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A Multicenter, Phase 1 Study of KITE-753 in Patients With Relapsed/ Refractory B-Cell Lymphoma: Updated Safety and Efficacy Results

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Objective

- To report updated safety and efficacy results of KITE-753 in patients with R/R B-cell lymphoma from Phase 1 of the PALISADES-1 open-label, multicenter trial (NCT04989803)

Conclusions

- KITE-753, built on a unique construct and using a rapid manufacturing process that preserves a naive T-cell phenotype, showed promising efficacy and safety in R/R B-cell lymphoma at the highest dose level:
  - High ORR of 89% and CR rate of 78% in CAR-naive patients (post-data cutoff, March 16, 2026)
  - A 6-month CR rate of 71% among CAR-naive patients (post-data cutoff, April 3, 2026), an endpoint validated as a surrogate for long-term outcomes[1]
  - A favorable safety profile consisting of only low-grade CRS and ICANS
- Favorable pharmacokinetic and pharmacodynamic profiles were observed with KITE-753 at the highest dose level, which may reflect the optimized CAR T-cell dose that mitigates toxicity and rapid manufacturing process that preserves CAR T-cell fitness
- The results of this study support the continued development of KITE-753
  - Additional dose expansion cohorts of PALISADES-1 Phase 1 in 1L LBCL and R/R MCL are currently open
  - Phase 2 of PALISADES-1 aims to evaluate the efficacy of KITE-753 at the RP2D (2×10^5 CAR T cells/kg) in patients with R/R LBCL after ≥2 lines of therapy; this trial is open and currently enrolling patients globally

Plain Language Summary

KITE-753 is a type of anticancer treatment called **chimeric antigen receptor (CAR) T-cell therapy** that is made from a person's own immune cells. It uses a new, unique approach to kill cancer cells by targeting multiple parts of each cell.

This clinical trial looked at how safe and well KITE-753 worked for people with a type of blood cancer called **B-cell lymphoma**.

This study showed that KITE-753 treatment had low rates of severe side effects, including a common side effect of CAR T-cell therapies called **ICANS**.

After treatment with KITE-753 at the highest dose of therapy, most people had their cancer go away partially or completely.

Words in **bold text** are defined in the glossary that is accessible through the QR code.

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Table 1. Baseline Patient and Disease Characteristics

Characteristic		All Treated Patients (N=34)	Dose Level 3 (n=23)
Patient Characteristics	Median age (range), years	60 (25-84)	61 (28-80)
	≥65 years / ≥75 years, n (%)	16 (47) / 8 (24)	11 (48) / 7 (30)
	Male, n (%)	23 (68)	15 (65)
	ECOG performance status 1, n (%)	21 (62)	14 (61)
Disease Characteristics	Stage III/IV disease at study entry, n (%)	26 (76)	16 (70)
	Bulky disease (≥7.5 cm), n (%)	7 (21)	5 (22)
	Double- or triple-hit status (LBCL only), n/N (%)	4/30 (12)	3/21 (13)
	IPI score 3-4 (LBCL only), n/N (%)	6/30 (20)	5/21 (24)
	Elevated pretreatment LDH, n (%)	17 (50)	12 (52)
	Mean SPD at enrollment, mm^2 (SD)	3062 (2756)	2771 (2678)
Treatment History	Median lines of prior therapy, n (range)	2 (1-7)	2 (1-7)
	1 prior line (primary refractory)[a] / ≥2 prior lines, n (%)	9 (26) / 25 (74)	7 (30) / 16 (70)
	Prior anti-CD19 CAR T-cell therapy, n (%)	10 (29)	5 (22)
Bridging Therapy	Bridging therapy received (steroids ± RT),[b] n (%)	12 (35)	9 (39)
	Steroids only / Radiation only / Steroids + radiation	8 (24) / 2 (6) / 2 (6)	6 (26) / 2 (9) / 1 (4)
	PR as best response to bridging therapy,[c] n/N (%)	1/12 (8)	0

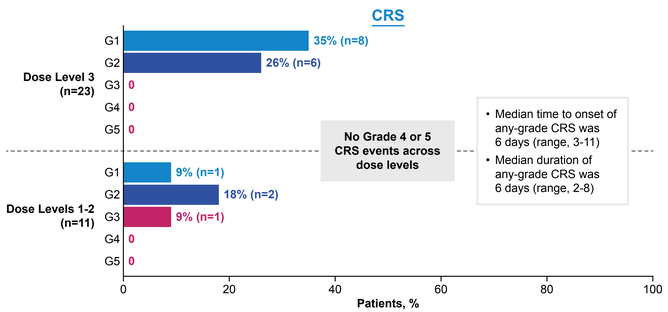
[a] Primary refractory disease was defined as chemorefractory disease in which the best response to 1L therapy was PD, stable disease lasting ≤6 months after ≥4 cycles, or PR after ≤6 cycles.
[b] All eligibility criteria, including presence of measurable disease, must have remained confirmed after bridging therapy and before initiation of lymphodepleting chemotherapy. Corticosteroid bridging therapy ± local RT was administered at the discretion of the investigator; systemic chemoimmunotherapy was not used. [c] No patients had a CR to bridging therapy.

Table 2. Incidence of TEAEs

TEAEs, n (%)	Dose Levels 1-2 (n=11)		Dose Level 3 (n=23)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any	10 (91)	8 (73)	23 (100)	21 (91)[a]
Serious	6 (55)	4 (36)	11 (48)	6 (26)
Cardiac disorders	5 (45)	1 (9)	3 (13)	0 (0)
Heme toxicity	6 (55)	5 (45)	7 (30)	4 (17)
Neutropenia	1 (9)	1 (9)	4 (17)	3 (13)
Anemia	5 (45)	4 (36)	3 (13)	1 (4)
Hypogammaglobulinemia	2 (18)	0 (0)	6 (26)	0 (0)

[a] All Grade 4 events in dose level 3 were heme related.

Figure 1. CRS and ICANS



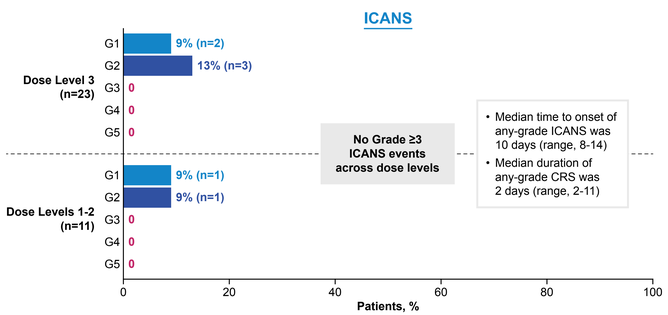
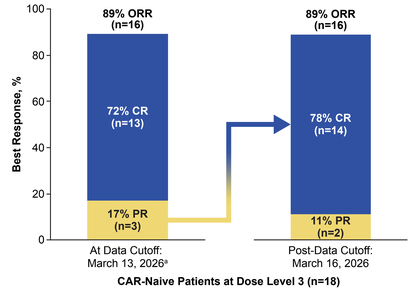
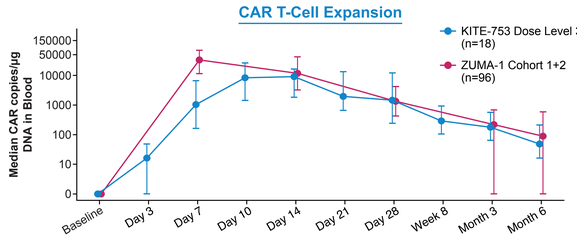


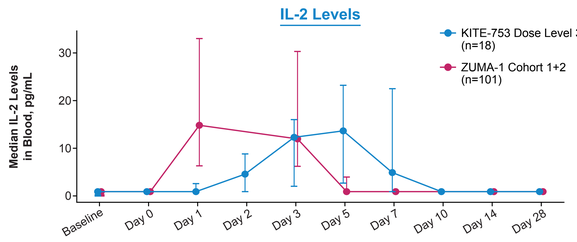
Figure 2. Response in CAR-Naive Patients at Dose Level 3

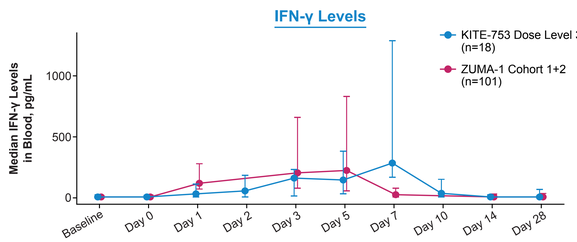


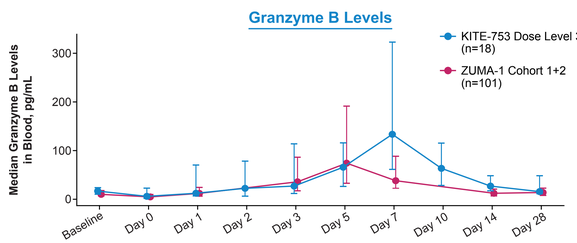
[a] Median follow-up was 9.5 months (range, 3.2-16.2) in dose level 3 (n=23).

Figure 3. CAR T-Cell and Serum Biomarker Kinetics Following KITE-753 and Axi-Cel Infusion[a]









[a] Error bars represent IQR.

BACKGROUND

- CD19 chimeric antigen receptor (CAR) T-cell therapy has substantially improved outcomes for patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL); however, there are limits to its curative potential[2,3]
  - Some patients are refractory to CD19 CAR T-cell therapy and a subset of responders eventually relapse[2,3]
- KITE-753 is an investigational CD19/CD20 CAR T-cell therapy for patients with R/R B-cell lymphoma
- KITE-753 uses a unique bicistronic construct to optimally engage CD19 and CD20 with dual synergistic CD28/4-1BB costimulation that enhances T-cell activation and proliferation, and a rapid manufacturing process that preserves naive and memory T cells (**Figure S1**)
  - Preclinical evidence suggests that combining costimulatory domains can result in superior T-cell performance compared to either domain alone[4,5]
- In an initial analysis of the multicenter PALISADES-1 Phase 1 study of KITE-753 in patients with R/R B-cell lymphoma (4.0 months median follow-up), KITE-753 was previously reported to demonstrate the following[6]:
  - An objective response rate (ORR) of 86% and a complete response (CR) rate of 79% in patients who had not received prior CAR T-cell therapy (CAR-naive) at the highest dose level (n=14)
  - A safety profile of low-grade cytokine release syndrome (CRS) and 2 cases of low-grade immune effector cell-associated neurotoxicity syndrome (ICANS) among patients treated at the highest dose level (n=19)

METHODS

- Patients with B-cell lymphoma R/R after ≥2 lines of therapy or with second-line primary refractory disease were eligible (**Figure S2**)
- Phase 1 of the PALISADES-1 trial included Phase 1a for dose escalation and Phase 1b for dose expansion (LBCL only; **Figure S2**)
- After undergoing leukapheresis and lymphodepleting chemotherapy, patients received KITE-753 at dose level 1 (0.3×10^5 CAR T cells/kg), dose level 2 (1×10^5 CAR T cells/kg), or dose level 3 (2×10^5 CAR T cells/kg; **Figure S3**)
- The primary endpoints were incidence of dose-limiting toxicities (DLTs) in Phase 1a and investigator-assessed ORR per Lugano[7] in Phase 1b (**Figure S2**)

RESULTS

- As of March 13, 2026, a total of 34 patients were treated with KITE-753 (**Table 1**)
  - Median follow-up was 10.7 months (range, 3.2-28.3) in all treated patients (N=34) and 9.5 months (range, 3.2-16.2) in dose level 3 (n=23)
- Median time between leukapheresis and delivery back to trial site was 14 days (range, 10-25) in all treated patients and 13 days (range, 10-25) in dose level 3

Safety

- Among patients that received KITE-753 in dose escalation, no DLTs occurred
- Grade ≥3 TEAEs occurred in 73% of patients who received dose level 1 or 2 and 91% who received dose level 3 (**Table 2**)
- A total of 6 patients died across all dose levels: 4 due to disease progression and 2 due to infections unrelated to KITE-753
- No Grade ≥3 CRS occurred in patients who received dose level 3 of KITE-753 (**Figure 1**)
  - In dose level 2, 1 patient had Grade 3 CRS (LBCL)
  - Among all treated patients, median time to onset of any grade CRS was 6 days (range, 3-11)
  - Median duration of any-grade CRS was 6 days (range, 2-8)
    - Median duration included CRS-free days in between CRS events and was calculated as the time from the first onset date to the last ending date of all qualified events, with both dates included
  - CRS was managed with tocilizumab in 47% of patients, corticosteroids in 35% of patients, and anakinra in 0 patients
- No Grade ≥3 ICANS occurred in patients who received KITE-753 (**Figure 1**)
  - Median time to onset of any-grade ICANS was 10 days (range, 8-14); median duration was 2 days (range, 2-11)
    - Median duration was calculated as the time from the first onset date to the last ending date of all qualified events, with both dates included
  - ICANS was managed with tocilizumab in 0 patients, corticosteroids in 21% of patients, and anakinra in 6% of patients

Efficacy

- As of March 16, 2026 (post-data cutoff), among CAR-naive patients at dose level 3 (n=18), the ORR was 89% and the CR rate was 78% (**Figure 2**)
  - The CR rate was 72% at the data cutoff (March 13, 2026); 1 patient subsequently converted from a PR to a CR
- At the data cutoff of March 13, 2026:
  - Among CAR-naive patients with LBCL at dose level 3 (n=16), the ORR was 88%, with 75% of patients achieving a CR
  - In patients with prior CAR exposure among all dose levels (n=10), the ORR was 50%, with 30% of patients achieving CR
  - Median time to first response was 29 days among all patients and in dose level 3
- As of April 3, 2026 (post-data cutoff), among CAR-naive patients at dose level 3, the 6-month CR rate was 71% (12/17)

Pharmacokinetics and Pharmacodynamics

- Among CAR-naive patients who received KITE-753, median peak CAR T-cell level was 26,325 copies/µg (interquartile range [IQR], 1879-43,740) and the CAR T-cell area under the curve between Days 0 and 28 ($AUC_{0\text{-}28}$) after infusion was 189,585 (IQR, 24,073-393,069; **Figure 3**)
- In a comparative analysis of KITE-753 versus axi-cel (ZUMA-1), peak CAR T-cell expansion was later with KITE-753 (**Figure 3**); time to peak was 15 days (IQR, 11-15) with dose level 3 of KITE-753 and 8 days (IQR, 8-14) with axi-cel
  - IL-2, interferon gamma, and granzyme B kinetics correlated with later time to CAR T-cell peak (**Figure 3**)

Abbreviations

1L, first line; $AUC_{0\text{-}28}$, area under the curve between Days 0 and 28; axi-cel, axicabtagene ciloleucel; CAR, chimeric antigen receptor; CR, complete response; CRS, cytokine release syndrome; DLT, dose-limiting toxicity; ECOG, Eastern Cooperative Oncology Group; ICANS, immune effector cell-associated neurotoxicity syndrome; IL-2, interleukin 2; IFN-γ, interferon gamma; IPI, International Prognostic Index; IQR, interquartile range; LBCL, large B-cell lymphoma; LDH, lactate dehydrogenase; MCL, mantle cell lymphoma; ORR, objective response rate; PD, progressive disease; PR, partial response; RP2D, recommended phase 2 dose; R/R, relapsed/refractory; RT, radiation therapy; SD, standard deviation; SPD, sum of products of diameters; TEAE, treatment-emergent adverse event.

References

1. Ghobadi A, et al. *Transplant Cell Ther.* 2026;32(5):623.
2. Neelapu SS, et al. *Blood.* 2023;141(19):2307-2315.
3. Kamdar M, et al. *J Clin Oncol.* 2025;43(24):2671-2678.
4. Drent E, et al. *Clin Cancer Res.* 2019;25(13):4014-4025.
5. Muliaditan T, et al. *Cell Rep Med.* 2021;2(12):100457.
6. Dahiya S, et al. *Blood.* 2025;146(Suppl 1):265.
7. Swerdlow SH, et al. *Blood.* 2016;127:2375-2390.
8. Dahiya S, et al. *HemaSphere.* 2026;10(S1):3732-3733.

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Disclosures

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Full author disclosures are available through the Quick Response (QR) code.