A Phase 1 Study of KITE-753 or KITE-363 in Patients With Relapsed/Refractory B-Cell Lymphoma: Initial Safety and Preliminary Efficacy of KITE-753 and Updated Results of KITE-363

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Scan the QR code to view supplementary methods and a plain language summary infographic

Disclosures

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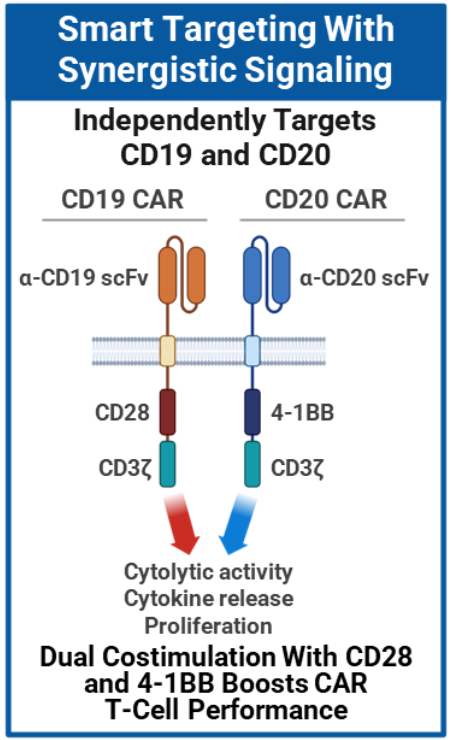
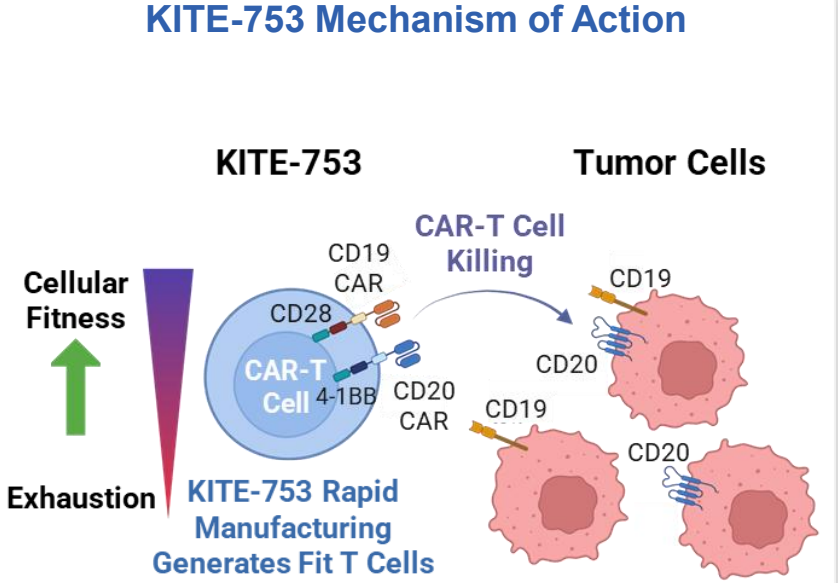
KITE-363 and KITE-753 CAR Design Enables Two Independent CARs to Work Synergistically





Unmet Need

- Although CD19 CAR T-cell therapies have been transformational in R/R LBCL, there is an opportunity for further improvement
  - e.g., In ZUMA-7, EFS rate at 48 months with axi-cel was 36.5% for patients with primary refractory LBCL vs 46.1% for early relapsed LBCL[1]

KITE DuoCore™ Construct

- KITE-363 and KITE-753 are investigational, **bicistronic, CAR T-cell therapies with synergistic signaling** designed to prevent antigen escape
- KITE-753 uses a **rapid manufacturing** process that preserves **naive and stem cell memory T cells**
- Here we report the initial safety and preliminary efficacy of KITE-753 and updated results of KITE-363 (NCT04989803)

1. Westin JR, et al. TCT 2025. Abstract 244.
scFv, single-chain variable fragment.

Study Design and Dose Levels

Phase 1a Dose Escalation[a]

KITE-363 Dose Levels	KITE-753 Dose Levels
1: 0.5×10^6 CAR T cells/kg	1: 0.03×10^6 CAR T cells/kg
2: 1×10^6 CAR T cells/kg	2: 0.1×10^6 CAR T cells/kg
3: 2×10^6 CAR T cells/kg	3: 0.2×10^6 CAR T cells/kg

KITE-753 dose levels were 10-67× lower than dose level 3 of KITE-363

→ **Phase 1b Dose Expansion**

Key Inclusion Criteria

- **Phase 1a: Histologically confirmed R/R B-cell lymphoma** (per WHO criteria[1]) after >2 lines of therapy or 2L primary refractory disease[b]
- **Phase 1b: R/R LBCL only (including 2L primary refractory disease)**
- Aged ≥18 years
- ECOG PS 0 or 1

Key Exclusion Criteria

- Richter transformation
- CNS involvement of lymphoma
- Active infection
- Clinically significant CNS disorder, autoimmune disease, or cardiac disease

Systemic chemo-immunotherapy was not permitted as bridging therapy; if radiation therapy was used, patients were required to have measurable disease prior to infusion

Primary Endpoint

- Phase 1a: Incidence of DLTs
- Phase 1b: ORR (investigator assessed per Lugano 2014 classification[2])

Secondary Endpoints

- CR rate
- DOR
- PFS
- TTNT
- OS
- Safety
- Levels of CAR T cells and cytokines in blood

Data cutoff date: August 21, 2025

[a] Additional details on study design are included in the supplementary methods, available via the QR code. [b] B-cell lymphoma included LBCL (including primary refractory disease and transformed iNHL), iNHL (Grades 1-3a FL; nodal, extranodal, or splenic MZL), NLPHL, and MGZL.

1. Cheson BD, et al. *J Clin Oncol.* 2014;32:3059-3068. 2. Swerdlow SH, et al. *Blood.* 2016;127:2375-2390.

KITE-363 Update[a]: No DLTs or Pausing Criteria; Durable Responses With Dose Level 3 in Highly Refractory CAR-Naive LBCL

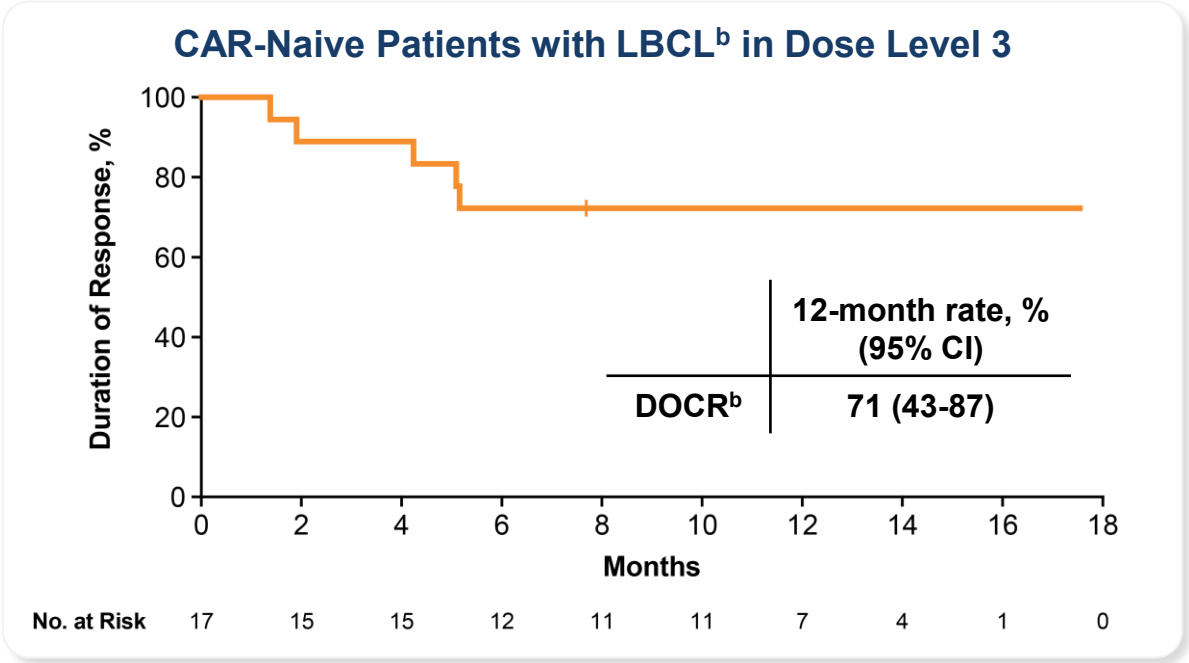
- Median follow-up: 17.5 months (range, 11.2-44.3); N=37
- In CAR-naive patients with LBCL in dose level 3 (N=22), 68% were primary refractory and 73% had elevated baseline LDH

Safety Update

- CRS and ICANS events that occurred with KITE-363 were primarily Grade 1 or 2
- No Grade 4 or 5 CRS or ICANS events occurred

Efficacy Update

- ORR: 87% (CR rate: 78%) among CAR-naive patients in dose level 3
- Median DOCR[c]: Not yet reached, with a plateau appearing near Month 6

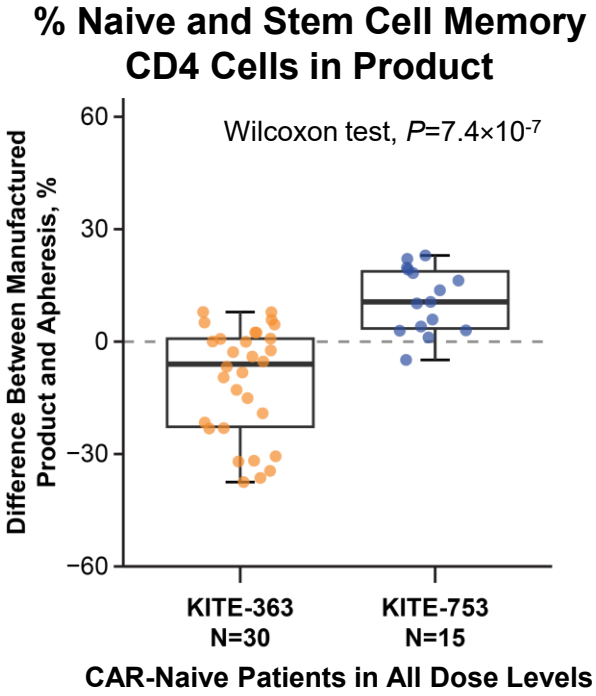


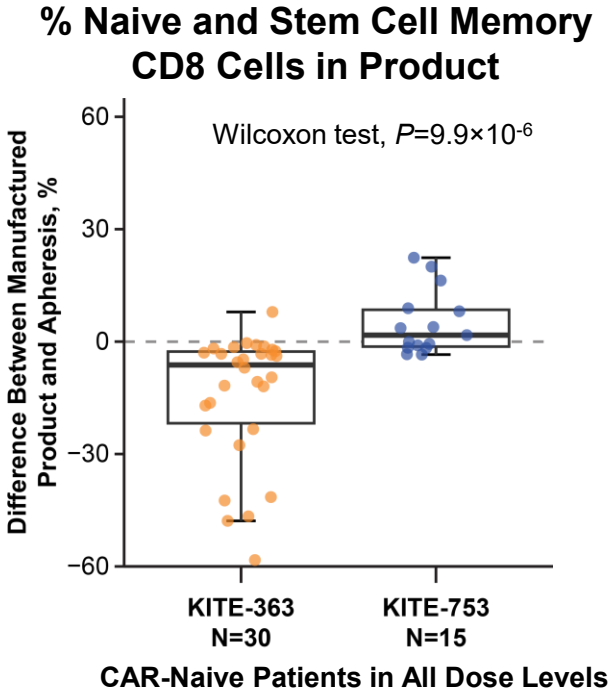
The censoring observed was not due to loss to follow-up or withdrawal but due to the observation window ending before an event occurred and indicates that patients were event-free up to the data cutoff. At the time of data cutoff, all but 1 censored patient remained in response

[a] Initial KITE-363 safety and efficacy data were previously reported.[1] [b] One CAR-naive patient with nodular lymphocyte predominant Hodgkin lymphoma was excluded. [c] DOCR was defined as DOR among all patients who achieved a best response of CR.

1. Dahiya S, et al. ASCO 2025. Abstract 7003.

KITE-753 Rapid Manufacturing Preserves More Naive T Cells vs KITE-363





Naive CD4 or CD8 cells were defined as those that were CD45RA+ CCR7+

KITE-753 Baseline Patient and Disease Characteristics

Characteristic		All Treated Patients (N=30)	Dose Level 3 (n=19)
Patient Characteristics	**Median age (range), years**	59.0 (25-84)	59.0 (28-79)
	≥65 years / ≥75 years, n (%)	13 (43) / 6 (20)	8 (42) / 5 (26)
	Male, n (%)	20 (67)	12 (63)
	ECOG performance status 1, n (%)	17 (57)	10 (53)
Disease Characteristics	**Stage III/IV disease at study entry, n (%)**	22 (73)	12 (63)
	Histological subtype: LBCL / iNHL, n (%)	26 (87) / 4 (13)	17 (89) / 2 (11)
	Bulky disease (≥7.5 cm), n (%)	5 (17)	5 (17)
	Double-/triple-hit status (LBCL only), n/N (%)	3/26 (12)[a]	2/17 (12)
	IPI score 3-4 (LBCL only), n/N (%)	6/26 (23)	5/17 (29)
	Elevated pretreatment LDH, n (%)	16 (53)	11 (58)
	Mean SPD at enrollment, mm^2 (StdDev)	2809.3 (3002.1)	2539.8 (2790.6)
Treatment History	**Median lines of prior therapy, n (range)**	2 (1-7)	2 (1-7)
	1 prior line (primary refractory)[b] / ≥2 prior lines, n (%)	8 (27) / 22 (73)	5 (26) / 13 (68)
	Prior anti-CD19 CAR T-cell therapy, n (%)	10 (33)	5 (32)
Bridging Therapy[d]	**Received bridging therapy (steroids ± RT),[c] n (%)**	10 (33)	7 (37)
	Steroids only / Radiation only / Steroids + radiation	6 (20) / 2 (7) / 2 (7)	4 (21) / 2 (11) / 1 (5)
	PR as best response to bridging therapy, n (%)	1 / 10 (10)	0 / 0

- mFU in treated patients with KITE-753 (N=30) was 4.0 months (range, 1.1-21.6) and 2.9 months (range, 1.1-9.5) in dose level 3 (n=19)
- Median time between leukapheresis and delivery back to trial site was 13.5 days (range, 10-25) in all treated patients and **13 days (range, 10-25) in dose level 3**

[a] Updated post-data cutoff on October 24, 2025. [b] Primary refractory disease was defined as chemorefractory disease in which the best response to 1L therapy is PD, SD lasting ≤6 months after ≥4 cycles, or PR following ≤6 cycles. [c] All eligibility criteria, including presence of measurable disease, must have remained confirmed following bridging therapy and prior to initiation of lymphodepleting chemotherapy. [d] Corticosteroid bridging therapy ± local RT was administered at the discretion of the investigator. Systemic chemo-immunotherapy was not permitted as bridging therapy.
DL, dose level.

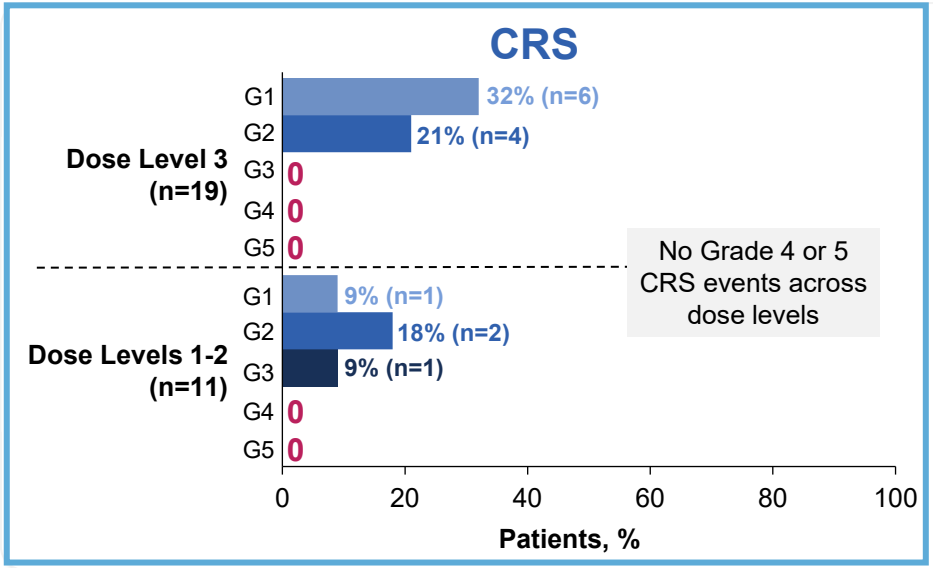
No DLTs Occurred With KITE-753 in Dose Escalation

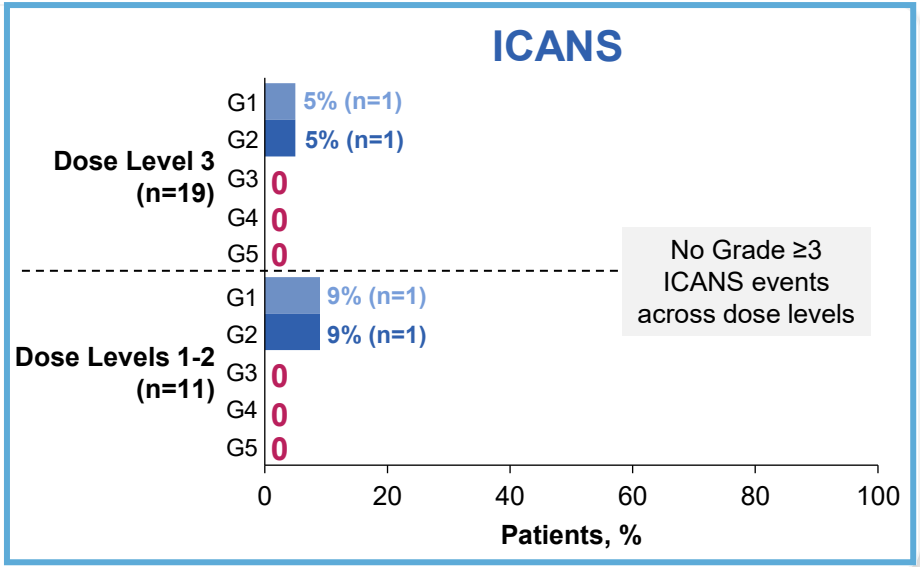
AEs, n (%)	Dose Levels 1-2 (n=11)		Dose Level 3 (n=19)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any	10 (91)	8 (73)	19 (100)	18 (95)
Serious	5 (45)	4 (36)	8 (42)	5 (26)
Cardiac disorders[a]	5 (45)	1 (9)	2 (11)	0
Infections	5 (45)	4 (36)	4 (21)	0
Heme toxicity				
Neutropenia	1 (9)	1 (9)	4 (21)	3 (16)
Thrombocytopenia	0	0	0	0
Anemia	5 (45)	3 (27)	2 (11)	1 (5)
Hypogammaglobulinemia	2 (18)	0	4 (21)	0

- A total of 5 patients died (4 in dose level 2, 1 in dose level 3)
  - 2 due to infections unrelated to KITE-753 (1 respiratory syncytial virus [Day 213] and 1 *aspergillus* [Day 23])
  - 3 due to progression

[a] Cardiac disorders were primarily tachycardia (n=6) or atrial fibrillation (n=2).

No Grade ≥3 CRS or ICANS Occurred With Dose Level 3 of KITE-753



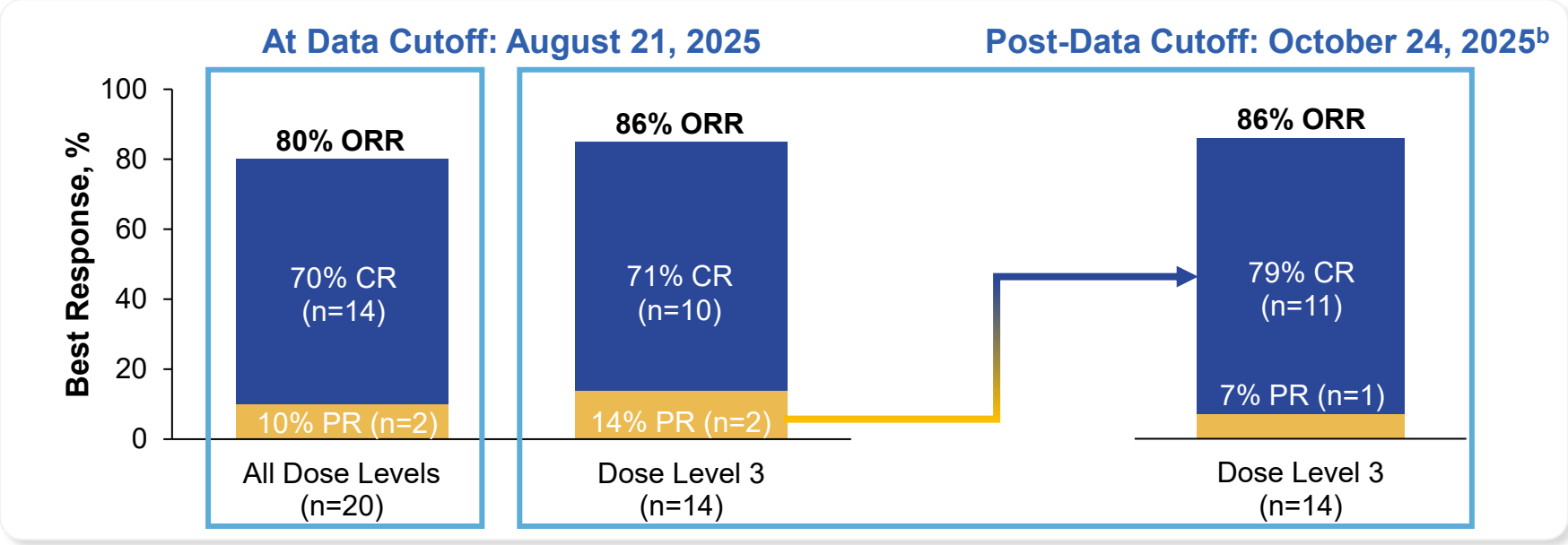


CRS		Dose Level 1-2 (n=11)	Dose Level 3 (n=19)
Median time to onset (range), days		9.5 (7-11)	6.0 (3-8)
Median duration of event (range), days		6.5 (2-8)	5.0 (2-7)
AE management, n (%)	Tocilizumab	3 (27)	9 (47)
	Corticosteroids	2 (18)	8 (42)
	Anakinra	0	0

ICANS		Dose Level 1-2 (n=11)	Dose Level 3 (n=19)
Median time to onset (range), days		12.5 (11-14)	10.0 (10-10)
Median duration of event (range), days		6.5 (2-11)	2.0 (2-2)
AE management, n (%)	Tocilizumab	0	0
	Corticosteroids	2 (18)	2 (11)
	Anakinra	0	2 (11)

No prophylactic steroids and/or tocilizumab were used on study

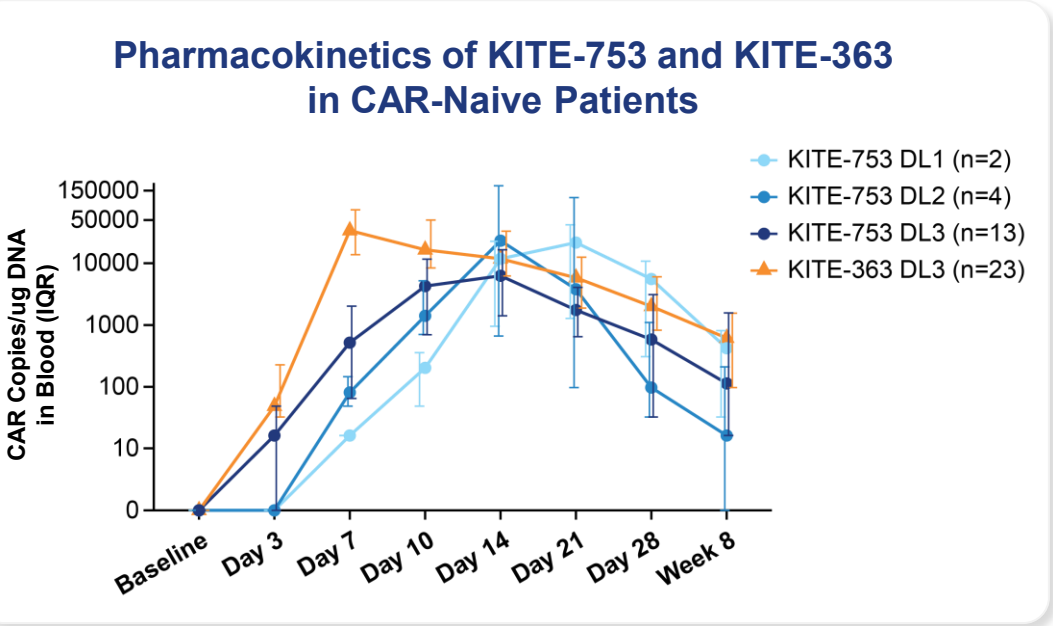
High ORR and CR Rate With KITE-753 in CAR-Naive Patients[a]



- Median time to first response among all patients (N=30) was 29 days
- In CAR-naive patients in dose level 3, 9 of the 11 patients with CRs had a CR at their 1-month assessment; the remaining 2 patients had a CR by their 3-month assessment (1 after the data cutoff)
- In patients with prior CAR exposure (n=10), 3 achieved a CR and 2 had a PR

[a] One non-responder had T-cell histiocyte-rich LBCL. [b] Median follow-up was 4.0 months (range, 1.1-21.6). One patient had an additional assessment after the data cutoff date of August 21, 2025.

Profound CAR T-Cell Expansion With KITE-753 at a 10× Lower Dose



	KITE-753 Dose Level 3 (n=13)	KITE-363 Dose Level 3 (n=23)
Time to peak, days (IQR)	15 (13-16)	8 (8-14)
$AUC_{0\text{-}28}$, median (IQR)	128,093.4 (21,124.8-203,909.4)	340,272.9 (178,175.7-677,662.2)
Peak (copies/µg), median (IQR)	19,602.0 (1684.8-36,126.0)	44,064.0 (14,952.6-75,816.0)

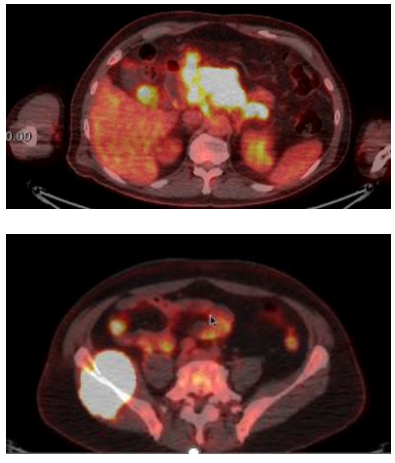
- KITE-753 expansion kinetics in CAR-naive patients were delayed compared with KITE-363
- KITE-753 showed pronounced expansion despite a 10× lower dose vs KITE-363, highlighting its robust proliferative potential

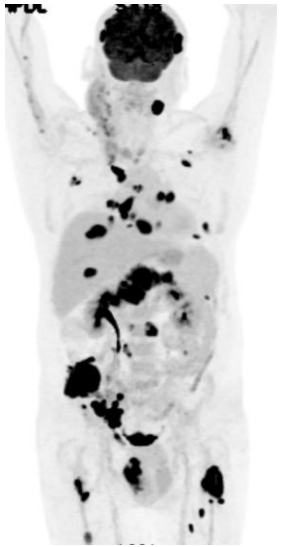
$AUC_{0\text{-}28}$, area under the curve (CAR copies/µg gDNA×28 days); DL, dose level.

Rapid CR with KITE-753 in a Patient With Highly Inflamed, Kinetically Fast-Moving Disease

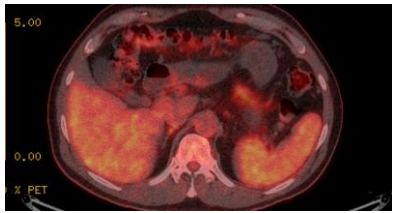
- 51-year-old male with double-hit, primary refractory LBCL, SPD of 8617 mm^2, ferritin 1500 ng/mL, and CRP 25.6 mg/dL at baseline
- Max Grade 2 CRS; no ICANS; no prolonged cytopenias/late ICAHT
- CR detected at Day 28 response assessment post-infusion

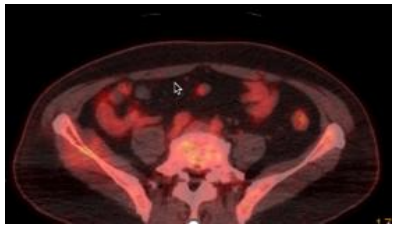
Baseline

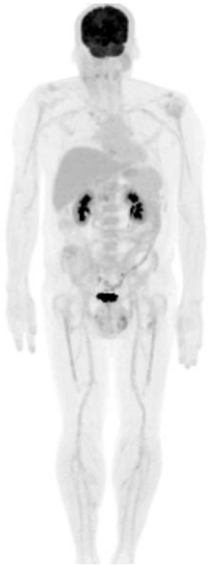




Day 28







CRP, C-reactive protein; ICAHT, immune effector cell-associated hematotoxicity.

Conclusions

- KITE-363 and KITE-753's unique CAR design (KITE DuoCore™), with bicistronic independent dual-targeting (CD19/20) and synergistic dual co-stimulation (CD28/4-1BB), demonstrates strong potential for substantial clinical benefit in R/R LBCL
- These results support the continued development of KITE-363 and KITE-753:
  - KITE-363 dose level 3 demonstrated high overall and complete response rates, durable complete responses, and a low incidence of high-grade CRS and ICANS
  - KITE-753 dose level 3, with a rapid manufacturing process that preserves naive T-cell phenotype and fitness, demonstrated high CR rate of 79% and a safety profile consisting of only low-grade CRS and only 2 cases of low-grade ICANS (n=2/19)
- Pivotal studies of KITE-753 are planned for early 2026 in 3L+ LBCL and Phase 3 RCT in 2L LBCL

Acknowledgments and Additional Resources

- **We thank the patients, families, friends, and caregivers**
- **We also thank the study investigators, coordinators, and healthcare staff at each study site**
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- These data were previously presented at the 2025 American Society of Hematology Annual Meeting[1]
- This study was funded by Kite

- Supplementary methods and a plain language summary infographic are available via the QR code

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1. Dahiya S, et al. ASH 2025. Abstract 265.