Poster CT-526

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Updated Results From a Rapcabtagene Autoleucel (YTB323) Phase I Study Demonstrate Durable Efficacy and a Manageable Safety Profile in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL)

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CONCLUSIONS

- Rapcabtagene autoleucel (YTB323), a next-generation autologous CD19-directed CAR-T cell therapy, preserved T-cell stemness and demonstrated promising durable efficacy with manageable safety
- Rapcabtagene autoleucel (YTB323) is manufactured on a pioneering T-Charge™ platform providing reliable and rapid manufacturing
- For further investigation in Phase II/III studies, the recommended dose is 12.5×10^6 CAR+ viable T cells (DL2), based on the CR rate, favorable safety profile, and cellular kinetics

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INTRODUCTION

- Despite novel treatment options, a substantial proportion of patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) do not achieve sustained remission[1,2] or do not have timely access to these therapies
  - There remains an unmet need to further improve response rates, durability, and accessibility to patients
- Rapcabtagene autoleucel (YTB323) is an autologous CD19-directed chimeric antigen receptor (CAR)-T cell therapy rapidly manufactured (<2 days) using the next-generation T-Charge™ platform that preserves T-cell stemness
- This poster focuses on the R/R DLBCL cohort (N=47) with 13 months' median follow-up (data cutoff September 15, 2022) in the Phase I, first-in-human trial[3] of rapcabtagene autoleucel (NCT03960840)
  - Results presented here represent an interim data cut to drive dose decisions for the expansion phase of the trial

METHODS

Study Design

- Patient flow for the R/R DLBCL treatment cohort is shown in **Figure 1**

Eligibility Criteria

- Eligible patients had R/R DLBCL after ≥2 lines of prior treatment, measurable disease at enrollment, and ECOG 0-1

Treatment

- Patients received lymphodepleting chemotherapy prior to rapcabtagene autoleucel
- Rapcabtagene autoleucel was administered as a single intravenous injection at one of 4 dose levels (DL)

Objectives

- Primary endpoints characterized safety and dose-limiting toxicities
- Secondary endpoints include response rate per Lugano criteria[4] and cellular kinetics

Figure 1. DLBCL Treatment Arm



CAR, chimeric antigen receptor; DL, dose level; DLBCL, diffuse large B-cell lymphoma; DLT, dose-limiting toxicity; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HSCT, hematopoietic stem cell transplantation; IV, intravenous; ORR, overall response rate; OS, overall survival.
[a]Optional bridging therapies were investigator's decision. [b]Relapsed/refractory disease is defined as patients who have failed two or more lines of chemotherapy and either progressed (or relapsed) after autologous HSCT or were ineligible for or did not consent to the procedure. [c]Within 28 days of receiving rapcabtagene autoleucel.

RESULTS

Patient and Disease Baseline Characteristics

Table 1. Patient and Disease Baseline Characteristics

Baseline Variable	Rapcabtagene Autoleucel Infused (N=47)
Median age (range), y	65 (35-79)
IPI score, n (%)	
<3	25 (53.2)
≥3	20 (42.6)
Unknown	2 (4.3)
Rearrangements in *MYC/BCL2/BCL6* genes, n (%)	
Double/triple hits	16 (34.0)
Negative	14 (29.8)
Unknown	17 (36.2)
Relapsed/refractory disease status, n (%)	
Refractory to all prior lines	10 (21.3)
Refractory to last line of therapy only	16 (34.0)
Relapsed after last line of therapy	21 (44.7)
Histology, n (%)	
DLBCL	45 (95.7)
Transformed lymphoma/other	2 (4.3)
Elevated LDH (>ULN),[a] n (%)	26 (55.3)
Prior HSCT, n (%)	14 (29.8)
No. prior lines of therapy, n (%)	
2	34 (72.3)
≥3	13 (27.7)
Time since most recent relapse/progression to rapcabtagene autoleucel infusion, median (range), mo	2.8 (1.4-11.1)
Received bridging therapy,[b] n (%)	32 (68.1)

DLBCL, diffuse large B-cell lymphoma; HSCT, hematopoietic stem cell transplantation; IPI, International Prognostic Index; LD, lymphodepleting; LDH, lactate dehydrogenase; ULN, upper limit of normal.
[a]Varies depending on the ULN for each site. [b]Bridging was defined as the time after leukapheresis to the start of LD chemotherapy.

- As of September 15, 2022, 47 patients with R/R DLBCL (median age, 65 years) received rapcabtagene autoleucel: 4 at DL1, 30 at DL2, 7 at DL3, and 6 at DL4
- The majority of patients received two prior lines of therapy (72%) and required bridging chemotherapy (68%) (**Table 1**)
- 30% of patients received previous autologous stem cell transplantation
- Nearly half (43%) of patients had an International Prognostic Index (IPI) score ≥3
- Rearrangements (double/triple hits) in *MYC/BCL2/BCL6* were observed in 34% of patients
- Median time since most recent relapse/progression was 2.8 months (range, 1.4-11.1)

Rapcabtagene Autoleucel Clinical Response Was Durable

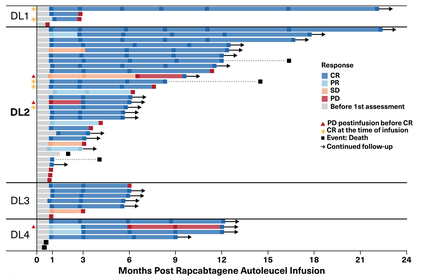
Table 2. Rapcabtagene Autoleucel Best Overall Response

	Rapcabtagene Autoleucel Dose Levels			
	DL1 2.5×10^6 (N=4)	DL2 12.5×10^6 (N=30)	DL3 25×10^6 (N=7)	DL4 40×10^6 (N=6)
	n (%)	n (%)	n (%)	n (%)
Best overall response				
CR	3 (75)	22 (73)	5 (71)	4 (67)
PR	0	3 (10)	0	0
Overall response rate[a] [95% CI][b]	3 (75) [19.4-99.4]	25 (83) [65.3-94.4]	5 (71) [29.0-96.3]	4 (67) [22.3-95.7]

CR, complete response; DL, dose level; PR, partial response.
Patients infused at least 28 days before cutoff.
[a]Overall response rate = CR + PR. [b]95% CIs are exact Clopper-Pearson CIs.

- In the full analysis set (N=47), median follow-up was 13 months (range, 4.4-34.3)
- The best overall response rate (complete response [CR] + partial response [PR]) of 83% was observed at DL2 (**Table 2**)
- Responses at DL2 appear to be durable, with CR rates of 60% (18/30) at 3 months and 61.5% (16/26) at 6 months (**Table 3**)
  - At DL2, 3 patients were in CR prior to receiving rapcabtagene autoleucel due to either a late effect of prior therapies or bridging chemotherapy
  - CR, excluding patients with CR before infusion, at DL2 was 70% (19/27)
  - Median duration of response at DL2 was 16 months (range, 10.4 to not estimable)
- Individual patient responses over time by DL are shown in **Figure 2**
  - Following rapcabtagene autoleucel infusion, 3 patients experienced progressive disease (PD) and then later, without receiving any further antilymphoma therapy, achieved CR

Figure 2. Patient Response Over Time



CR, complete response; DL, dose level; PD, progressive disease; PR, partial response; SD, stable disease.

Rapcabtagene Autoleucel Has a Manageable Safety Profile

Table 4. Rapcabtagene Autoleucel Safety Profile

	Treated Patients (N=47)			
AEs,[a] n (%)	DL1 2.5×10^6 (N=4)	DL2 12.5×10^6 (N=30)	DL3 25×10^6 (N=7)	DL4 40×10^6 (N=6)
Any AE				
Any grade	4 (100)	30 (100)	7 (100)	6 (100)
Grade ≥3	4 (100)	28 (93)	7 (100)	6 (100)
Dose-limiting toxicities	0	2 (7)	0	0
Death	2 (50)	9 (30)	1 (14)	2 (33)
Related to rapcabtagene autoleucel	0	0	0	0
Infections				
Any grade	3 (75)	9 (30)	4 (57)	3 (50)
Grade ≥3	1 (25)	5 (17)	1 (14)	2 (33)

AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; DL, dose level; MedDRA, Medical Dictionary for Regulatory Activities.
MedDRA version 25.0 and CTCAE version 5.0 have been used for the reporting of AEs.
[a]All AEs reported regardless of study drug relationship.

- All patients reported 1 adverse event (AE) of any grade and 96% had ≥1 AE grade ≥3 (**Table 4**)
  - Two dose-limiting toxicities were experienced at DL2. These consisted of grade 4 cytokine release syndrome (CRS) (per Lee 2014 criteria[5]) and grade 4 pancytopenia lasting >28 days post rapcabtagene autoleucel infusion
- In total, 14 deaths were reported (**Table 4**). Six deaths were due to disease progression (1 at DL1, 3 at DL2, 1 at DL3, and 1 at DL4), 2 deaths were due to COVID or COVID-related pneumonia (at DL2), 1 was due to intestinal hemorrhage (at DL2), 1 was due to acute respiratory failure (at DL2), 1 was due to tumor lysis syndrome (at DL2), 1 was due to septic shock (at DL4), 1 was due to sepsis (at DL1), and 1 was due to an unknown reason (at DL2)

Cytokine Release Syndrome (CRS) Was Low Grade

Table 5. CRS Incidence and Management

	Treated Patients (N=47)			
	DL1 2.5×10^6 (N=4)	DL2 12.5×10^6 (N=30)	DL3 25×10^6 (N=7)	DL4 40×10^6 (N=6)
CRS,[a] n (%)	1 (25)	11 (37)	2 (29)	2 (33)
Grade 1/2	1 (25)	9 (30)	2 (29)	2 (33)
Grade 3/4	0	2 (7)	0	0
Time to onset, days	9	8 (1-17)[b]	7, 36	2, 9
Time from onset to resolution, days	5	6 (2-25)[b]	5, 10	5, 7
Admitted to ICU for CRS, n/N (%[c])	0	3/11 (27)	0	0
Management of CRS, n/N (%[c])				
Tocilizumab	0	8/11 (73)	1/2 (50)	0
Corticosteroids	0	4/11 (36)	0	0
Vasopressors	0	2/11 (18)	0	0

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; DL, dose level; ICU, intensive care unit.
[a]Per ASTCT 2019 criteria. [b]Median (range). [c]Percentage calculated based on the number of patients with CRS.

- Any-grade CRS was experienced by 16 patients (34%): 1 at DL1, 11 at DL2, 2 at DL3, and 2 at DL4. One patient (4%) at DL2 experienced grade 4 CRS (**Table 5**)
  - At DL2, the median time to CRS onset was 8 days (range, 1-17) and median time to resolution was 6 days (range, 2-25)

Table 3. Rapcabtagene Autoleucel DL2 Duration of Response

	DL2 12.5×10^6 (N=30)
Median follow-up (range)	16 mo (4.4-27.5)
BOR of CR	22/30 (73%)
CR at 3 mo	18/30[a] (60%)
CR at 6 mo	16/26[b] (62%)
CR at 9 mo	8/19[c] (42%)
CR at 12 mo	8/16[d] (50%)
Median DOR (95% CI)	16 mo (10.4-NE)

BOR, best overall response; CR, complete response; DL, dose level; DOR, duration of response; NE, not estimable.
[a]Patients infused ≥3 months before cutoff. [b]Patients infused ≥6 months before cutoff. [c]Patients infused ≥9 months before cutoff. [d]Patients infused ≥12 months before cutoff.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) Was Manageable

Table 6. ICANS Incidence and Management

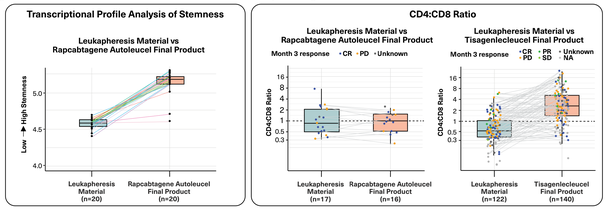
	Treated Patients (N=47)			
	DL1 2.5×10^6 (N=4)	DL2 12.5×10^6 (N=30)	DL3 25×10^6 (N=7)	DL4 40×10^6 (N=6)
ICANS,[a] n (%)	0	3 (10)	0	2 (33)
Grade 1/2	0	1 (3)	0	2 (33)
Grade 3/4	0	2 (7)	0	0
Time to onset, days	–	16 (10-28)[b]	–	6, 28
Time from onset to resolution, days	–	16 (11-24)[b]	–	1, 25
Management of CRS, n/N (%[c])				
Dexamethasone	–	2/3 (67)	–	1/2 (50)
Methylprednisolone	–	1/3 (33)	–	0
Anakinra	–	1/3 (33)	–	0

ASTCT, American Society for Transplantation and Cellular Therapy; DL, dose level; ICANS, immune effector cell-associated neurotoxicity syndrome.
[a]Per ASTCT 2019 criteria. ICANS adverse events are neurologic adverse events that occurred within 12 weeks post rapcabtagene autoleucel infusion in patients with ICANS grades 1-4. [b]Median (range). [c]Percentage calculated based on the number of patients with ICANS.

- Five patients (11%) experienced ICANS events: 3 at DL2 and 2 DL4. Two patients (7%) at DL2 experienced grade 3 ICANS (no patients experienced grade 4-5) (**Table 6**)
  - At DL2, the median time to onset of ICANS was 16 days (range, 10-28) and median time to resolution was 16 days (range, 11-24)

T-Charge™ Manufacturing Process Preserved T-Cell Stemness and CD4:CD8 Ratio in Rapcabtagene Autoleucel

Figure 3. T-Cell Stemness and CD4:CD8 Ratio in Rapcabtagene Autoleucel Final Product

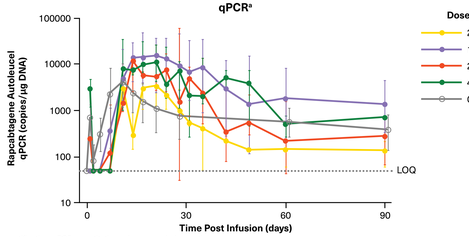


CD, cluster of differentiation; CR, complete response; NA, not available; PD, progressive disease; PR, partial response; SD, stable disease.

- Rapcabtagene autoleucel CAR-T cells showed T_{SCM} and stemness gene signatures that closely resembled the starting material, indicating a preservation of stemness following manufacturing (**Figure 3**)
  - Rapcabtagene autoleucel retained a high percentage of naive/T_{SCM}-cells (CD45RO−/CCR7+) from the input leukapheresis material
- A 1:1 CD4:CD8 ratio was maintained between the leukapheresis material and the rapcabtagene autoleucel final product (**Figure 3**)
  - Retaining the CD4:CD8 ratio may further contribute to the promising antitumor efficacy of rapcabtagene autoleucel[6]

Rapcabtagene Autoleucel Expansion Was Robust

Figure 4. Rapcabtagene Autoleucel Expansion Kinetics Measured by qPCR



LOQ, limit of quantification; qPCR, quantitative polymerase chain reaction.
[a]Median and IQR (interquartile range) over time measured by qPCR.

- At a 25-fold lower dose than tisagenlecleucel in the JULIET trial, rapcabtagene autoleucel in vivo expansion at DL2 by quantitative polymerase chain reaction (qPCR) (geometric mean C_{max} 26,500 copies/µg DNA) was at the higher end of tisagenlecleucel expansion in patients with R/R DLBCL (**Figure 4**)[7,8]
- No further increases in expansion were observed at higher doses

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