

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 uMRD (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

Treatment

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

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

Screening

R 1:1

Efficacy will be assessed in accordance with 2018 iwCLL guidelines¹ with modification of treatment-related lymphocytosis for patients with CLL.²

^aDefined as CR or CR with incomplete recovery. ^bAt <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.

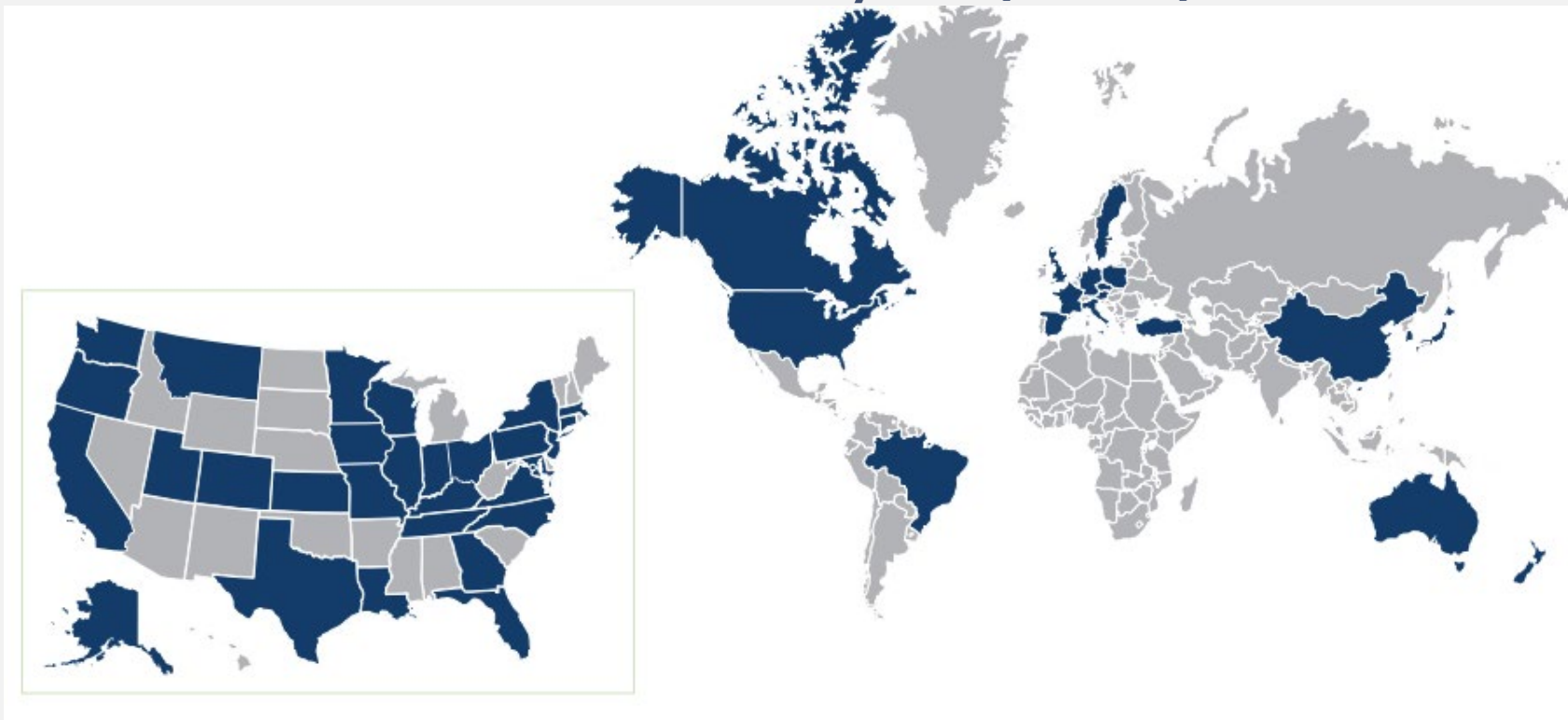
Patten P, et al. Poster Presentation at ASH 2024;3257.1.

Study Status



CELESTIAL-TN Trial in Progress

CELESTIAL-TN CLL Study Sites (Planned)



- Enrollment for CELESTIAL-TN CLL 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