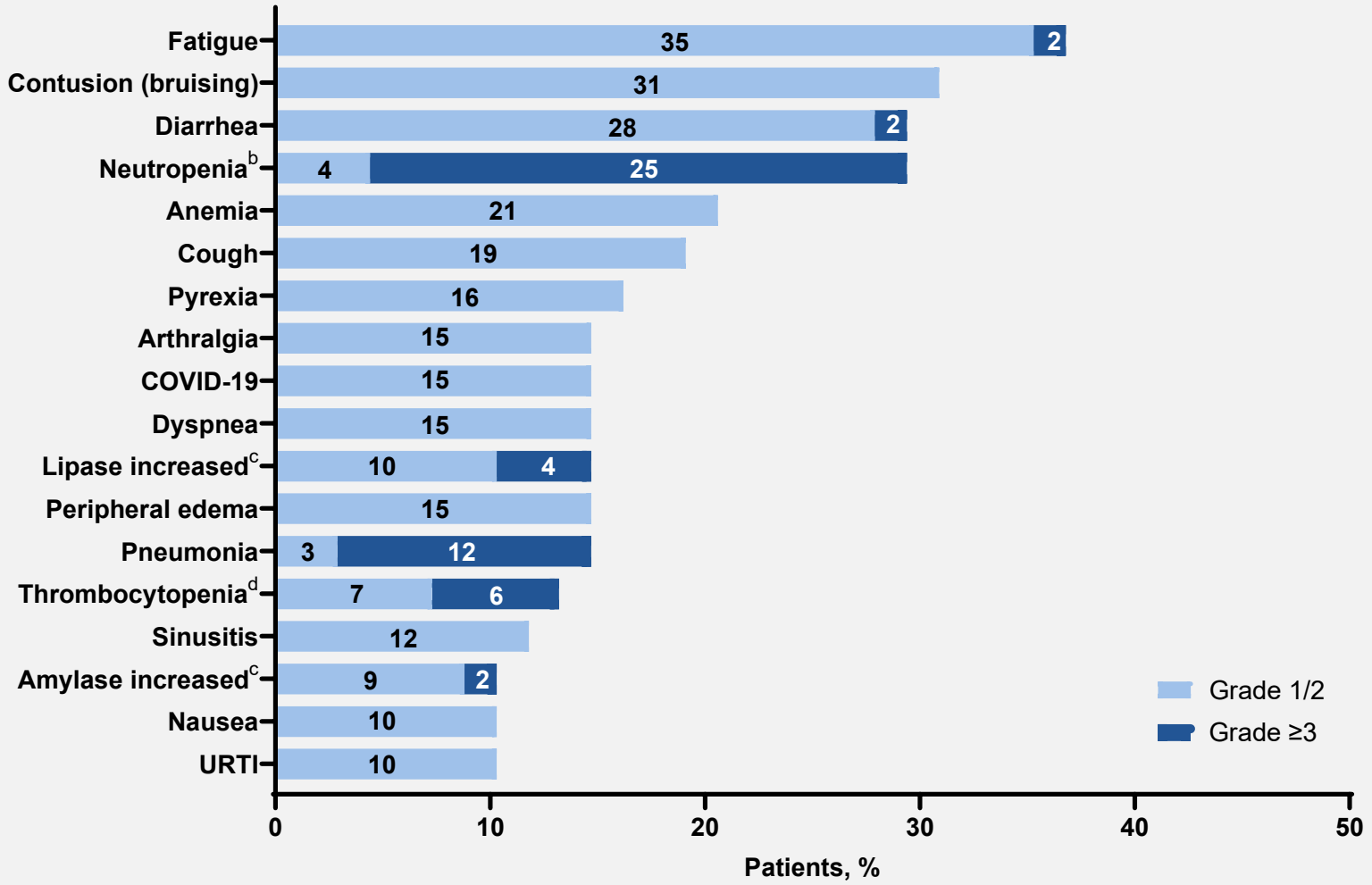
Patients, n (%)	Total (N=68)
Any TEAE	65 (95.6)
Any treatment-related	52 (76.5)
Grade ≥3	42 (61.8)
Treatment-related grade ≥3	23 (33.8)
Serious	33 (48.5)
Treatment-related serious	9 (13.2)
Leading to death	5 (7.4)
Treatment-related leading to death	0
Leading to treatment discontinuation	12 (17.6)
Treatment-related leading to treatment discontinuation	3 (4.4)

Data cutoff: August 22, 2025.
Median study follow-up in safety-evaluable patients: 19.8 months (range, 0.3-34.0+ months).
TEAE, treatment-emergent adverse event.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

Summary of All-Grade TEAEs in ≥10% of All Patients

R/R CLL/SLL

- Most common TEAEs were fatigue (36.8%) and contusion (bruising; 30.9%)
- Grade ≥3 neutropenia: n=17 (25.0%); 16 patients (23.5%) had grade ≥2 neutropenia at baseline
  - Neutropenic fever: n=1
- Atrial fibrillation: n=3 (Grade 1, n=1; Grade 2, n=2, all in the context of infection and PD and were assessed as unrelated to treatment)
- Treatment-related major hemorrhagea: n=2 (one Grade 3 subdural hemorrhage and one Grade 3 post-procedural hematuria)



Data cutoff: August 22, 2025.
Median follow-up in safety-evaluable patients: 19.8 months (range, 0.3-34.0+ months).
[a]Grade ≥3, serious, or any central nervous system bleeding. [b]Neutropenia combines preferred terms neutrophil count decreased and neutropenia. [c]All events were laboratory findings and were transient, mostly occurring during the first 1-3 cycles of treatment, with no clinical pancreatitis. [d]Thrombocytopenia combines preferred terms platelet count decreased and thrombocytopenia.
PD, progressive disease; TEAE, treatment-emergent adverse event; UTRI, upper respiratory tract infection.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

CaDAnCe-101

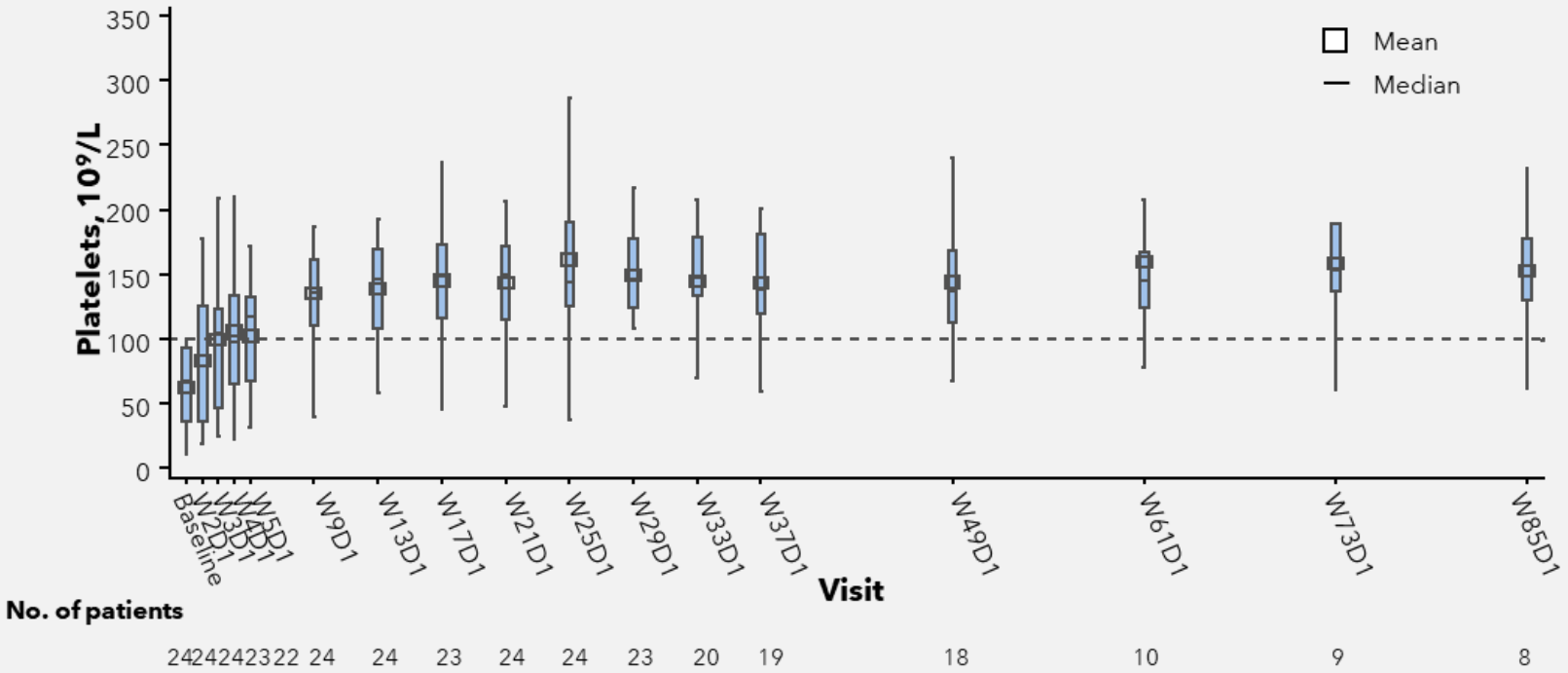
Cytopenia Improvement in Patients With Treatment Response

R/R CLL/SLL

	Baseline	W9D1
Platelet count,[a] median, 10^9/L	67.5	136.0
Neutrophil count,[b] median, 10^9/L	1.1	2.4

	Baseline	W13D1
Hemoglobin level,[c] median, g/L	99.0	111.0

Platelet Count in Patients Who Had Baseline Thrombocytopenia and Responded to Treatment



Data cutoff: August 22, 2025.
[a]In n=25 patients based on 100×10^9/L cutoff. [b]In n=14 patients based on 1.5×10^9/L cutoff. [c]In n=25 patients based on 11.0 g/dL cutoff.
D, day; W, week.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

CaDAnCe-101

Overall Response Rate

R/R CLL/SLL

- Significant responses, particularly at 200-mg dose level

	50 mg (n=1)	100 mg (n=22)	200 mg (n=18)	350 mg (n=15)	500 mg (n=12)	Total (N=68)
Best overall response, n (%)						
CR/CRi	0	1 (4.5)	1 (5.6)	0	0	**2 (2.9)**
PR[a]	1 (100)	14 (63.6)	12 (66.7)	11 (73.3)	11 (91.7)	49 (72.1)
PR-L	0	2 (9.1)	4 (22.2)	0	1 (8.3)	7 (10.3)
SD	0	5 (22.7)	0	0	0	5 (7.4)
PD	0	0	1 (5.6)	1 (6.7)	0	2 (2.9)
Discontinued prior to first assessment	0	0	0	3 (20.0)	0	3 (4.4)
ORR, n (%)[b]	1 (100)	17 (77.3)	**17 (94.4)**	11 (73.3)	12 (100)	**58 (85.3)**
Time to first response, median (range), months[c]	2.9 (2.9-2.9)	2.8 (2.0-6.2)	2.9 (2.6-8.3)	2.9 (2.6-19.4)	2.8 (2.7-13.8)	2.8 (2.0-19.4)
Time to best response, median (range), months	2.9 (2.9-2.9)	2.9 (2.0-11.1)	3.0 (2.6-13.8)	5.6 (2.6-19.4)	8.4 (2.7-13.8)	4.2 (2.0-19.4)
Duration of exposure, median (range), months	29.6 (29.6-29.6)	12.3 (3.4-25.4)	14.4 (2.9-30.3)	19.8 (0.2-28.5)	20.4 (6.8-27.1)	13.6 (0.2-30.3)

Data cutoff: August 22, 2025.
[a]Of 49 patients with PRs,16 achieved all nodes normalized. [b]Includes best overall response of PR-L or better. [c]In patients with a best overall response of PR-L or better.
CR=complete response, CRi=complete response with incomplete marrow recovery, ORR=overall response rate, PD=progressive disease, PR=partial response, PR-L=partial response with lymphocytosis, SD=stable disease.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

CaDAnCe-101

High Overall Response Rates in High-Risk Subgroups

R/R CLL/SLL

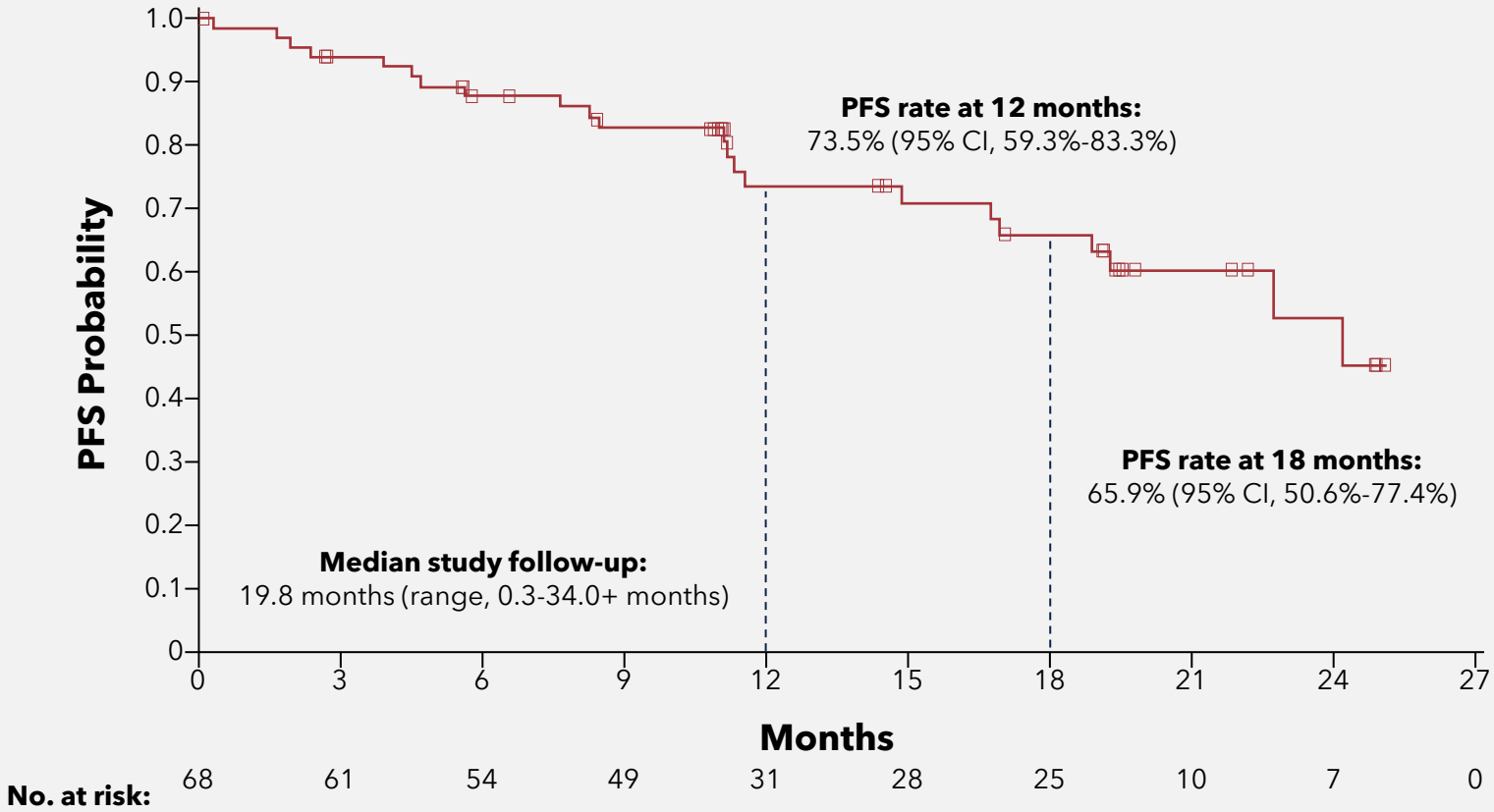
Characteristic, n/N with known status (%)	ORR
Prior cBTKi + BCL2i	41/44 (93.2)
Prior cBTKi + ncBTKi + BCL2i	9/12 (75.0)
6 or more prior lines of therapy	13/16 (81.3)
del(17p) and/or *TP53* mutation	37/46 (80.4)
Complex karyotype (≥3 abnormalities)	16/22 (72.7)
***BTK* mutations**	20/26 (76.9)
***PLCG2* mutations**	9/10 (90.0)

Data cutoff: August 22, 2025.
BCL2i=B-cell lymphoma 2 inhibitor, cBTKi=covalent Bruton tyrosine kinase inhibitor, ncBTKi=noncovalent Bruton tyrosine kinase inhibitor, ORR=overall response rate.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

CaDAnCe-101

Progression-Free Survival

R/R CLL/SLL



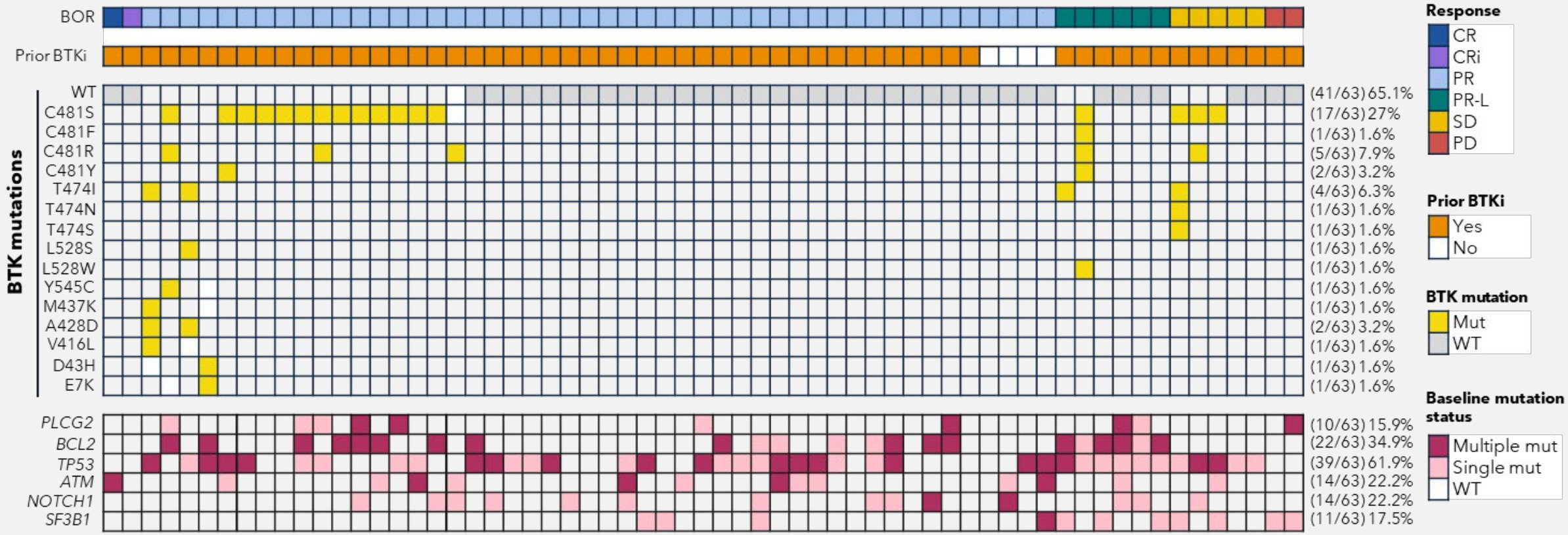
Data cutoff: August 22, 2025.
CI=confidence interval, PFS=progression-free survival.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

CaDAnCe-101

Responses Occurred Regardless of Baseline Mutations

R/R CLL/SLL

Best overall response vs baseline mutation[a]



Data cutoff: August 22, 2025.
[a]Genomic mutations were centrally assessed by targeted next-generation sequencing.
BTKi=Bruton tyrosine kinase inhibitor, BOR=best overall response, CR=complete response, CRi=complete response with incomplete marrow recovery, mut=mutation, PD=progressive disease, PR=partial response, PR-L=partial response with lymphocytosis, SD=stable disease, WT=wild type.
Ahn IE, et al. Oral Presentation at ASH 2025;8349.

CaDAnCe-101

R/R FL and MZL

BGB-16673 in Patients With Relapsed or Refractory B-Cell Malignancies

BGB-16673-101 – CADANCE-101 (R/R FL and MZL)

Phase 1

Study Identifier:
BGB-16673-101, CaDAnCe-101, NCT05006716

Primary Endpoint: Safety[a] and tolerability, define MTD and RP2D
Key Secondary Endpoints: Characterize PK, pharmacodynamics, and preliminary antitumor activity[b]

Key eligibility criteria

- Received ≥2 prior therapies (≥1 prior therapy for RT)
- Received a cBTKi if approved for their disease
- ECOG PS 0-2
- Adequate end-organ function
- No current of history of central nervous system involvement by B-cell malignancy

Part 1: Monotherapy Dose Finding

Part 1a: Dose escalation
Selected R/R B-cell malignancies
(MZL, FL, MCL, CLL/SLL, WM, DLBCL, RT)
n≤72
Oral, QD, 28-day cycle[c]
Doses: 50mg, 100mg, 200mg, 350mg, 500mg, 600mg

Part 1b: Safety expansion
Selected R/R B-cell malignancies
(MZL, MCL, CLL/SLL, WM)
n≤120

Part 1c: Additional safety expansion
Selected R/R B-cell malignancies
(MZL, WM, RT, DLBCL, FL)
n≤100

Part 1d: Additional safety expansion
R/R CLL/SLL
n≤30

Part 1e: Additional safety expansion
Selected R/R B-cell malignancies (Japan only)
(MZL, FL, MCL, CLL/SLL, WM)
n=6-9

Part 1e: Monotherapy safety expansion
Selected BTK inhibitor-naïve B-cell malignancies
(MZL, MCL, CLL/SLL, WM, RT)
n≤40

Part 2: Dose Expansion

Determination of BGB-16673 RP2D

- **Cohort 1:** Post-BTK inhibitor, R/R CLL/SLL
- **Cohort 2:** Post-BTK inhibitor, R/R MCL
- **Cohort 3:** Post-BTK inhibitor, R/R WM
- **Cohort 4:** Post-BTK inhibitor, R/R MZL
- **Cohort 5:** R/R FL
- **Cohort 6:** R/R non-GCB DLBCL
- **Cohort 7:** Post-BTK inhibitor, R/R RT

[a]Safety was assessed according to CTCAE v5.0 in all patients. [b]Response was assessed per Lugano 2014 criteria after 12 weeks.
BTK=Bruton tyrosine kinase, cBTKi=covalent Bruton tyrosine kinase inhibitor, CLL=chronic lymphocytic leukemia, DLCBL=diffuse large B-cell lymphoma, ECOG PS=Eastern Cooperative Oncology Group performance status, FL=follicular lymphoma, GCB=germinal center B-cell type, IGHV=immunoglobulin heavy chain variable region, MCL=mantle cell lymphoma, MTD=maximum tolerated dose, MZL=marginal zone lymphoma, PK=pharmacokinetics, QD=once daily, RP2D=recommended phase 2 dose, R/R=relapsed/refractory, RT=Richter transformation, SLL=small lymphocytic leukemia, TP53=tumor protein 53, WM=Waldenström macroglobulinemia.

1. Zinzani PL, et al. Poster Presentation at ICML 2025; 436. 2. https://clinicaltrials.gov/study/NCT05006716?term=NCT05006716&rank=1. Accessed October 9, 2025.

CaDAnCe-101

Baseline Demographics and Disease Characteristics

R/R FL and MZL

- As of March 3, 2025, 17 patients with FL and 29 with MZL had received BGB-16673
- Patients were heavily pretreated, with a median of 3 prior lines of therapy for both FL (range, 2-9) and MZL (range 1-9)
- The median study follow-up was 3.4 months (range, 0.7-29.9 months) and 8.0 months (range, 0.3-25.1 months) in the FL and MZL cohorts, respectively

	FL (n=17)	MZL (n=29)
Age, median (range), years	70 (52-86)	75 (33-88)
Male, n (%)	13 (76.5)	13 (44.8)
ECOG PS, n (%)		
0	8 (47.1)	16 (55.2)
1	9 (52.9)	13 (44.8)
Ann Arbor stage III/IV at study entry, n/N (%)[a]	14/16 (87.5)	23/24 (95.8)
Tumor bulk, n (%)		
Longest diameter ≥5 cm	6 (35.3)	6 (20.7)
No. of prior lines of therapy, median (range)	3.0 (2-9)	3.0 (1-9)
Prior therapy, n (%)		
cBTK inhibitor	2 (11.8)	25 (86.2)
ncBTK inhibitor	1 (5.9)	4 (13.8)
BCL2 inhibitor	0	7 (24.1)
Anti-CD20-based therapy	17 (100)	29 (100)
Chemotherapy	16 (94.1)	28 (96.6)
Discontinued prior BTK inhibitor due to PD, n/N (%)	3/3 (100)	21/25 (84.0)[b]

Data cutoff: March 3, 2025.
[a]Excludes patients with unknown status. [b]Reasons for five discontinuations of BTK inhibitor apart from PD were toxicity (n=3) and other (n=1); one patient in the MZL cohort had an adverse event in the context of progressive disease.
BLC2=B-cell lymphoma 2, BTK=Bruton tyrosine kinase, cBTK=covalent BTK, ECOG PS=Eastern Cooperative Oncology Group performance status, FL=follicular lymphoma, MZL=marginal zone lymphoma, ncBTK=noncovalent BTK, NHL=non-Hodgkin lymphoma, PD=progressive disease.
Zinzani PL, et al. Poster Presentation at ICML 2025; 436.

Overall Safety Summary

R/R FL and MZL

- Five patients with MZL had a TEAE that led to treatment discontinuation (pleural effusion in the context of progressive disease; hepatocellular carcinoma; and treatment-related TEAEs of intracranial hemorrhage, rhabdomyolysis, and pulmonary aspergillosis; n=1 each)
  - One patient had a TEAE (intracranial hemorrhage) leading to death
- One patient with FL had a treatment-related TEAE of cardiac arrest which led to both treatment discontinuation and death

Patients, n (%)	FL (n=17)	MZL (n=29)
Any TEAE	16 (94.1)	29 (100)
Any treatment-related	9 (52.9)	22 (75.9)
Grade ≥3	5 (29.4)	13 (44.8)
Treatment-related Grade ≥3	3 (17.6)	8 (27.6)
Serious	3 (17.6)	10 (34.5)
Treatment-related serious	2 (11.8)	3 (10.3)
Leading to death	1 (5.9)	1 (3.4)
Treatment-related leading to death	1 (5.9)	1 (3.4)
Leading to treatment discontinuation	1 (5.9)	5 (17.4)
Treatment-related leading to treatment discontinuation	1 (5.9)	3 (10.3)
Leading to treatment modification	6 (35.3)	9 (31.0)
Dose interruption	6 (35.3)	9 (31.0)

Data cutoff: March 3, 2025.
FL=follicular lymphoma, MTD=maximum tolerated dose, MZL=marginal zone lymphoma, NHL=non-Hodgkin lymphoma, TEAE=treatment-emergent adverse event.
Zinzani PL, et al. Poster Presentation at ICML 2025; 436.

TEAEs in ≥3 Patients in Either Group

R/R FL and MZL

- The most common TEAEs were URTI in the FL group and neutropenia and fatigue in the MZL group; across both histologies, neutropenia was the most frequently reported grade ≥3 TEAE
- One patient each in the FL and MZL groups had a grade 3 TEAE of hypertension; the patient in the MZL group had a history of hypertension
- Three patients in the MZL group experienced major hemorrhage (gastrointestinal, intracranial, and hemothorax; n=1 each)
- Six patients (FL, n=2; MZL, n=4) experienced grade ≥3 infection

	FL (n=17)		MZL (n=29)	
Patients, n (%)	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**
URTI	4 (23.5)	1 (5.9)	4 (13.8)	0
Fatigue	3 (17.6)	0	7 (24.1)	0
Contusion (bruising)	3 (17.6)	0	6 (20.7)	0
Diarrhea	3 (17.6)	0	4 (13.8)	0
Thrombocytopenia[a]	2 (11.8)	1 (5.9)	3 (10.3)	0
Neutropenia[b]	2 (11.8)	2 (11.8)	8 (27.6)	6 (20.7)
Lipase increased	1 (5.9)	0	4 (13.8)	0
Amylase increased	1 (5.9)	0	3 (10.3)	0
Anemia	1 (5.9)	0	3 (10.3)	1 (3.4)
COVID-19	1 (5.9)	0	3 (10.3)	1 (3.4)
Headache	1 (5.9)	0	3 (10.3)	0
Pyrexia	1 (5.9)	0	4 (13.8)	0
Asthenia	0	0	4 (13.8)	1 (3.4)
Petechiae	0	0	4 (13.8)	0
Decreased appetite	0	0	3 (10.3)	0
Hematoma	0	0	3 (10.3)	0

Data cutoff: March 3, 2025.
[a]Thrombocytopenia combines preferred terms *platelet count decreased* and *thrombocytopenia*. [b]Neutropenia combines preferred terms *neutrophil count decreased* and *neutropenia*.
FL=follicular lymphoma, MTD=maximum tolerated dose, MZL=marginal zone lymphoma, NHL=non-Hodgkin lymphoma, TEAE=treatment-emergent adverse event, URTI=upper respiratory tract infection.
Zinzani PL, et al. Poster Presentation at ICML 2025; 436.

Responses by Histology

R/R FL and MZL

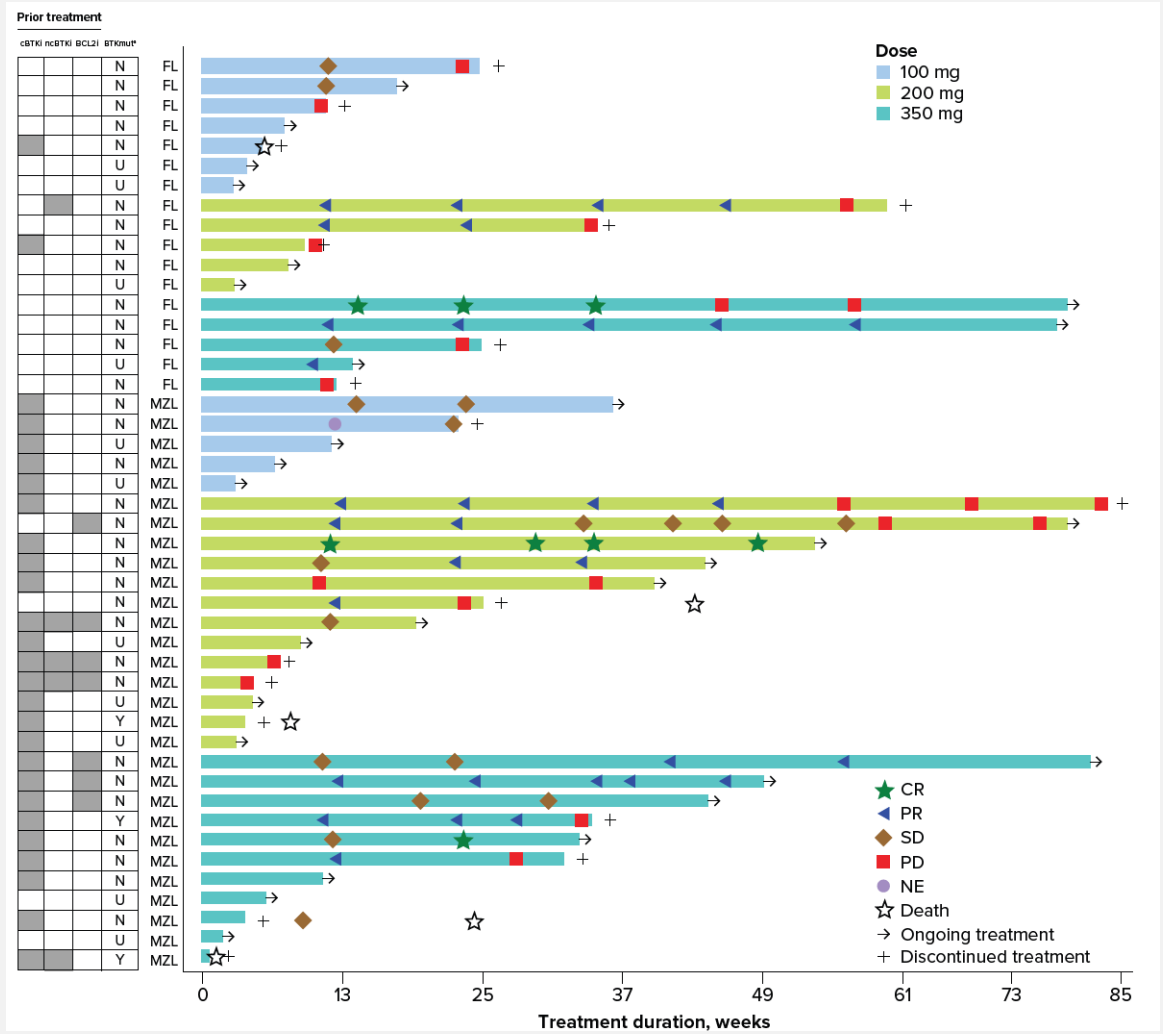
- In response-evaluable patients, the investigator-assessed ORR was 50.0% (10/20) in patients with MZL and 41.7% (5/12) in patients with FL
  - Three patients achieved CR (MZL, n=2; FL, n=1)
  - Responses were also seen in patients with MZL who had previously received a covalent BTK inhibitor (8/18)
- The disease control rate was 75.0% (15/20) in patients with MZL and 66.7% (8/12) in patients with FL

Patients, n (%)	FL (n=12)	MZL (n=20)
Best overall response, n (%)		
CR	1 (8.3)	2 (10.0)
PR	4 (33.3)	8 (40.0)
SD	3 (25.0)	5 (25.0)
PD	3 (25.0)	3 (15.0)
ORR, n (%)[a]	5 (41.7)	10 (50.0)
Disease control rate, n (%)[b]	8 (66.7)	15 (75.0)
Time to first response, median (range), months[c]	2.6 (2.3-3.3)	2.9 (2.6-9.9)
Duration of response, median (95% CI), months[c]	9.5 (5.7-NE)	10.8 (2.8-NE)

Data cutoff: March 3, 2025.
[a]Includes best overall responses of PR or CR. [b]Includes best overall responses of SD or better. [c]In patients with best overall response better than SD.
BTK=Bruton tyrosine kinase, CR=complete response, FL=follicular lymphoma, MZL=marginal zone lymphoma, NE=not estimable, NHL=non-Hodgkin lymphoma, ORR=overall response rate, PD=progressive disease, PR=partial response, SD=stable disease.
Zinzani PL, et al. Poster Presentation at ICML 2025; 436.

Treatment Duration and Response

R/R FL and MZL



Data cutoff: March 3, 2025.
[a]BTK mutation status is classifed as yes (Y), no (N), or unknown (U).
BCL2i=B-cell lymphoma 2 inhibitor, BTK=Bruton tyrosine kinase, BTKmut=mutated BTK, cBTKi=covalent BTK inhibitor, CR=complete response, FL=follicular lymphoma, MZL=marginal zone lymphoma, ncBTKi=noncovalent BTKi, NE=not estimable, NHL=non-Hodgkin lymphoma, PD=progressive disease, PR=partial response, SD=stable disease
Zinzani PL, et al. Poster Presentation at ICML 2025; 436.

BGB-11417-201

Sonrotoclax Monotherapy in R/R MCL

BGB-11417-201

Baseline Characteristics

Parameters	Sonrotoclax 320 mg (n=115)
Age, median (range), years	68 (39-85)
≥65 years, n (%)	74 (64.3)
Male, n (%)	87 (75.7)
Race, n (%)	
Asian	45 (39.1)
Black or African American	3 (2.6)
White	61 (53.0)
Other/not reported	6 (5.2)
Ethnicity, n (%)	
Not Hispanic or Latino	87 (75.7)
Hispanic or Latino	25 (21.7)
ECOG performance status, n (%)	
0	34 (29.6)
1	74 (64.3)
2	7 (6.1)
Disease stage at study entry, n (%)	
III	11 (9.6)
IV	90 (78.3)
Disease status to last prior therapy, n (%)	
Refractory[a]	100 (87.0)
Relapsed[b]	14 (12.2)
MIPI, n (%)	
High	39 (33.9)
Intermediate	41 (35.7)

Parameters	Sonrotoclax 320 mg (n=115)
Bulky disease status, n (%)	
LDi ≥5 cm	46 (40.0)
LDi ≥10 cm	12 (10.4)
Bone marrow involvement at baseline, n (%)	58 (50.4)
Ki67 status, n/N with known status (%)	
Positive	92/98 (93.9)
≥30%	41/98 (41.8)
TP53 mutation, n/N with known status (%)	27/78 (34.6)
Prior lines of therapy, median (range)	3 (1-8)
≥3 prior lines, n (%)	68 (59.1)
Prior BTK inhibitor treatment, n (%)	115 (100)
≥2 prior BTK inhibitors	22 (19.1)
Prior ASCT, n (%)	17 (14.8)
Prior CAR-T therapy, n (%)	3 (2.6)
Reason for ending last line of anticancer therapy, n (%)	
Progressive disease	79 (68.7)
Treatment completed	17 (14.8)
Toxicity	12 (10.4)
Other	7 (6.1)

Data cutoff: July 18, 2025.
aNon-responsive to last line or progressive disease within 6 months after the last line end date. bInitial treatment response followed by progressive disease >6 months after the last line end date.
ASCT=autologous stem cell transplant, BTK=Bruton tyrosine kinase, CAR-T=chimeric antigen receptor T-cell, LDi=longest diameter, MIPI=Mantle Cell Lymphoma International Prognostic Index.
Wang M, et al. Oral Presentation at ASH 2025;7671.

BGB-11417-201

Safety Summary and Most Common TEAEs

- Sonrotoclax was generally well-tolerated and adverse events were manageable

Patients, n (%)	Sonrotoclax 320 mg (n=115)
Any TEAE	111 (96.5)
Treatment-related	92 (80.0)
Grade ≥3 TEAE	60 (52.2)
Treatment-related	42 (36.5)
Serious TEAE	43 (37.4)
Treatment-related	20 (17.4)
Leading to death	15 (13.0)
Treatment-related	4 (3.5)
Leading to treatment discontinuation	16 (13.9)
Leading to treatment modification	31 (27.0)
Dose interruption	31 (27.0)
Dose reduction	1 (0.9)

	Sonrotoclax 320 mg (n=115)	
Patients, n (%)	**Any grade**	**Grade ≥3**
Neutropenia[a]	41 (35.7)	22 (19.1)
Thrombocytopenia[b]	28 (24.3)	11 (9.6)
Anemia[c]	28 (24.3)	9 (7.8)
White blood cell count decreased	25 (21.7)	3 (2.6)
Hyperuricemia	22 (19.1)	0
Hypokalemia	20 (17.4)	0
Pneumonia	18 (15.7)	12 (10.4)
Diarrhea	16 (13.9)	5 (4.3)
AST increased	14 (12.2)	1 (0.9)
ALT increased	12 (10.4)	0
Constipation	12 (10.4)	0
Lymphopenia[d]	12 (10.4)	7 (6.1)
Select TEAEs by category/AE/SOC		
Infections (SOC)	45 (39.1)	19 (16.5)
Febrile neutropenia	2 (1.7)	2 (1.7)
TLS (AE)	8 (7.0)	8 (7.0)

Data cutoff: July 18, 2025.
aIncludes preferred terms neutrophil count decreased, neutropenia, and febrile neutropenia. bIncludes preferred terms thrombocytopenia and platelet count decreased. cIncludes preferred terms anemia and hemoglobin decreased. dIncludes preferred terms lymphocyte count decreased and lymphopenia.
AE=adverse event, ALT=alanine aminotransferase, AST=aspartate aminotransferase, DLT=dose-limiting toxicity, MTD=maximum tolerated dose, QD=once daily, RDI=relative dose intensity, RP2D=recommended phase 2 dose, R/R=relapsed/refractory, SOC=system organ class, TEAE=treatment-emergent adverse event, TLS=tumor lysis syndrome.
Wang M, et al. Oral Presentation at ASH 2025;7671.

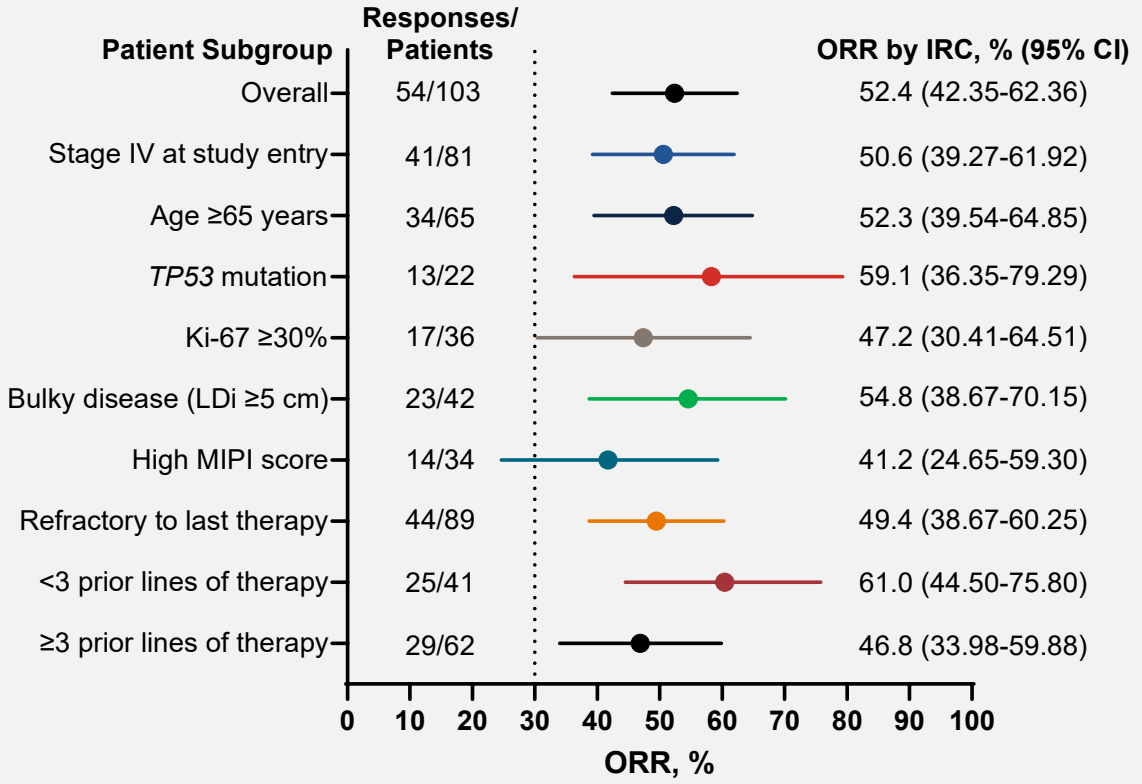
BGB-11417-201

Efficacy for Sonrotoclax at RP2D 320 mg QD

- Primary endpoint was met: relative to the historical control ORR of 30%, IRC-assessed ORR of 52.4% represents a clinically meaningful improvement
- Median study follow-up: 14.2 months (range, 0.3-24.9 months)
- All subgroups with ≥5 patients in part 2 showed a consistent superior ORR benefit relative to the historical control of 30%

	Part 2: Sonrotoclax 320 mg (n=103)	
Parameters	**IRC-assessed**	**INV-assessed**
ORR, n (%)	54 (52.4)	49 (47.6)
95% CI, %	42.4-62.4	37.6-57.6
1-sided P value	<.0001	N/A
CR rate, n (%)	16 (15.5)	23 (22.3)
95% CI, %	9.1-24.0	14.7-31.6
TTR, median (range), months	1.9 (1.6-6.2)	1.9 (1.6-4.0)

IRC-assessed ORR benefit was consistent across patients with high-risk disease subtypes

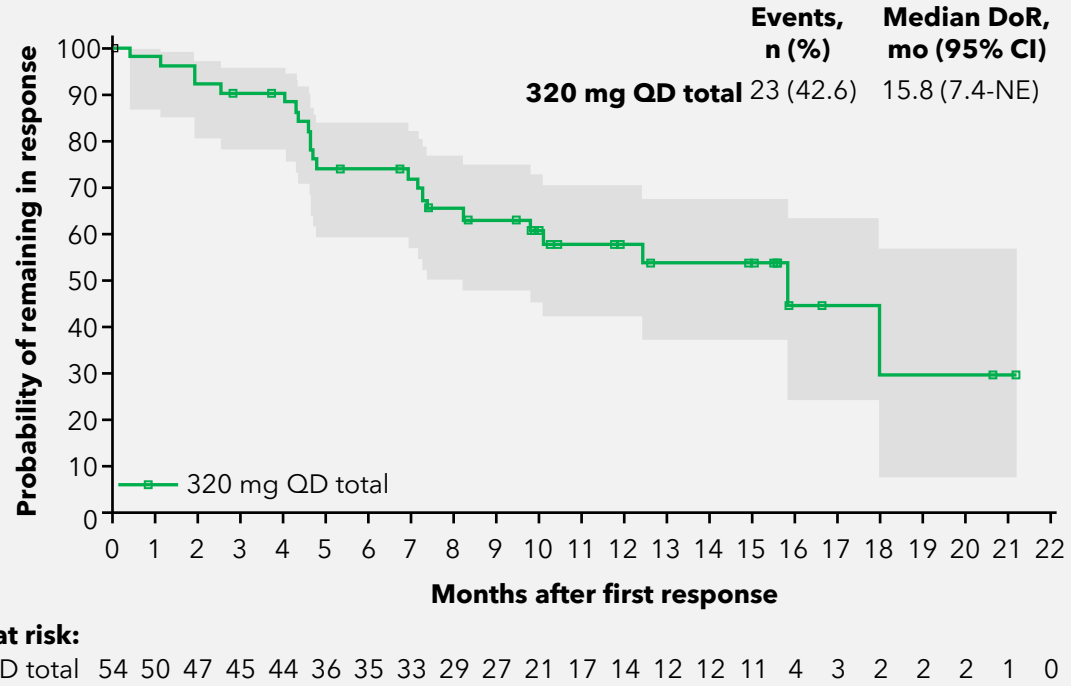


Data cutoff: July 18, 2025.
Dotted line represents the historical control ORR of 30%.
CI=confidence interval, CR=complete response, INV=investigator, IRC=independent review committee, LDi=longest diameter, MIPI=Mantle Cell Lymphoma International Prognostic Index, N/A=not applicable, ORR=overall response rate, QD=once daily, RP2D=recommended phase 2 dose, TTR=time to response.
Wang M, et al. Oral Presentation at ASH 2025;7671.

BGB-11417-201

DoR, PFS, OS

- Promising efficacy in heavily pretreated patients with sonrotoclax 320 mg QD across multiple endpoints
- With a median study follow-up of 14.2 months, patients who received sonrotoclax 320 mg in part 2 demonstrated:
  - Median DoR by IRC was 15.8 months (95% CI, 7.4 months-NE); 63% of patients who responded remained in remission after 9 months
  - Median PFS by IRC was 6.5 months (95% CI, 4.0-10.4 months)
  - Median OS was not reached (95% CI, 14.8 months-NE)



Data cutoff: July 18, 2025.
CI=confidence interval, DoR=duration of response, IRC=independent review committee, NE=not estimable, OS=overall survival, PFS=progression-free survival, QD=once daily, RP2D=recommended phase 2 dose.
Wang M, et al. Oral Presentation at ASH 2025;7671.

CELESTIAL-TN CLL

TN CLL

CELESTIAL-TN CLL Trial Design

Randomized, open-label, phase 3 study comparing sonrotoclax + zanubrutinib vs venetoclax + obinutuzumab in patients with TN CLL.

Phase 3

Study Identifier:
BGB-11417-301; NCT06073821

Primary Endpoint: PFS (IRC; iwCLL 2018)

Key Secondary Endpoints: CRR[a] (IRC and investigator), rates of uMRD4 (BM and PB)[b], OS, PFS (investigator), ORR (IRC, investigator), DoR (IRC, investigator), PROs, safety and tolerability

Key eligibility criteria

- Age ≥18 years
- Confirmed CLL diagnosis, no previous treatment
- Measurable disease by CT/MRI
- ECOG PS of 0-2
- Adequate BM and organ function
- No history of, or currently suspected, Richter's transformation

Stratification factors

- Age (<65 vs ≥65 years)
- IGHV status
- del(17p)/TP53 mutation status

Screening

R 1:1

Zanubrutinib lead-in (3 cycles) followed by Sonrotoclax + zanubrutinib (12 cycles) (n=~320)

Venetoclax (12 cycles) + obinutuzumab (6 cycles) (n=~320)

Efficacy will be assessed in accordance with 2018 iwCLL guidelines[1] with modification of treatment-related lymphocytosis for patients with CLL.[2]

[a]Defined as CR or CR with incomplete recovery. [b]At <10-4 sensitivity at the first post-treatment follow-up based on next-generation sequencing by clonoSEQ® and flow cytometry.

1. Hallek M, et al. *Blood*. 2018;131:2745-2760; 2. Cheson BD, et al. *J Clin Oncol*. 2012;30:2820-2822.

BM=bone marrow, CLL=chronic lymphocytic leukemia, CR=complete response, CRR=complete response rate, DoR=duration of response, ECOG=Eastern Cooperative Oncology Group, INV=investigator, IRC=independent review committee, ORR=overall response rate, OS=overall survival, PB=peripheral blood, PFS=progression-free survival, PS=performance status, R=randomized, uMRD=undetectable minimal residual disease.

Patten P, et al. Poster Presentation at ASH 2024;3257.1.

Study Status

CELESTIAL-TN Trial in Progress

CELESTIAL-TN CLL Study Sites (Planned)

- Enrollment for CELESTIAL-TNCLL began in December 2023, and the study is currently recruiting
- Approximately 230 study sites in 20 countries are planned, with an estimated enrollment of 640 patients. In the Americas, there are approximately 50 sites in the US, 6 in Brazil and 15 in Canada

Patten P, et al. Poster Presentation at ASH 2024;3257.1.