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Poster# **ABCL-1093**

Rapcabtagene Autoleucel (YTB323) Phase 2 Trial in Patients With Relapsed/Refractory Diffuse Large B-cell Lymphoma (r/r DLBCL): Clinical Update

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CONCLUSIONS

- At the 12.5 × 10^6 cell dose, rapcabtagene autoleucel achieved high response rates (ORR: 88%; CRR: 65%; median follow-up: 16 months)
- Rapcabtagene autoleucel responses were durable
  - 12-month DOR probability was 54% for all responders and 69% for patients with a BOR of CR
  - 12-month PFS probability was 48% for all patients and 79% for patients with a CR at month 3
- Rapcabtagene autoleucel has a favorable safety profile
  - Low rates of grade ≥3 CRS (6%) and ICANS (5%) were reported in the overall patient population
- Benefit-risk analyses support use of the lower-dose LD regimen before infusion

Poster presented at the Society of Hematologic Oncology 2025 Annual Meeting; September 3-6, 2025; Houston, TX.

INTRODUCTION

- Rapcabtagene autoleucel is a next-generation cluster of differentiation (CD)19–directed chimeric antigen receptor (CAR)–T cell therapy that utilizes the T-Charge™ platform to preserve T-cell stemness
- The phase 1 study identified the 12.5 × 10^6 CAR+ viable T-cell dose for further investigation in the treatment of patients with relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL)[1]
- Here we report an interim descriptive analysis of the ongoing phase 2 clinical trial (NCT03960840)[2]

METHODS

Study Design

- Patient flow through this phase 2, open-label, single-arm, multicenter study is shown in **Figure 1**

Eligibility Criteria

- Eligible patients had r/r DLBCL after ≥2 lines of prior therapy, measurable disease at enrollment, and Eastern Cooperative Oncology Group performance status (ECOG PS) 0-1

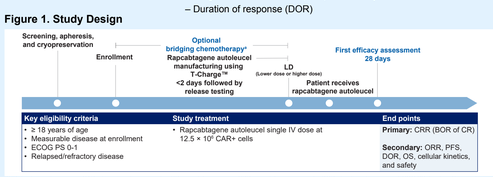
Treatment

- Patients received lymphodepletion (LD) chemotherapy prior to rapcabtagene autoleucel
  - Two LD regimens were assessed as a part of this phase 2 trial
    - Lower-dose LD was defined as fludarabine/cyclophosphamide 25/250 mg/m^2 for 3 days
    - Higher-dose LD was defined as fludarabine/cyclophosphamide 30/500 mg/m^2 for 3 days
  - Bridging therapy before infusion was permitted
- Rapcabtagene autoleucel (12.5 × 10^6 CAR+ cells) was administered as a single intravenous (IV) infusion

End Points

- Primary end point is complete response rate (CRR) as assessed by local investigator
- Secondary end points include
  - Overall response rate (ORR)
  - Progression-free survival (PFS)
  - Duration of response (DOR)
  - Overall survival (OS)
  - Cellular kinetics
  - Safety

Figure 1. Study Design



BOR, best overall response; CAR, chimeric antigen receptor; CR, complete response; CRR, complete response rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; LD, lymphodepletion; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.
[a]Optional bridging therapies were investigator's decision.

RESULTS

Patient and Disease Characteristics

- As of February 1, 2024, 63 patients with r/r DLBCL received rapcabtagene autoleucel
- The majority of patients received two prior lines of therapy (73%), and 60% received bridging chemotherapy (**Table 1**)
- Almost half (46%) of patients were ≥65 years of age
- Rearrangements (double/triple hits) in *MYC/BCL2/BCL6* were reported in 25% of patients
- Nearly half of patients (43%) had elevated lactate dehydrogenase (LDH)
- A third of patients (30%) had history of previous hematopoietic stem cell transplant (HCT)

Table 1. Disease History and Baseline Patient Characteristics

Baseline variable	All infused set (N = 63)[a]
Median age, years (range)	64 (26-81)
≥65 y, n (%)	29 (46.0)
IPI score, n (%)	
<3	34 (54.0)
≥3	24 (38.1)
Unknown	5 (7.9)
Rearrangements in *MYC/BCL2/BCL6* genes, n (%)	
Double/triple hits	16 (25.4)
Negative	25 (39.7)
Unknown	22 (34.9)
Relapsed/refractory disease status, n (%)	
Refractory to last line of therapy	37 (58.7)
Refractory to all prior lines	13 (20.6)
Relapsed after last line of therapy	26 (41.3)
Histology, n (%)	
DLBCL	52 (82.5)
Transformed lymphoma	8 (12.7)
Elevated LDH (>ULN), n (%)	27 (42.9)
Prior HCT, n (%)	19 (30.2)
Prior lines of therapy, n (%)	
2	46 (73.0)
≥3	17 (27.0)
Received bridging therapy, n (%)	38 (60.3)

DLBCL, diffuse large B-cell lymphoma; HCT, hematopoietic cell transplant; IPI, International Prognostic Index; LDH, lactate dehydrogenase; ULN, upper limit of normal.
[a]Two patients were pending infusion as of data cutoff. One patient died prior to infusion of intestinal obstruction related to the study indication.

Rapcabtagene Autoleucel Clinical Response Was Durable

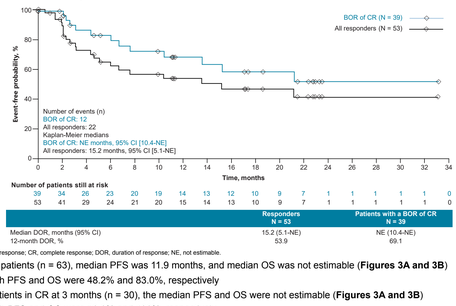
- In the full analysis set of 60 infused patients with ≥1 month of follow-up, the median follow-up was 16.4 months
- The best ORR was 88.3% (**Table 2**)
  - 65% of patients achieved a complete response (CR)
  - Excluding the 4 patients with CR prior to infusion, the CRR was 62.5%
- Responses appear to be durable, with CRRs of 54.5% (30/55) at 3 months and 56.8% (25/44) at 6 months
- The median DOR was 15.2 months among responders, and it was not estimable in patients with a CR (**Figure 2**)

Table 2. Best Overall Response

	Rapcabtagene autoleucel 12.5 × 10^6 (N = 60[a]) n (%)
Median follow-up, months (range)	16.4 (0.1-44.1)
ORR,[b] n (%) [95% CI][c]	**53 (88.3) [77.4-95.2]**
BOR	
CR, n (%) [95% CI]	**39 (65.0) [51.6-76.9]**
CR excluding patients with CR before infusion, n/N (%)[d]	**35/56 (62.5)**
PR, n (%)	14 (23.3)
CRR, n/N (%)	
Month 3	30/55[e] (54.5)
Month 6	25/44[e] (56.8)
Month 12	18/38[e] (47.4)

BOR, best overall response; CR, complete response; CRR, complete response rate; ORR, overall response rate; PD, progressive disease; PR, partial response.
[a]Patients infused at least 28 days before cutoff.
[b]ORR = CR + PR.
[c]95% CIs are exact Clopper-Pearson CIs.
[d]Excludes patients who were in CR prior to receiving rapcabtagene autoleucel due to either a late effect of prior therapies or bridging chemotherapy.
[e]Patients infused at least 3, 6, or 12 months prior to data cutoff and have a month 3, 6, or 12 assessment, or discontinued due to PD/death/new therapy prior to their month 3, 6, or 12 assessment.

Figure 2. Duration of Response

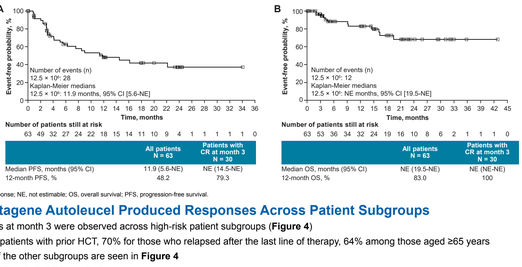


	Responders N = 53	Patients with a BOR of CR N = 39
Median DOR, months (95% CI)	15.2 (5.1-NE)	NE (10.4-NE)
12-month DOR, %	53.9	69.1

BOR, best overall response; CR, complete response; DOR, duration of response; NE, not estimable.

- Among all patients (n = 63), median PFS was 11.9 months, and median OS was not estimable (**Figures 3A and 3B**)
  - 12-month PFS and OS were 48.2% and 83.0%, respectively
- Among patients in CR at 3 months (n = 30), the median PFS and OS were not estimable (**Figures 3A and 3B**)
  - 12-month PFS and OS were 79.3% and 100%, respectively

Figure 3. PFS and OS



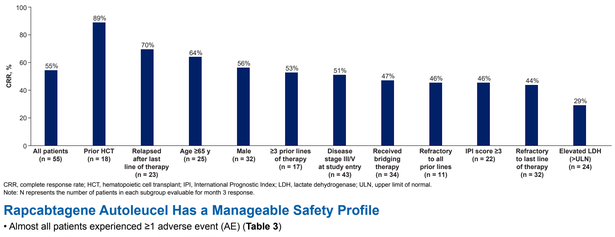
	All patients N = 63	Patients with CR at month 3 N = 30
Median PFS, months (95% CI)	11.9 (5.6-NE)	NE (14.5-NE)
12-month PFS, %	48.2	79.3
Median OS, months (95% CI)	NE (19.5-NE)	NE (NE-NE)
12-month OS, %	83.0	100

CR, complete response; NE, not estimable; OS, overall survival; PFS, progression-free survival.

Rapcabtagene Autoleucel Produced Responses Across Patient Subgroups

- High CRRs at month 3 were observed across high-risk patient subgroups (**Figure 4**)
  - 89% for patients with prior HCT, 70% for those who relapsed after the last line of therapy, 64% among those aged ≥65 years
  - CRRs of the other subgroups are seen in **Figure 4**

Figure 4. Month 3 CRR by Subgroups



CRR, complete response rate; HCT, hematopoietic cell transplant; IPI, International Prognostic Index; LDH, lactate dehydrogenase; ULN, upper limit of normal.
Note: N represents the number of patients in each subgroup evaluable for month 3 response.

Rapcabtagene Autoleucel Has a Manageable Safety Profile

- Almost all patients experienced ≥1 adverse event (AE) (**Table 3**)
  - Grade ≥ 3 AEs were reported in 84.1% (53/63) of patients
  - There were 12 deaths: 6 (50%) were from disease progression and 6 (50%) were from AEs, 4 of which were considered nonrelapse mortality
    - AEs resulting in death included COVID-19 (n = 2), acute respiratory failure (n = 1), intestinal hemorrhage (n = 1), septic shock (n = 1), and tumor lysis syndrome (n = 1)
  - Among the 6 deaths due to AE, 2 patients had documented disease progression prior to death (tumor lysis syndrome and septic shock)

Cytokine Release Syndrome (CRS) Was Mostly Low Grade

- Any-grade CRS was experienced by 28 patients (44.4%); median time to onset was 8 days (range: 1-20 days) and median time to resolution was 6 days (range: 1-25 days) (**Table 4**)
  - Grade ≥3 CRS was experienced by 4 patients (6.3%)

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

- Any-grade ICANS was experienced by 5 patients (7.9%); median time to onset was 13 days (range: 10-28 days) and median time to resolution was 17 days (range: 11-24 days) (**Table 5**)
  - Grade ≥3 ICANS was experienced by 3 patients (4.8%)

Table 3. Rapcabtagene Autoleucel Safety Profile

	Rapcabtagene autoleucel 12.5 × 10^6 (N = 63)
AEs[a]	
Any grade	62 (98.4)
Grade ≥3	53 (84.1)
Grade 5	6 (9.5)
Serious AE	33 (52.4)
Deaths	12 (19.0)
Disease progression	6 (9.5)
AE	6 (9.5)
Nonrelapse mortality[b]	4 (6.3)

AE, adverse event.
[a]All AEs reported regardless of study drug relationship.
[b]Defined as any death due to an AE without documented disease progression.

Table 4. CRS Incidence and Management

	Rapcabtagene autoleucel 12.5 × 10^6 (N = 63)
CRS,[a] n (%)	28 (44.4)
Grade 1	17 (27.0)
Grade 2	7 (11)
Grade 3	2 (3.2)
Grade 4	2 (3.2)
Median time to onset, days (range)	8 (1-20)
Grade 3/4[b]	7.5 (7-11)
Median time from onset to resolution, days (range)	6 (1-25)
Admitted to ICU for CRS, n/N (%[b])	6/28 (21.4)
Management of CRS, n/N (%[b])	
Tocilizumab	15/28 (53.6)
Corticosteroids	7/28 (25.0)

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICU, intensive care unit.
[a]Based on ASTCT grading (per Lee 2019).[3]
[b]Percentage calculated based on the number of patients with CRS.

Table 5. ICANS Incidence and Management

	Rapcabtagene autoleucel 12.5 × 10^6 (N = 63)
ICANS, n (%)	
Grade 1	2 (3.2)
Grade 2	0
Grade 3	2 (3.2)
Grade 4	1 (1.6)
Median time to onset, days (range)	13 (10-28)
Grade 3/4[a]	18.5 (13-24)
Median time from onset to resolution, days (range)	17 (11-24)
Management of ICANS, n/N (%[a])	
Dexamethasone	4/5 (80.0)
Methylprednisolone	2/5 (40.0)
Anakinra	2/5 (40.0)

ICANS, immune effector cell-associated neurotoxicity syndrome.
[a]Percentage calculated based on the number of patients with ICANS.

Most Grade ≥3 Cytopenias Ongoing at Month 1 Resolved by 3 Months

- 27% of patients experienced grade ≥3 infections (**Table 6A**)
  - Grade 5 infections included COVID-19 pneumonia in 2 patients and septic shock in 1 patient
- The most common grade ≥3 cytopenia reported was neutropenia (62%)
  - Probability of resolution by 3 months for grade ≥3 neutropenia and anemia ongoing at month 1 was 100%
  - Probability of grade ≥3 thrombocytopenia and lymphopenia ongoing at month 1 resolving by 3 and 6 months was 92%/100% and 65%/74%, respectively (**Table 6B**)
- A single event of grade 3 hemophagocytic lymphohistiocytosis was reported

Table 6A. Frequency of Infections and Cytopenias

	Rapcabtagene autoleucel 12.5 × 10^6 N = 63		
	Any grade, n (%)	Grade ≥3, n (%)	Grade 5, n (%)
Infections	31 (49.2)	17 (27.0)	3 (4.8)
Cytopenias			
Neutropenia	41 (65.1)	39 (61.9)	0
Anemia	32 (50.8)	21 (33.3)	0
Thrombocytopenia	21 (33.3)	16 (25.4)	0
Lymphopenia	11 (17.5)	10 (15.9)	0

Table 6B. Resolution of Grade ≥ 3 Cytopenias

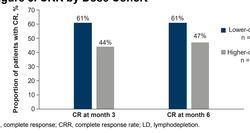
	Rapcabtagene autoleucel 12.5 × 10^6 N = 63		
	Grade ≥3, n (%)	Resolution by month 3, %[b]	Resolution by month 6, %[b]
Month 1 event[a]			
Neutropenia	24 (38.1)	100	100
Anemia	5 (7.9)	100	100
Thrombocytopenia	19 (30.2)	91.8	100
Lymphopenia	27 (42.9)	64.9	73.7

[a]Cytopenias experienced by month 1 were based on lab abnormalities.
[b]Resolution was defined as lab values corresponding to grade ≤2.

Lower-Dose vs Higher-Dose Lymphodepletion

- CR rates at both month 3 and month 6 were numerically higher in the lower-dose LD cohort than in the higher-dose LD cohort (**Figure 5**)
- Notable differences in demographic and baseline characteristics between the lower- and higher-dose LD cohorts included elevated LDH before infusion (36% vs 49%), International Prognostic Index score ≥3 (43% vs 30%), and the proportion of patients ≥65 years of age (57% vs 36%) (**Table 7**)
- Summary of AEs in both cohorts can be seen in **Table 8**

Figure 5. CRR by Dose Cohort



CR, complete response; CRR, complete response rate; LD, lymphodepletion.

Table 7. Baseline Characteristics by Dose Cohort

Baseline variable	Lower-dose LD[a] (N = 28)	Higher-dose LD[a] (N = 33)
Median age, years (range)	65.5 (35-79)	60 (26-81)
≥65 y, n (%)	16 (57.1)	12 (36.4)
IPI score, n (%)		
<3	14 (50.0)	20 (60.6)
≥3	12 (42.9)	10 (30.3)
Unknown	2 (7.1)	3 (9.1)
Rearrangements in *MYC/BCL2/BCL6* genes, n (%)		
Double/triple hits	9 (32.1)	7 (21.2)
Negative	10 (35.7)	13 (39.4)
Unknown	9 (32.1)	13 (39.4)
Relapsed/refractory disease status, n (%)		
Refractory to last line of therapy	16 (57.1)	20 (60.6)
Refractory to all prior lines	5 (17.9)	8 (24.2)
Relapsed after last line of therapy	12 (42.9)	13 (39.4)
Histology, n (%)		
DLBCL	24 (85.7)	27 (81.8)
Transformed lymphoma	4 (14.3)	3 (9.1)
Elevated LDH (>ULN), n (%)	10 (35.7)	16 (48.5)
Prior HCT, n (%)	9 (32.1)	9 (27.3)
Prior lines of therapy, n (%)		
2	22 (78.6)	23 (69.7)
≥3	6 (21.4)	10 (30.3)
Received bridging therapy, n (%)	20 (71.4)	18 (54.5)

DLBCL, diffuse large B-cell lymphoma; HCT, hematopoietic cell transplant; IPI, International Prognostic Index; LD, lymphodepletion; LDH, lactate dehydrogenase; ULN, upper limit of normal.
[a]Two patients received LD regimens other than fludarabine/cyclophosphamide.

Table 8. Rapcabtagene Autoleucel Safety Profile by LD Regimen

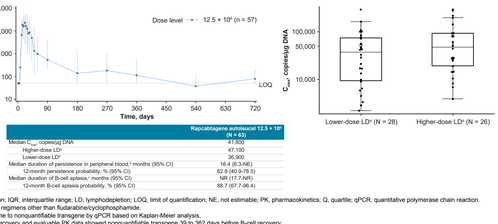
	Lower-dose LD[a] (N = 28)	Higher-dose LD[a] (N = 33)
Median follow-up, months (range)	32.8 (21.3-44.1)	5.4 (0.1-23.4)
AEs, n (%)[b]		
Any grade	28 (100)	32 (97.0)
Grade ≥3	27 (96.4)	25 (75.8)
Deaths, n (%)	10 (35.7)	2 (6.1)
Infections, n (%)		
Any grade	14 (50.0)	16 (48.5)
Grade ≥3	9 (32.1)	8 (24.2)
Cytopenias, n (%)		
Anemia	17 (60.7)	14 (42.4)
Leukopenia	0	3 (9.1)
Lymphopenia	7 (25.0)	4 (12.1)
Neutropenia	19 (67.9)	22 (66.7)
Thrombocytopenia	11 (39.3)	9 (27.3)
CRS,[c] n (%)		
Any grade	11 (39.3)	116 (48.5)
Grade 3/4	1 (3.6)	3 (9.1)
ICANS, n (%)		
Any grade	4 (14.3)	1 (3.0)
Grade 3/4	2 (7.1)	1 (3.0)

AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; LD, lymphodepletion.
[a]Two patients received LD regimens other than fludarabine/cyclophosphamide.
[b]All AEs reported regardless of study drug relationship.
[c]Based on ASTCT grading (per Lee 2019).[3]

Rapcabtagene Autoleucel In Vivo Expansion

- Rapcabtagene autoleucel showed high in vivo cellular expansion with extended persistence (by quantitative polymerase chain reaction), and B-cell aplasia at 12 months (**Figure 6**)
- Comparable cellular expansion was seen at both LD dose regimens
- Median maximal concentration was 47,100 copies/µg DNA for patients who received higher-dose LD and 36,900 copies/µg DNA for patients who received lower-dose LD

Figure 6. Rapcabtagene Autoleucel Cellular Kinetics



	Rapcabtagene autoleucel 12.5 × 10^6 (N = 63)
Median C_{max}, copies/µg DNA	41,600
Higher-dose LD[a]	47,100
Lower-dose LD[a]	36,900
Median duration of persistence in peripheral blood,[b] months (95% CI)	16.4 (6.3-NE)
12-month persistence probability, % (95% CI)	62.8 (40.9-78.5)
Median duration of B-cell aplasia,[c] months (95% CI)	NR (17.7-NR)
12-month B-cell aplasia probability, % (95% CI)	88.7 (67.7-96.4)

C_{max}, maximal concentration; IQR, interquartile range; LD, lymphodepletion; LOQ, limit of quantification; NE, not estimable; PK, pharmacokinetics; Q, quartile; qPCR, quantitative polymerase chain reaction.
[a]Two patients received LD regimens other than fludarabine/cyclophosphamide.
[b]Persistence defined as time to undetectable transgene by qPCR based on Kaplan-Meier analysis.
[c]All 5 patients with B-cell recovery and evaluable PK data showed nonquantifiable transgene 39 to 362 days before B-cell recovery.
[d]The diamond represents the mean. Lower and upper whiskers extend to most extreme points within 1.5*IQR of Q1 and Q3, respectively.

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Acknowledgments

The authors sincerely thank the patients, their families, and the principal investigators and support staff.
The study was sponsored by Novartis Pharmaceuticals.
All analyses in this presentation were conducted by Novartis Pharmaceuticals.
Medical writing support was provided by Jasmine Ann Javier, MD, of IHCD, and was funded by Novartis Pharmaceuticals.

Disclosures

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