

Phase I/II BGB-11417-201 primary analysis:
Sonrotoclax monotherapy in R/R MCL

Population: N = 125

Part 1: n = 22

Part 2: n = 103

Eligibility: Aged ≥18 years, histologically confirmed MCL per WHO 2016 classification, ECOG PS 0–2, ≥1 line of anti-CD20-based therapy and ≥1 BTKi, and no prior BCL-2i

TRIAL DESIGN (NCT05471843)

PART 1A + 1B

Dose escalation and safety expansion

Primary endpoint: DLTs (Part 1A), TEAEs, SAEs, AEs leading to discontinuation, TLS events

Sonrotoclax

Target dose 1 (n = 10)
160 mg QD

Target dose 2 (n = 12)
320 mg QD

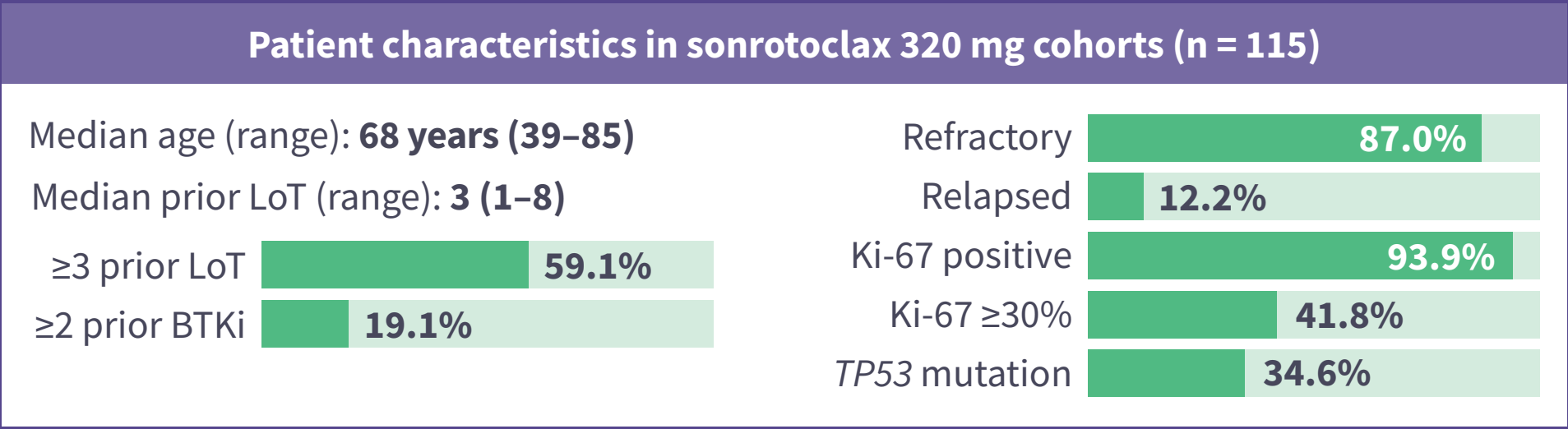
PART 2

Efficacy expansion

Primary endpoint: ORR by IRC

Sonrotoclax

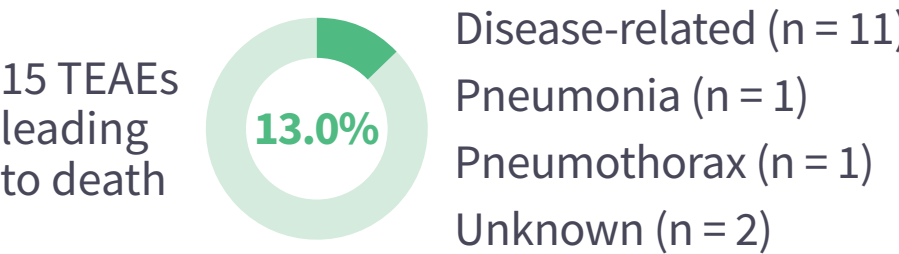
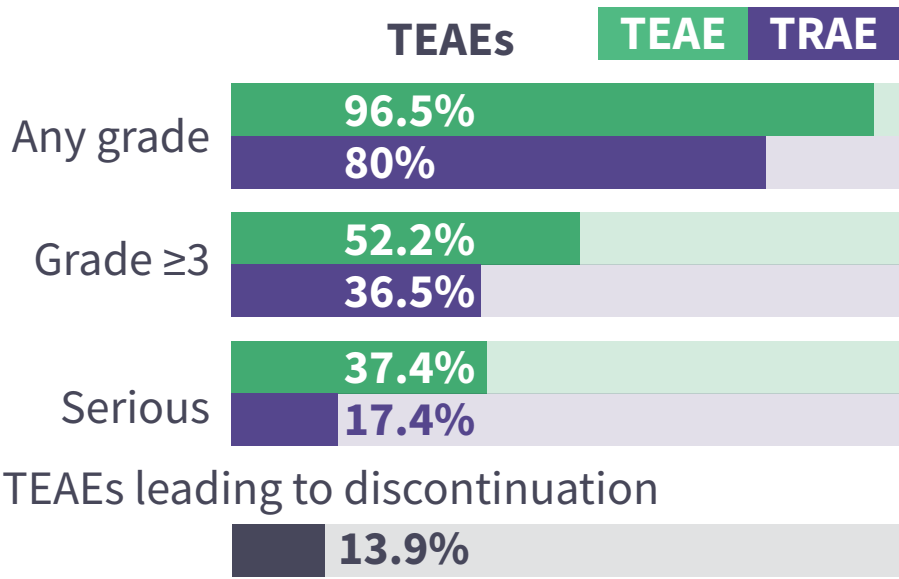
RP2D | 320 mg QD until PD



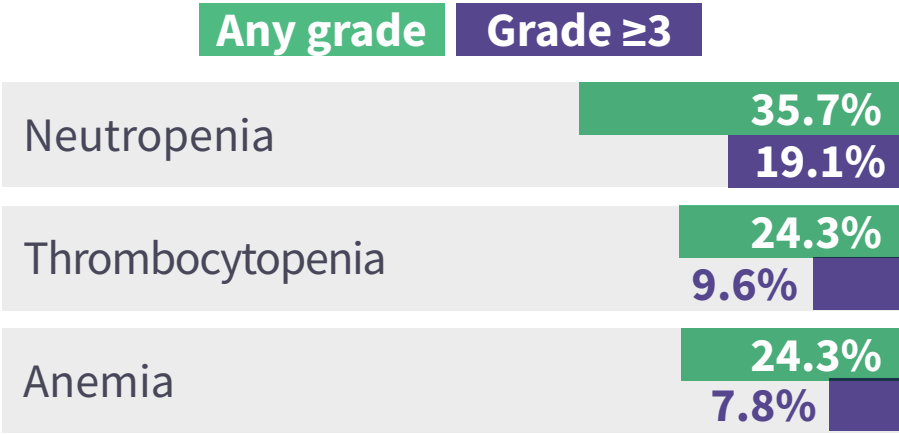
SAFETY

Part 1 + 2 – Sonrotoclax 320 mg cohorts (n = 115)

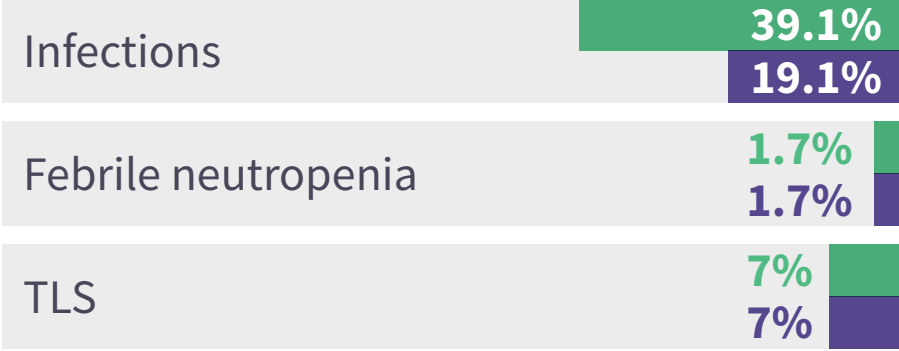
In Part 1, no DLTs were observed, and the MTD was not reached. Sonrotoclax 320 mg QD was selected as the RP2D.



Most common TEAEs



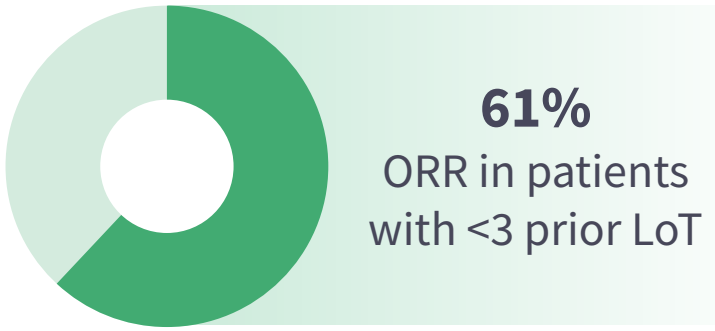
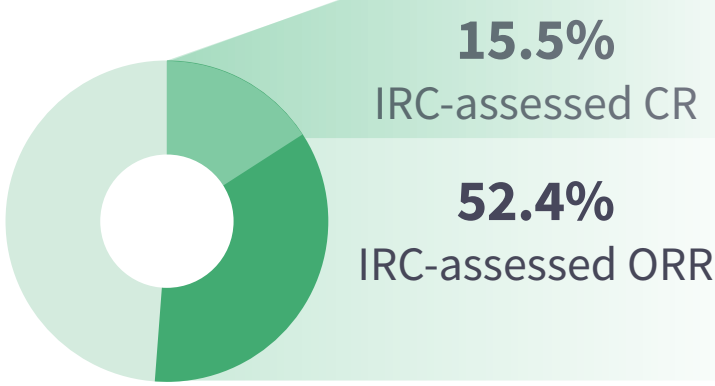
Select TEAEs



EFFICACY

Part 2 – Sonrotoclax 320 mg cohort (n = 103)

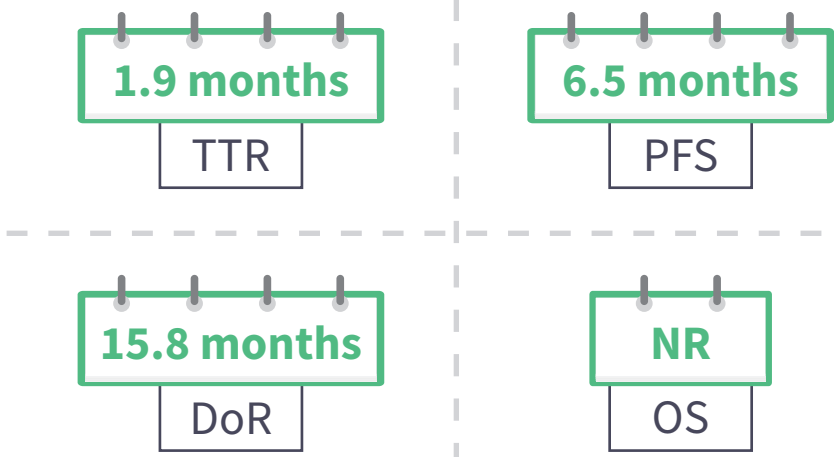
Primary endpoint was met:
Relative to historical control ORR of 30%, IRC-assessed ORR of 52.4% represents a clinically meaningful improvement.



The ORR benefit was consistent across high-risk subgroups.

Median follow-up: 14.2 months

Median outcomes



Sonrotoclax monotherapy demonstrated clinical benefit and a manageable safety profile in heavily pretreated patients with MCL. Sonrotoclax + zanubrutinib for R/R MCL is being evaluated in the ongoing phase III CELESTIAL-RRMCL trial (NCT06742996).

AE, adverse event; BCL-2i, B-cell lymphoma-2 inhibitor; BTKi, Bruton’s tyrosine kinase inhibitor; CR, complete response; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, independent review committee; LoT, line of therapy; MCL, mantle cell lymphoma; MTD, maximum tolerated dose; NR, not reached; ORR, overall response rate; OS, overall survival; PD, progression of disease; PFS, progression-free survival; QD, daily; RP2D, recommended phase II dose; R/R, relapsed/refractory; SAE, serious AE; TEAE, treatment-emergent AE; TLS, tumor lysis syndrome; TRAE, treatment-related AE; TTR, time to response; WHO, World Health Organization.

Wang M. Oral Abstract #663. 67th ASH Annual Meeting and Exposition; Dec 6–9, 2025; Orlando, US.