# BGB-11417-201

## Sonrotoclax Monotherapy in R/R MCL

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# 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.

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# 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.

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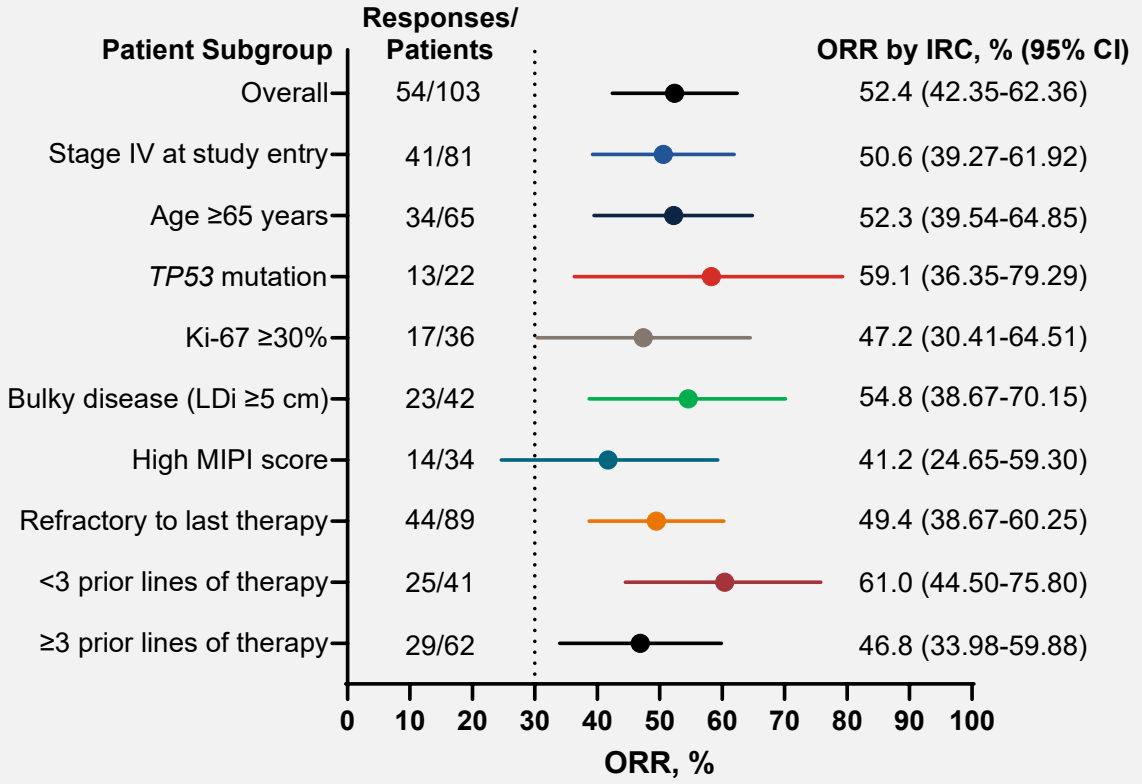
# Efficacy for Sonrotoclax at RP2D 320 mg QD

- 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.

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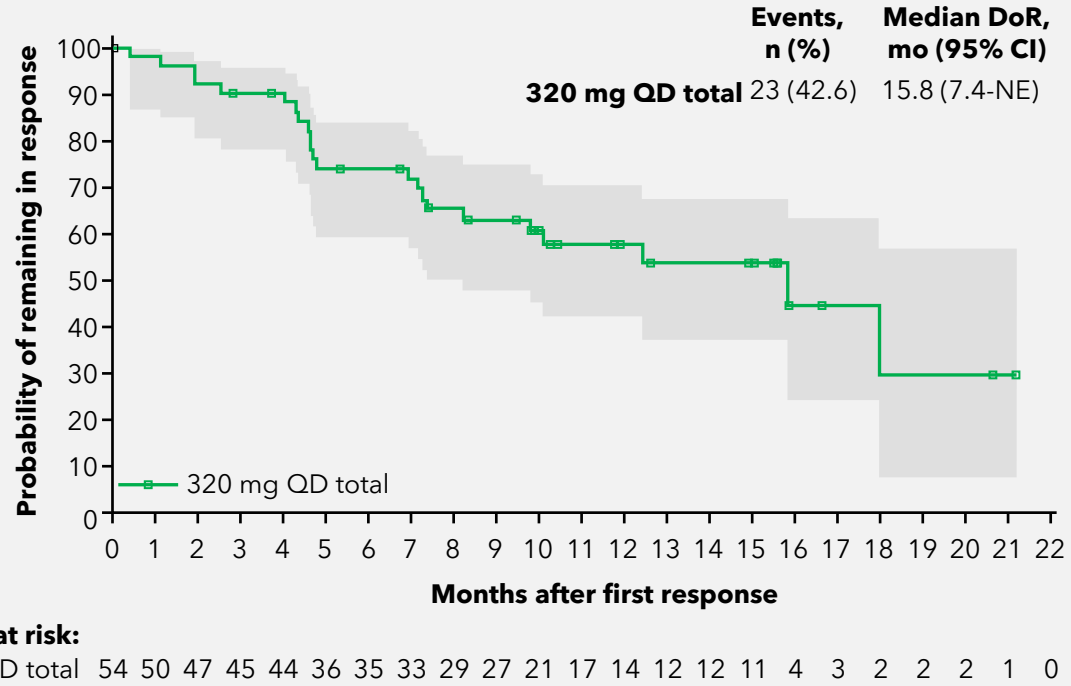
# DoR, PFS, OS

- 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.