Three-Year Follow-Up of FUMANBA-1: a Phase 1b/2 Study of Fully Human Anti-BCMA CAR-T Equecabtagene Autoleucel in Patients with Relapsed/Refractory Multiple Myeloma

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Interest disclosure

Author

Jie Chen, Huan Ye, and Hongyu Gui are employees of Nanjing IASO Biotechnology Co., Ltd.

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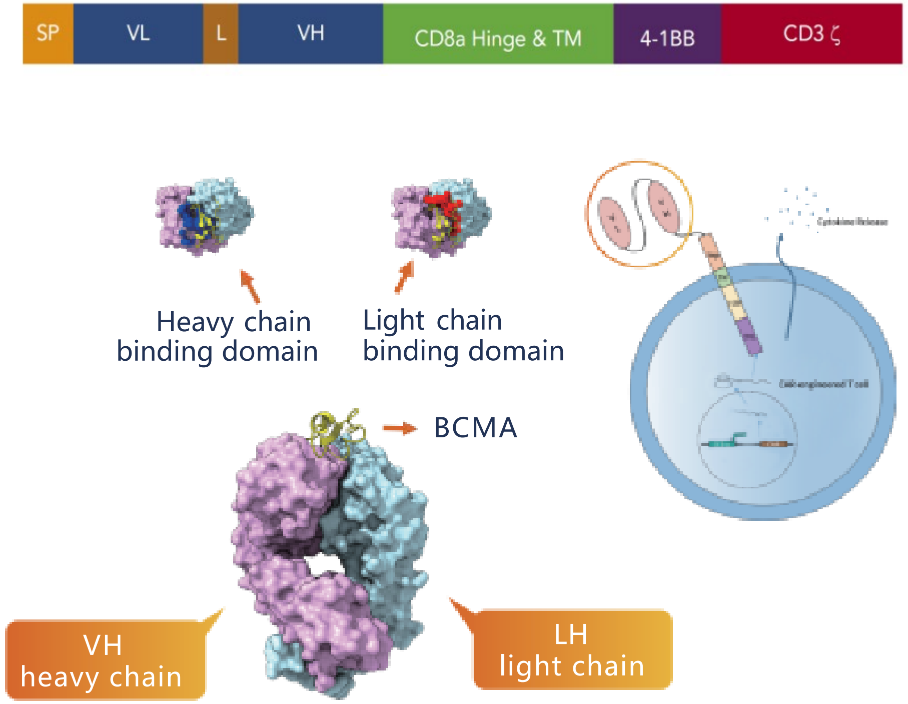
Equecabtagene Autoleucel (Eque-cel)

Breakthrough Fully Human CAR Structure and 4-1BB Signaling Domain

- Fully human scFv overcomes the immunogenicity of animal-derived scFv [1], which is more conducive **to rapid cell expansion and long-term persistence** of CAR-T cells.
- Full epitope binding of BCMA by light and heavy chain structures [2].
- Rapid dissociation facilitates modest fluidity of tumor cell killing, and low cell exhaustion enhances cell proliferation and durable retention [3].
- CAR-T cells with 4-1BB costimulatory domain have better durability than CAR-T cells with CD28 costimulatory domain.



Eque-cel was approved by China's National Medical Products Administration (NMPA) on June 30, 2023, for treating adult patients with relapsed or refractory multiple myeloma (R/RMM) who have received three or more lines of prior therapies, including at least one proteasome inhibitor and an immunomodulatory agent.

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Trial Overview: FUMANBA-1 [1,2,3]

- Single-arm, multi-center, open-label clinical study.
- To evaluate the efficacy and safety of Eque-cel in adult patients with RRMM after three or more prior therapies.

Key Inclusion Criteria

- 18-70 years
- ECOG score of 0-1
- **RRMM after three or more prior therapies**
- **With prior PI and IMiD regimens**
- Disease progression after last treatment

Risk Factor

- Extramedullary lesions
- With prior CAR-T

Bridging Treatment	Lymphodepletion	Infusion	Post-infusion Assessments	Long-term Follow-up
If necessary	Cyclophosphamide: 500 mg/m^2 Fludarabine: 30 mg/m^2	Dose: 1.0×10^6 CAR-T cells/kg	Day 1 - 2 years	Follow-up to 15 years

Screening and pre-infusion → **Infusion therapy** → **Post-infusion follow-up assessment**

17 subjects entered Phase 1b study
102 subjects entered Phase 2 study

Primary Endpoints

- Phase 1: Safety and tolerability
- Phase 2: 3 m ORR post-infusion

Other Endpoints

- PK&PD, MRD, OS, DOR, PFS, TTR

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1. *JAMA Oncol*. doi:10.1001/jamaoncol.2024.4879 Published online November 7, 2024.
2. 2023 ASH Oral Abstracts 761
3. 2023 IMS poster P290

Patient Characteristics

- As of December 31, 2024, a total of 109 patients with RRMM had received eque-cel, the median follow-up was 36 months. The median lines of prior therapy was 4.
- 12.8% had EMD and 11% had received prior BCMA CAR-T therapy.

Characteristics	N=109
Age, years, median (Range)	58 (39, 70)
Gender, Male, n(%)	58 (53.2)
ECOG score, n(%)	
0	24 (22.0)
1	85 (78.0)
Extramedullary disease (EMD), n(%)	14 (12.8)
MM type, n(%)	
IgG	57 (52.3)
Other	52 (47.7)
High-risk cytogenetic abnormality[†], n(%)	36 (33.0)
High-risk cytogenetic abnormality[§], n(%)	77 (70.6)
Prior lines of therapy, median (Range)	4 (3, 23)
Months since diagnosis, median (Range)	43.4 (6.6, 193.2)

Characteristics	N=109
R-ISS stage n(%)	
I	21 (19.3)
II	71 (65.1)
III	10 (9.2)
Not evaluable	7 (6.4)
Exposure status, n(%)	
Double-class[※]	109 (100)
Triple-class[**]	26 (23.9)
Petal-class[¶]	17 (15.6)
CAR-T cell therapy	12 (11.0)
Monoclonal antibody (mAb)	26 (23.9)
Stem cell transplantation	31 (28.4)

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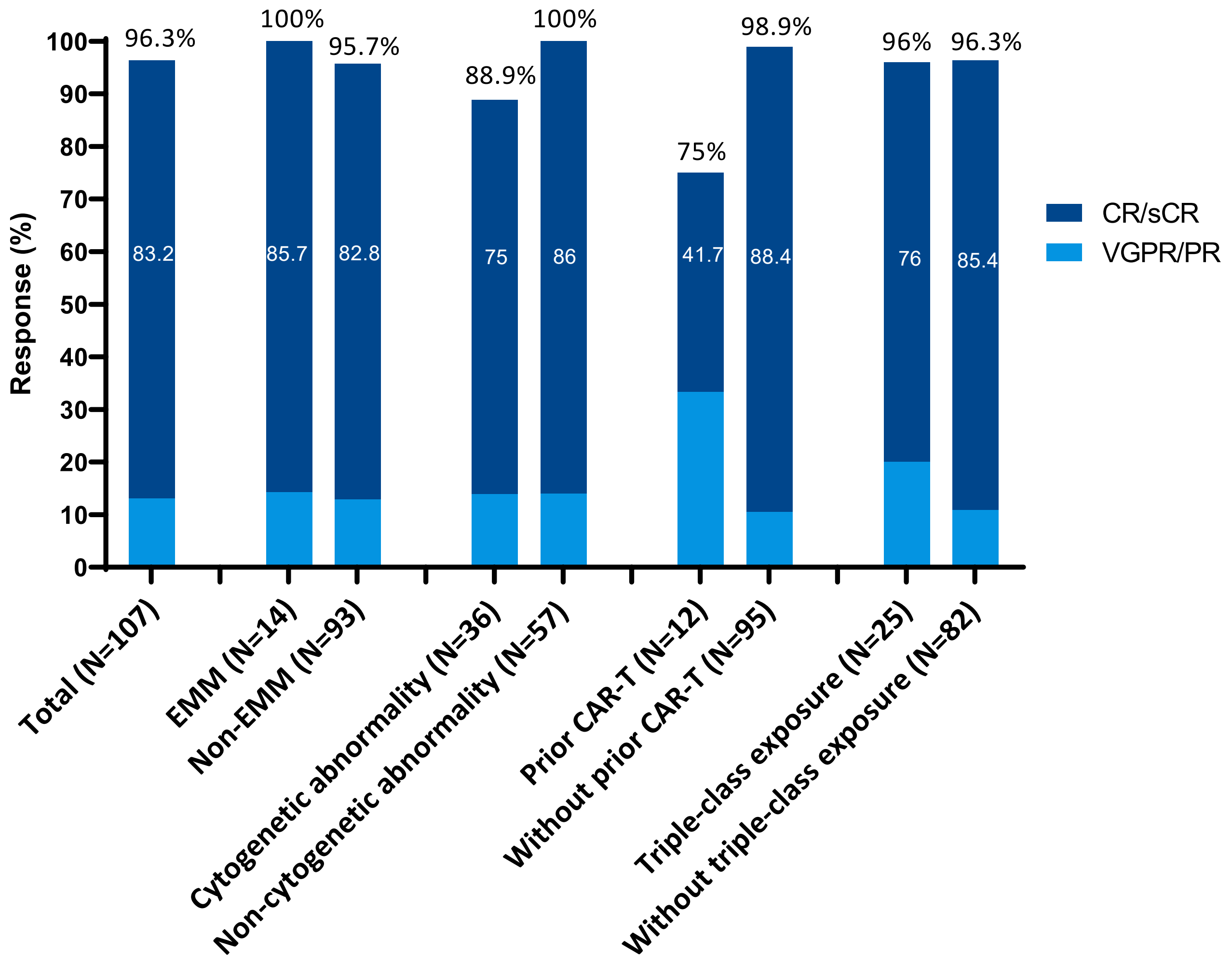
† Defined as that at least one of del (17), t (4:14), and t (14:16) detected by fluorescence in situ hybridization is positive.
§Defined as that at least one of t (4; 14), t (14; 16), t (14; 20), Del 17p and Gain 1q detected by fluorescence in situ hybridization is positive.
※ Exposed to PI and IMiD. ** Exposed to PI, IMiD, and mAb. ¶ Exposed to two PIs, two IMiDs, and one mAb.

Efficacy

- In patients with evaluable efficacy (N=107)
  - ORR: 96.3%
  - ≥CR: 83.2%
- In patients without prior CAR-T (N=95)
  - **ORR: 98.9%**
  - **≥CR: 88.4%**



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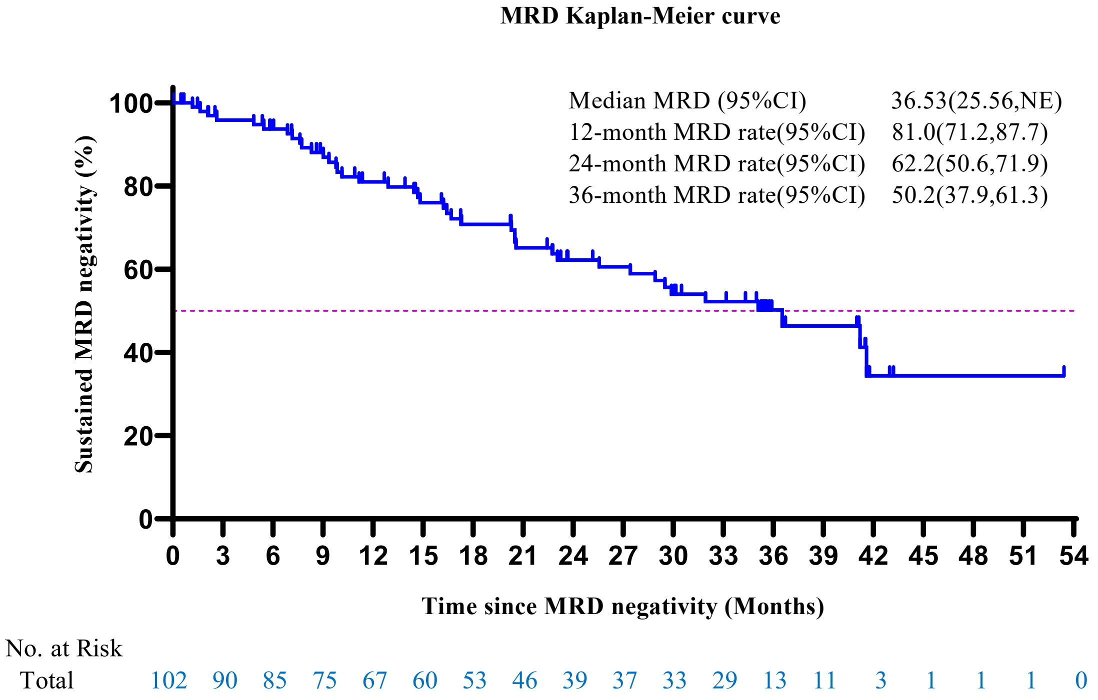
DOR: Duration of Response, PFS: Progression-free Survival, OS: Overall Survival

Efficacy: MRD analysis

- **MRD negativity rate: 95.3%**
  - In patients who achieved ≥CR (N=89) : 100%
  - In patients without prior CAR-T (N=95) : 98.9%
- **Sustained 12-month MRD negativity rate: 81.0%**
- Median duration of MRD negativity：36.5 months

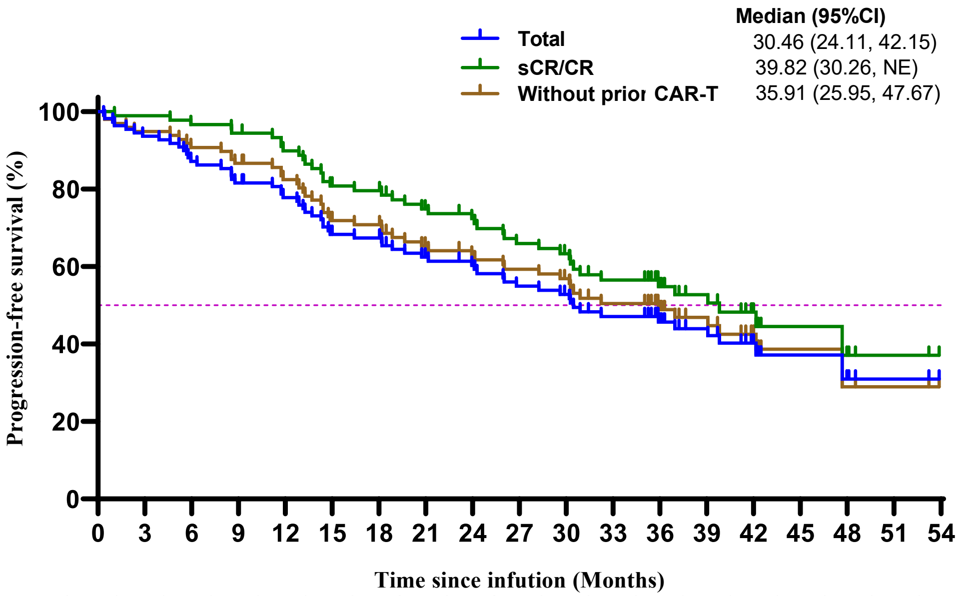


MRD: Minimal Residual Disease

Efficacy: survival analysis

- Median DOR：31.3 months
- Median PFS :
  - In all patients: 30.5 months
  - **In patients who achieved ≥CR: 39.8 months**
  - In patients without prior CAR-T: 35.9 months
- Median OS was not reached, **66.3%** of patients were alive at 3-year follow-up.

PFS Kaplan-Meier curve



No. at Risk																			
Total	109	102	94	88	82	72	70	60	57	51	48	40	31	24	13	6	4	2	0
sCR/CR	89	88	86	84	79	71	69	60	57	51	48	40	31	24	13	6	4	2	0
Without prior CAR-T	97	92	88	84	78	68	66	56	53	49	46	38	29	22	11	4	3	2	0

DOR: Duration of Response, PFS: Progression-free Survival, OS: Overall Survival

Safety

- CRS occurred in 93.6% of patients, with only one case ≥ grade 3.
- ICANS was only reported in two patients (grade 1–2).
- No late-onset neurotoxicity or secondary malignancies were observed.

N=109	CRS	ICANS
Any grade, n(%)	102 (93.6)	2 (1.8)
Grade 1	74 (67.9)	1 (0.9)
Grade 2	27 (24.8)	1 (0.9)
Grade ≥3	**1 (0.9)**	0
Time to first onset, days, median (range)	6 (1, 13)	6.5 (3, 10)
Duration, days, median (range)	5 (2, 30)	1.5 (1, 2)

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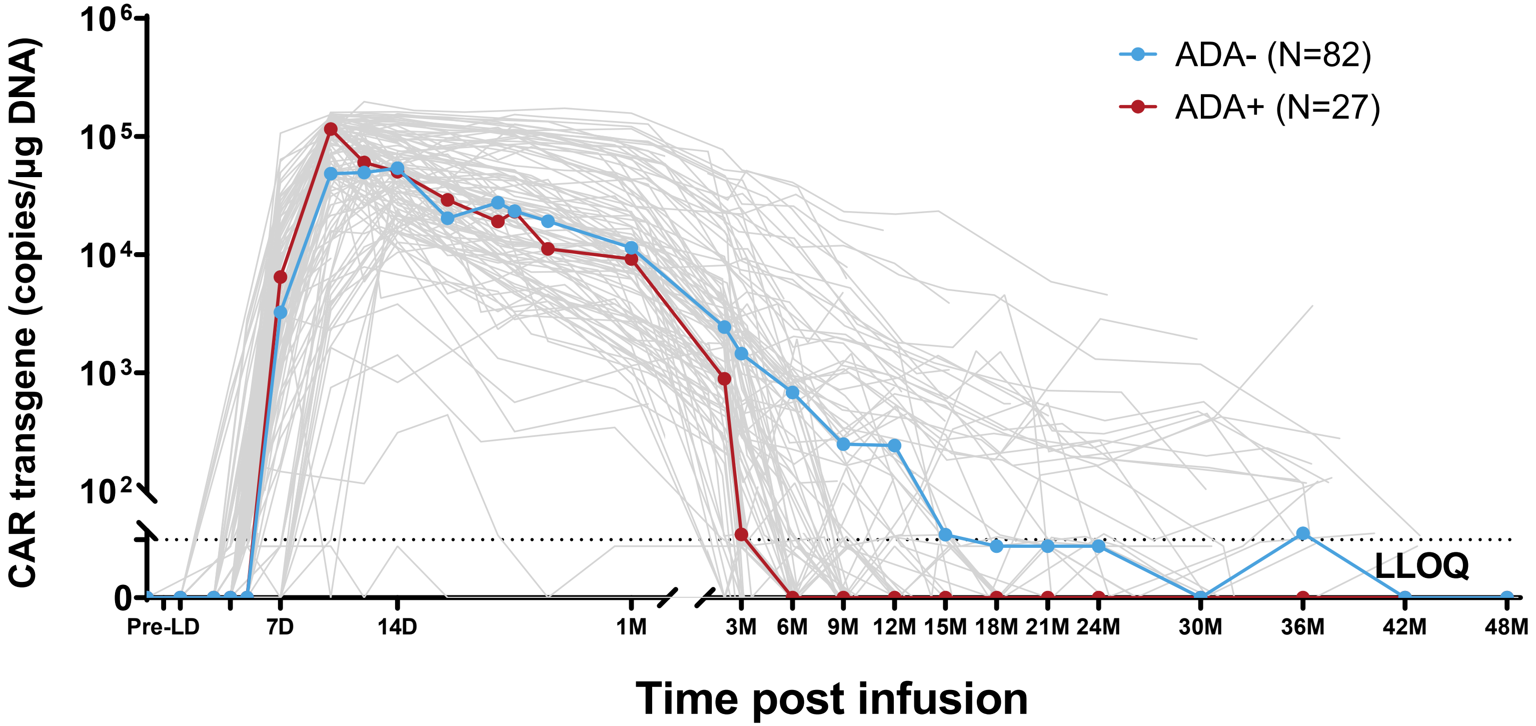
CRS: Cytokine Release Syndrome
ICANS: Immune Effector Cell–Associated Neurotoxicity Syndrome

PK/ADA

- CAR transgene persistence was observed in **52% (39/75) of patients at 12 months** and 37.5% (21/56) at 24 months.
- Anti-CAR antibodies were detected in 24.8% of patients. Only 3% ADA was detected in first 3 months.



Conclusion

- At a median follow-up of 36.0 months, Eque-cel showed vey promising long-term outcomes.
- The median PFS as followings:
  - In all patients: 30.5 months
  - In patients who achieved ≥CR: 39.8 months
  - In patients without prior CAR-T therapy: 35.9 months
- Eque-cel demonstrated deep, durable responses and sustained MRD negativity in heavily pretreated RRMM patients, including those with high-risk features.
- The long-term safety profile remained manageable, with no new safety signals identified.

Real-World Outcomes of Equecabtagene Autoleucel, the First Fully Human BCMA-Targeted CAR-T Therapy, in 150 Patients with Multiple Myeloma (MM): A Multicenter Experience from China

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INTRODUCTION

Equecabtagene Autoleucel (Eque-cel), a fully human B-cell maturation antigen (BCMA)-targeted chimeric antigen receptor (CAR) T-cell therapy, was approved by NMPA in June 2023 for adult relapsed/refractory multiple myeloma (RRMM) patients after ≥3 prior lines of therapy. The FUMANBA-1 trial showed its favorable safety and durable efficacy in heavily pretreated RRMM.

AIM

We conducted the first post-commercialization real-world data analysis of Eque-cel in multiple myeloma patients in China, providing clinical guidance for its application.

METHOD

- We conducted analysis on data from 150 patients who received infusion therapy across 48 centers between June 2023 and August 31, 2024.
- All patients received a single infusion of Eque-cel at the dose of 1.0 x 10^6 CAR-T cells/kg.
- Responses were evaluated per IMWG criteria, and the ORR was defined as at least ≥PR.

RESULTS

Baseline characteristics

- A total of 150 patients were enrolled.
- Baseline characteristics were shown in Table 1.

Characteristics	N=150
Median age, years(range)	60, (35-78)
Male，n(%)	86(57.3%)
Triple-class exposed - n(%)	118(78.6%)
Penta-class exposed - n(%)	61(40.7%)
Anti-CD38 antibody treated n(%)	123(82%)
Prior ASCT, n(%)	80(53.3%)
High-risk cytogenetics - n(%)	107(71.3%)
Plasma cell leukemia - n(%)	19(12.7%)
Extramedullary disease - n(%)	79(52.7%)
Central Nervous System involvement - n(%)	15(10.0%)

* Including 7 case with prior second ASCT

Table 1 Baseline characteristics

Efficacy

- In the efficacy-evaluable population(n=137), **the ORR was 98.5% (135/137)**, with73% (100/137) achieving complete response (CR) or better(Table2).
- Among 90 patients with ≥CR and MRD data, 97.8% (88/90) were MRD-negative(Table 2).

Characteristics	N=137
Best of follow-up(BOR)	
ORR， n(%)	135(98.5%)
≥CR， n(%)	100(73%)
Characteristics	**N=90**
MRD-negative, n(%)	**88(97.8%)**

Table 2 Efficacy evaluation.

- In the EMM subgroup, ORR was 98.6% vs 98.4% in non-EMM, with ≥CR rates 70.8% and 75.4%.(Figure1)

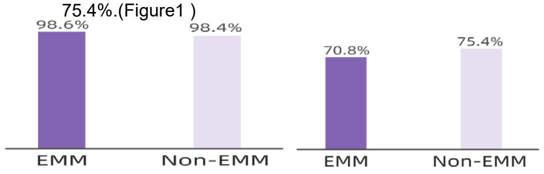

Figure 1 Effect evaluation of EMM and Non-EMM

- CR rates : 81.3% with early-line therapy versus 65.1% in late-line settings.
- Patients without high-risk cytogenetics had a higher ≥CR rate (77.8% vs 73.5%).
- In the low-risk CAR-HEMATOTOX group, the ≥CR rate was 91.7% vs 73.4% in the high-risk group(Figure 2)

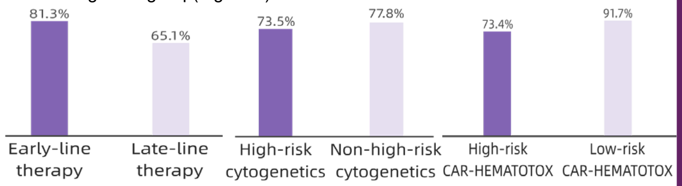

Figure 2 Comparison of effect evaluation in other subgroups

Safety

- 136 (90.7%) patients experienced CRS with most cases being grade 1~2.
- ICANS was 10.7% (16/150) , with 4% experienced ≥ Grade 3.
- The most common ≥ grade 3 treatment-related adverse events were hematologic toxicities.
- In the CAR-HEMATOTOX low-risk group, hematologic recovery was by Day 28, while the high-risk group had prolonged cytopenias and longer hospital stays.

N=150	CRS	ICANS
All grade	136(90.7%)	16(10.7%)
Grade 1	71(47.3%)	5(3.3%)
Grade 2	58(38.7%)	5(3.3%)
≥Grade 3	7(4.7%)	6(4%)

Table 3 The grades of CRS and ICANS during the treatment period

CONCLUSIONS

- Eque-cel, China's first fully human BCMA-targeted CAR-T therapy, demonstrated high efficacy in 137 evaluable patients. Despite high-risk features including EMM(52.7%), PCL(12.7%), and CNS infiltration (10%), outcomes were consistent with the pivotal FUMANBA-1 trial.
- Safety profiles showed predominantly low-grade CRS and limited but severe ICANS. These findings confirm Eque-cel as an effective therapy with manageable safety, though extended follow-up is needed to assess survival benefits and optimize strategies.

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