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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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