Phase 1/2 Study of Sonrotoclax (BGB-11417) Monotherapy in Bruton Tyrosine Kinase (BTK) Inhibitor–Pretreated Relapsed/Refractory (R/R) Mantle Cell Lymphoma (MCL): A Chinese Subpopulation Analysis

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Background: MCL is a rare, incurable subtype of B-cell non-Hodgkin lymphoma. Sonrotoclax (sonro), a next-generation B-cell lymphoma 2 (BCL2) inhibitor, is a more selective and pharmacologically potent BCL2 inhibitor than venetoclax, with a shorter half-life and no drug accumulation. BGB-11417-201 (NCT05471843) is an ongoing global, open-label, phase 1/2 study. In the global population, sonro was well tolerated, and patients (pts) receiving sonro (n=103) had a significantly higher overall response rate (ORR; 52.4%) vs the historic control (30%; *P*<.0001), meeting the primary endpoint.

Aims: To report phase 1/2 data for sonro monotherapy in patients in China with BTK inhibitor–pretreated R/R MCL from BGB-11417-201.

Methods: Eligible adults had R/R MCL and previous exposure to ≥1 anti-CD20–based therapy and ≥1 BTK inhibitor. Pts received once daily oral sonro in the part 1 dose-escalation and safety expansion (160 mg or 320 mg) and the part 2 efficacy expansion (320 mg) via gradual ≈4-wk ramp-up. This subgroup analysis in pts in China evaluated safety (parts 1 and 2) and efficacy endpoints (part 2) including ORR assessed by independent review committee (IRC) or investigator (INV), time to response (TTR), duration of response (DOR), progression-free survival (PFS), and overall survival (OS).

Results: As of July 18, 2025, 55 pts in China were enrolled and assigned to sonro 160-mg (n=10) or 320-mg (part 1, n=11; part 2, n=34) cohorts. Results in the 320-mg cohort (n=45) are reported. Median study follow-up was 14.1 (range, 0.1-28.7) mo. Median age was 66 y and 73% were male. At study entry, 89% of pts had stage III/IV MCL, 27% had bulky disease (longest diameter ≥5 cm), 64% had an intermediate/high simplified MCL International Prognostic Index, and 24% had *TP53* mutation. The median number of

prior lines of therapy was 2 (range, 1-8); 47% of pts received ≥3 prior therapies, 20% had ≥2 prior BTK inhibitors, and 80% discontinued their last therapy due to progression. Pt characteristics were generally similar in the global and China population.

In part 2 (n=34), efficacy outcomes by IRC and INV were similar (**Table**). The ORR-IRC was 62%. Median TTR-IRC was 1.8 mo; median DOR-IRC was 15.8 mo. Median PFS-IRC was 11.9 mo; median OS was not reached. As in the global population, clinically meaningful ORR, DOR, and TTR results were observed.

For pts in China who received sonro 320 mg in parts 1 and 2 (n=45), neutrophil count decreased was the most common any-grade (53%) and grade ≥3 TEAE (20%). At cutoff, 27% of pts continued on treatment and 58% discontinued treatment due to disease progression. Serious TEAEs were observed in 27%, most commonly pneumonia and platelet count decreased (each 7%). TEAEs led to treatment discontinuation in 4 pts (9%) and death in 2 (4%; multi-organ disorder and respiratory failure; both assessed as related to disease under study and study treatment). Tumor lysis syndrome (TLS) occurred in 3 pts (7%; 2 laboratory and 1 clinical; all transient and resolved without sequelae). No TLS led to treatment discontinuation. The incidences of grade ≥3 and serious TEAEs and TEAEs leading to death or treatment discontinuation/modification were generally similar in pts in China vs the global population.

Summary/Conclusion: As in the global population, sonro monotherapy demonstrated meaningful clinical activity and a manageable safety profile in pts in China with R/R MCL. A global phase 3 trial evaluating sonro + zanubrutinib in pts with R/R MCL (NCT06742996) is ongoing.

Table. Part 2 Efficacy Endpoints in a Subpopulation of Patients in China With R/R MCL Receiving Sonrotoclax Monotherapy

	Sonrotoclax 320 mg total n=34	
	Assessed by IRC	**Assessed by INV**
ORR, n (%)[a] 95% CI, %[b]	21 (61.8) 43.6-77.8	19 (55.9) 37.9-72.8
CRR, n (%)[c] 95% CI, %[b]	9 (26.5) 12.9-44.4	12 (35.3) 19.7-53.5
TTR, median (range), months	1.8 (1.7-3.5)	1.8 (1.7-3.7)
DOR, median (95% CI), months Follow-up, median (95% CI), months	15.8 (7.4-NE) 15.6 (10.2-20.6)	17.2 (7.4-NE) 15.6 (10.2-20.6)
PFS, median (95% CI), months Follow-up, median (95% CI), months	11.9 (6.3-19.8) 17.4 (12.0-22.8)	9.0 (1.7-19.8) 17.4 (12.1-22.8)
OS, median (95% CI), months Follow-up, median (95% CI), months	NE (7.7-NE) 18.7 (16.2-21.0)	

Medians estimated by the Kaplan-Meier method with 95% CIs estimated using the Brookmeyer and Crowley method with log-log transformation unless otherwise specified. [a]Overall response included patients who achieved a best overall response of CR or PR per the Lugano classification. [b]The 95% CI was estimated using the Clopper-Pearson method. [c]Complete response includes patients who achieved a best overall response of CR.

CR, complete response; CRR, complete response rate; DOR, duration of response; INV, investigator; IRC, independent review committee; NE, not evaluable; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; TTR, time to response.