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ORAL ABSTRACTS

642.CHRONIC LYMPHOCYTIC LEUKEMIA: CLINICAL AND EPIDEMIOLOGICAL

Lisocabtagene Maraleucel (liso-cel) in R/R CLL/SLL: 24-Month Median Follow-up of TRANSCEND CLL 004

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Background:Patients with R/R CLL/SLL who experience intolerance to or disease progression after Bruton tyrosine kinase inhibitor (BTKi) and venetoclax treatment have no established standard of care and poor outcomes, indicating a critical unmet need. Liso-cel, an autologous, CD19-directed, 4-1BB CAR T cell product, has demonstrated efficacy in large B-cell lymphoma and CLL/SLL. In the primary analysis of the phase 1/2, single-arm, multicenter TRANSCEND CLL 004 (NCT03331198) study, a single administration of liso-cel demonstrated rapid, deep, and durable responses and a manageable safety profile in patients with R/R CLL/SLL, including those with progression on previous BTKi and venetoclax failure (Siddiqi T, et al. *Lancet* 2023). The primary endpoint was met in the prespecified subset of efficacy-evaluable patients with disease progression on BTKi and venetoclax failure (primary efficacy analysis set [PEAS]) at a target dose of 100 × 10^6 CAR^+ T cells (null hypothesis: ≤ 5%) with the rate of complete response/remission (CR) and CR with incomplete marrow recovery (CRi) by an independent review committee (IRC) per 2018 International Workshop on CLL (iwCLL) criteria at 18.4% ($P = 0.0006$). Here we report results from TRANSCEND CLL 004 with a median follow-up of 23.5 months.
Methods: Patients must have received ≥ 2 prior lines of therapy, including a BTKi. Eligible patients received liso-cel at a target dose of either 50 × 10^6 (dose level [DL] 1) or 100 × 10^6 (DL2) CAR^+ T cells after lymphodepleting chemotherapy. The primary endpoint was CR/CRi in the PEAS at DL2. Key secondary endpoints were ORR and rate of undetectable MRD (uMRD; 10^{-4} by next-generation sequencing) in blood. All null hypotheses were tested at the primary analysis and not retested in this analysis.
Results:Of 137 leukapheresed patients, 118 received liso-cel (safety set), 97 (DL1 = 9; DL2 = 88) were efficacy evaluable, and 54 (DL1 = 4; DL2 = 50) were in the PEAS. In the safety set, median (range) age was 65 years (49-82), 83% had high-risk cytogenetics (del[17p], 42%; *TP53* mutation, 47%; unmuted immunoglobulin heavy-chain variable gene, 47%; ≥ 3 chromosomal aberrations, 61%), median (range) lines of prior therapy was 5 (2-14), and all patients had prior BTKi. As of data cutoff (February 28, 2023), median (range) on-study follow-up was 23.5 months (0.4-59.6) for the safety set. In the PEAS at DL2, CR/CRi rate was 20% (95% CI, 10.0-33.7; Table 1). ORR was 44% (95% CI, 30.0-58.7). One patient who had best overall response (BOR) of partial

response/remission (PR) at primary analysis had deepened to CR/CRi at 18 months without any additional therapy. Of 9 patients who had BOR of CR/CRi at the primary analysis, 8 had ongoing CR/CRi and 1 completed the study with the last assessment as CR/CRi. The uMRD rate was 64% (95% CI, 49.2-77.1) in blood and 60% (95% CI, 45.2-73.6) in marrow. Median (95% CI) duration of response was 35.3 months (12.4-not reached [NR]) and median duration of CR/CRi was NR. Median (95% CI) PFS was 11.9 months (5.7-26.2). Median (95% CI) OS was 30.3 months (15.0-NR). The efficacy outcomes were similar in the full population at DL2. Of 16 patients who had BOR of CR/CRi at primary analysis, 10 had ongoing CR/CRi. In the safety set, rates of any-grade and grade $\geq$ 3 treatment-emergent AEs were similar across age groups (Table 2). The rate of any-grade cytokine release syndrome (CRS) was 85% (grade 3, 8%; no grade 4/5) and neurological events (NE) was 45% (grade 3, 18%; grade 4, 1%; no grade 5); 69% received tocilizumab and/or corticosteroids for CRS/NEs. Median (range) time to onset and resolution was 4 days (1-18) and 6 days (2-37) for CRS and 7 days (1-21) and 7 days (1-83) for NEs, respectively. Prolonged cytopenia (grade $\geq$ 3 at Day 30 after liso-cel infusion), grade $\geq$ 3 infections, hypogammaglobulinemia, tumor lysis syndrome, second primary malignancy, and macrophage activation syndrome occurred in 54%, 18%, 15%, 11%, 9%, and 3%, respectively. Forty-five (33%) of 137 leukapheresed patients died after liso-cel infusion (disease progression, n = 27 [20%]; AE, n = 6 [4%]; other reasons, n = 12 [9%]).
Conclusions: With longer follow-up, liso-cel continued to demonstrate durable CR/CRi, high uMRD rates, and a manageable safety profile in patients with heavily pretreated, high-risk R/R CLL/SLL. The safety results from longer follow-up were similar to those reported in the primary analysis with no new safety signals and were consistent across age groups.

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Table 1. Efficacy outcomes at DL2[a]

	Full population (n = 88)	PEAS (n = 50)[b]
Primary endpoint: IRC-assessed CR/CRi rate (95% CI),[c] %	19.3 (11.7–29.1) n = 17	20.0 (10.0–33.7) n = 10
Key secondary efficacy endpoints		
IRC-assessed ORR (95% CI),[c] %	47.7 (37.0–58.6) n = 42	44.0 (30.0–58.7) n = 22
uMRD rate in blood (95% CI),[c] %	65.9 (55.0–75.7) n = 58	64.0 (49.2–77.1) n = 32
uMRD rate in marrow (exploratory endpoint, 95% CI),[c] %	60.2 (49.2–70.5) n = 53	60.0 (45.2–73.6) n = 30
Other secondary efficacy endpoints		
Median (range) time to first response, months	1.3 (0.8–17.4)	1.1 (0.8–17.4)
Median (range) time to first CR/CRi, months	5.5 (0.8–18.0)	2.1 (0.8–18.0)
Median (95% CI) duration of response,[d] months	35.3 (24.0–NR)	35.3 (12.4–NR)
Median (95% CI) duration of CR/CRi,[d] months	NR	NR
Median (95% CI) PFS,[d] months	17.9 (9.4–26.9)	11.9 (5.7–26.2)
Median (95% CI) OS,[d] months	43.2 (27.1–NR)	30.3 (15.0–NR)

[a]Response was assessed per iwCLL 2018 criteria. CR/CRi and PR/nodular PR must be confirmed with repeat assessment ≥ 8 weeks later; [b]At primary analysis, the conforming status of CAR T cell product for 1 patient was not available; therefore, the patient was not included in the efficacy and safety analyses. Afterwards, it was confirmed that the patient received liso-cel and was included in these analyses with 24-month median follow-up. This patient achieved PR/nodular PR; [c]Two-sided 95% exact Clopper-Pearson CI; [d]Kaplan-Meier method was used to obtain 2-sided 95% CI.

Table 2. Safety outcomes (DL1 + DL2)

	Total (n = 118)		Age < 65 y (n = 58)		Age ≥ 65 y and < 75 y (n = 49)		Age ≥ 75 y (n = 11)	
	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3
TEAE, n (%)	118 (100)	109 (92)	58 (100)	52 (90)	49 (100)	47 (96)	11 (100)	10 (91)
Most common (any grade in ≥ 25% of total patients), n (%)								
CRS[a]	100 (85)	10 (8)	50 (86)	3 (5)	39 (80)	7 (14)	11 (100)	0
Anemia	79 (67)	62 (53)	38 (66)	30 (52)	33 (67)	26 (53)	8 (73)	6 (55)
Neutropenia	73 (62)	71 (60)	36 (62)	35 (60)	31 (63)	30 (61)	6 (55)	6 (55)
Thrombocytopenia	59 (50)	49 (42)	27 (47)	22 (38)	31 (63)	21 (43)	6 (55)	6 (55)
Fatigue	41 (35)	8 (7)	21 (36)	2 (3)	19 (39)	6 (12)	1 (9)	0
Nausea	40 (34)	0	19 (33)	0	16 (33)	0	5 (45)	0
Diarrhea	35 (30)	2 (2)	19 (33)	0	12 (24)	2 (4)	4 (36)	0
Headache	34 (29)	1 (1)	20 (34)	0	12 (24)	1 (2)	2 (18)	0
Leukopenia	34 (29)	31 (26)	16 (28)	13 (22)	12 (24)	12 (24)	6 (55)	6 (55)
Hypokalemia	33 (28)	2 (2)	14 (24)	1 (2)	14 (29)	0	5 (45)	1 (9)
Pyrexia	33 (28)	1 (1)	19 (33)	0	11 (22)	1 (2)	3 (27)	0
Confusional state	31 (26)	11 (9)	8 (14)	2 (3)	16 (33)	7 (14)	7 (64)	2 (18)
Hypocalcemia	31 (26)	5 (4)	16 (28)	2 (3)	10 (20)	1 (2)	5 (45)	2 (18)
Decreased appetite	30 (25)	5 (4)	15 (26)	2 (3)	12 (24)	3 (6)	3 (27)	0
Dizziness	30 (25)	0	15 (26)	0	15 (31)	0	0	0

[a]CRS was graded based on the Lee 2014 criteria.
TEAE, treatment-emergent adverse event.

Figure 1

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