LONG-TERM CLINICAL OUTCOMES IN PATIENTS WITH RELAPSED OR REFRACTORY BCELL NON-HODGKIN LYMPHOMA TREATED WITH PRIZLONCABTAGENE AUTOLEUCEL

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Introduction

- Prizloncabtagene autoleucel, previously known as C-CAR039, is an autologous anti-CD20/CD19 dual-antigen targeting CAR-T therapy for the treatment of patients with relapsed or refractory (r/r) B-cell non-Hodgkin lymphoma (B-NHL).
- We previously reported the outcomes of 48 patients with r/r B-NHL treated with C-CAR039 at the 2025 EHA Congress (Yu et al. Abstract PS2159).
  - **ORR was 91.5%, with 85.1% CR**
  - **At a median follow-up (mFU) of 45.5 months, the estimated 4-year PFS and OS rates were 52.5% and 65.4%, respectively**
- Here, we report the long-term results with a mFU of 53.9 months.

Method

- This is a phase 1, open-label, dose escalation and expansion study conducted at four sites in China
- **Primary objective:**
  - Incidence and severity of treatment-emergent adverse events
- **Secondary Objectives:**
  - ORR, DOR, PFS, OS by investigator (Lugano 2014)
- **Key Eligibility Criteria**
  - 18–75 years
  - r/r B-NHL including DLBCL, FL, MCL
  - Either CD19 or CD20 positive
  - No active CNS involvement
  - Prior regimens including anti-CD20 monoclonal antibodies

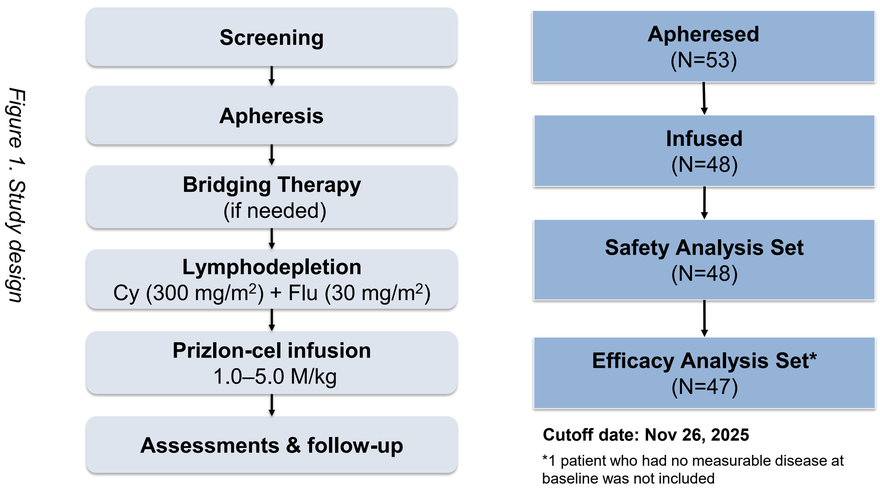


Figure 1. Study design

ORR, Overall Response Rate; DOR, Duration of Response; PFS, Progression–free Survival; OS, Overall Survival; M, Million

Results

Demographic and Baseline Characteristics

- Of 48 patients, 44 (91.7%) were large B-cell lymphoma (LBCL), which includes DLBCL, NOS, tFL, and PMBCL

Table 1. Baseline patient characteristics

Characteristics	N=48
Median Age, years (range) • Age ≥ 65, n (%)	55 (25–71) 11 (22.9)
Male, n (%)	30 (62.5)
NHL Subtype, n (%) • DLBCL,NOS • tFL • PMBCL • FL • MCL	 37 (77.1) 4 (8.3) 3 (6.3) 3 (6.3) 1 (2.1)
Dose Level, n (%) • 1.0 M/kg • 2.0/2.5 M/kg • 4.0/5.0 M/kg	 4 (8.3) 31 (64.6) 13 (27.1)
IPI Score 3/4, n (%)	15 (31.3)
Ann Arbor Stage III / IV, n (%)	36 (75.0)
Double-expressor Lymphoma, n (%)	15 (31.3)
Median Number of Prior Lines of Therapy, (range) • ≥4, n (%)	3 (1–7) 16 (33.3)
Never Achieved CR of Prior Therapies, n (%)	22 (45.8)
Received Bridging Therapy, n (%)	12 (25.0)

NHL, Non–Hodgkin Lymphom; DLBCL,NOS, Diffuse large B-celllymphoma, Not Otherwise Specified; PMBCL, Primary Mediastinal Large B-celllymphoma; tFL, Transformed Follicular Lymphoma; FL, Follicular Lymphoma; MCL, Mantle Cell Lymphoma; IPI, International Prognostic Index; CR, Complete Response

Deaths

- 17 deaths occurred, most due to disease progression

Table 2. Deaths

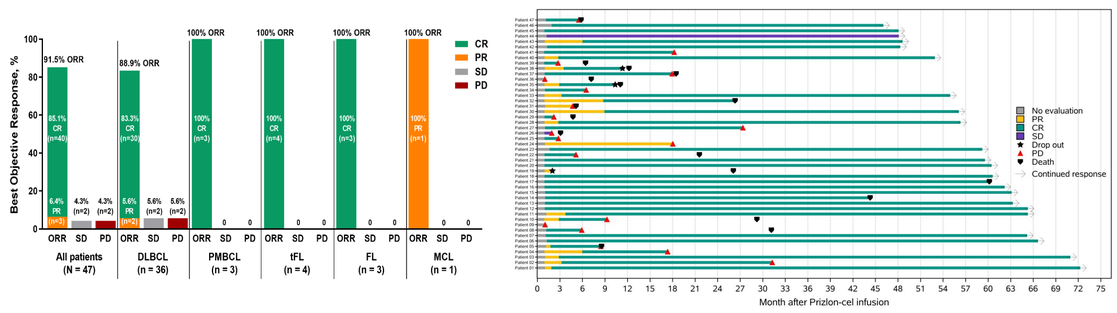
Death, n	N=48	Median days of death post infusion, (range)
Total death to cutoff date, n	17	371 (94–1831)
• **Due to disease progression**	11*	218 (94–948)
• **AE unrelated to Prizlon-cel**	6	797.5 (336–1831)
Acute myeloid leukemia	2	565 (336–794)
Myelodysplastic syndromes	1	1348
Unknown cause	1	371
Covid-19 related pulmonary fibrosis	2	1316 (801-1831)
• **AE related to Prizlon-cel**	1*	157
Pneumonia	1*	157

*1 MCL patient experienced disease progression during pneumonia and died 2 weeks after withdrawal. It was believed that the infection and disease progression together caused patient death

Responses with PRIZLONCABTAGENE AUTOLEUCEL are Deep and Durable

- The ORR and CR rate were 91.5% and 85.1%, respectively for all patients
- Among the 43 LBCL pts, ORR and CR were 90.7% and 86.0%, respectively
- With a median follow-up of 53.9 months (range, 3.1–72.2), median duration of response was not reached
- Among LBCL patients, 20 (46.5%) maintained response without treatment and 28 patients (65.1%) remained alive

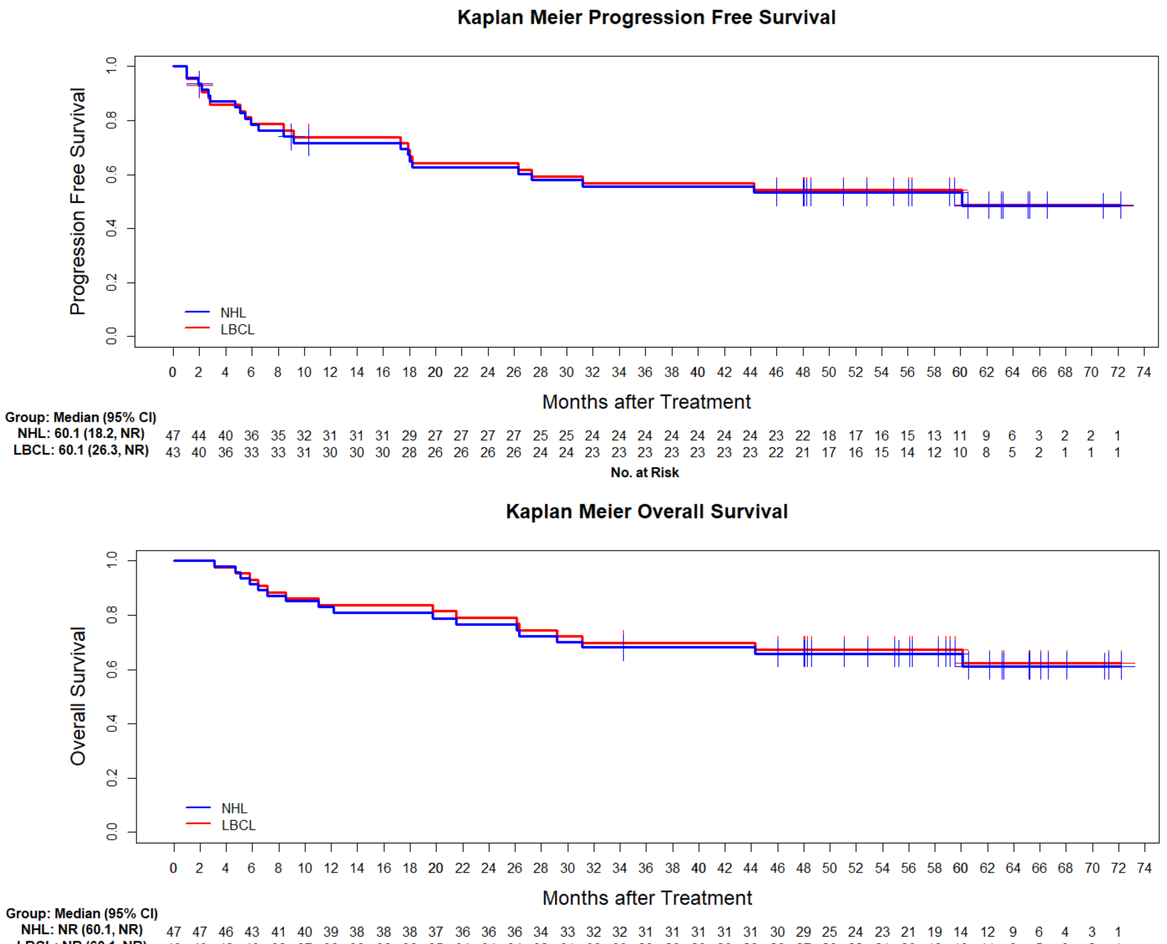
Figure 2. Response



FPS and OS

- With a median follow-up of 53.9 months, median PFS was 60.1 months, median OS was not reached
- KM estimates of 4-year PFS rate are 53.3% (all patients) and 54.2% (LBCL patients)
- KM estimates of 4-year OS rate are 65.9% (all patients) and 67.4% (LBCL patients)

Figure 3. Kaplan–Meier Estimates of the Progression–free Survival, and Overall Survival



Conclusions

- **PRIZLONCABTAGENE AUTOLEUCEL demonstrates a favorable safety profile; no new safety signals were observed since the last report**
- **With median follow-up of 53.9 months, deep and durable responses were observed in r/r B-NHL patients, especially those with LBCL**
  - Median PFS was 60.1 months; 48-m PFS rate were 53.3% (all patients) and 54.2% (LBCL)
  - Median OS has not been reached; 48-m OS rate were 65.9% (all patients) and 67.4% (LBCL)
- **These encouraging data demonstrated excellent durable efficacy and manageable safety profiles**
- **A registration pivotal study is ongoing at 2.5 M/kg in Chinese patients with r/r LBCL (NCT05800977)**
- **A global, multicenter, open-label study of JNJ-90014496 (formerly known as C-CAR039) sponsored by J&J is currently open and enrolling adult participants with B-NHL (NCT05421663)**

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