

Frontline Treatment of Sonrotoclax (BGB-11417) + Zanubrutinib for CLL/SLL Demonstrates High uMRD Rates With Favorable Tolerability: Updated Data From BGB-11417-101, An Ongoing Phase 1/1b Study

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CONCLUSIONS

- Sonrotoclax in combination with zanubrutinib was generally safe and well tolerated, with a median relative dose intensity of 99% across all dose levels
 - No cases of laboratory or clinical tumor lysis syndrome occurred
 - Majority of TEAEs were low grade; low rates of transient gastrointestinal TEAEs, predominantly grade 1, were observed
 - The most common grade ≥3 TEAE was neutropenia, which was transient and did not lead to higher rates of grade ≥3 infections
 - No fatal TEAEs, no complicated COVID-19 case or death
- Substantial efficacy was observed in this all-comer TN CLL/SLL population, including in patients with high-risk features
 - Sonrotoclax + zanubrutinib demonstrated a high response rate, including 100% ORR across all dose levels
 - With median follow-up of 30.7 months, no PFS events have been observed at the sonrotoclax RP2D of 320 mg
 - High blood uMRD4 rates were achieved early, with a median time to uMRD of 7.2 months, that continued to deepen over time with a best uMRD rate of 98% at data cutoff in the 320-mg cohort
 - No patient has progressed from uMRD4 to MRD4+ across both dose cohorts at data cutoff
- Sonrotoclax 320 mg in combination with zanubrutinib is currently being evaluated in patients with TN CLL in the phase 3 study, CELESTIAL-TNCLL (NCT06073821)

RESULTS

- As of August 29, 2025, a total of 137 patients were enrolled in the sonrotoclax 160-mg (n=51) and 320-mg (n=86) cohorts (**Figure 2**)
 - At the data cutoff date, 47% of patients (n=64) remained on treatment
 - Most sonrotoclax discontinuations (85%; 61/72) were protocol-defined elective discontinuations after 96 weeks of sonrotoclax target dose
- Median study follow-up across cohorts was 30.7 months (range, 3.1-45.5 months)

Figure 2. Patient Disposition

Discontinued sonrotoclax (n=32)

- Elective stopping (n=27)
- AE (n=2)
- Consent withdrawal (n=1)
- Physician decision (n=1)
- PD (n=1)

Discontinued sonrotoclax (n=40)

- Elective stopping (n=34)
- AE (n=3)
- Consent withdrawal (n=2)
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On treatment

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Enrolled

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