

CARsgen Therapeutics (HKEX: 02171)

July 2025

Making Cancer Curable

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We Develop Innovative and Differentiated Cell Therapies to Make Cancer and Other Diseases Curable



1

Marketed product:

- zevorcabtagene autoleucel (zevor-cel, CT053)

1

CAR-T product at NDA stage:

- Satri-cel (targeting Claudin18.2)

2

CAR-T products at IND stage:

- CT011 (targeting GPC3)
- CT071 (targeting GPRC5D)

300+

Patents (including 129 issued, as of December 31, 2024)

4+

Core technology platforms:

- CycloCAR®, THANK-uCAR®, THANK-u Plus™, LADAR®, CARcelerate®

10+ years

Focus on innovative CAR-T therapies since company initiation

Global Reach with Integrated R&D and Manufacturing Capabilities Complemented with Synergistic Partnership



CGMP Facility



Durham

Beijing Office



Beijing
Shanghai

Headquarter (Xuhui)



GMP Facility (Jinshan)



Shanghai

Headquarter, research, clinical development, GMP commercial and clinical manufacturing facility



Durham, North Carolina

CGMP manufacturing facility

Partnerships



(SZ: 000963)

Exclusive commercialization of zevor-cel in mainland China



(NASDAQ: MRNA)

Evaluate satri-cel in combination with an mRNA Cancer Vaccine



(KOSDAQ: 195940)

License of zevor-cel and CT032 in the Republic of Korea

Continuous Innovation and Technology Advancement to Tackle the Major Challenges with CAR-T therapies Since 2014



Allogeneic CAR-T

- THANK-uCAR®, THANK-u Plus™ platforms

Autologous CAR-T

- BCMA CAR-T (zevor-cel)
- first-in-class Claudin18.2 CAR-T (satri-cel)
- first-in-class GPC3 CAR-T (CT011)

Enabling Technologies



CycloCAR®
(co-expression of IL-7 + CCL21)



LADAR®
(precise targeting)



Lymphodepletion
(FNC regimen)



Binder
(humanized/fully-human antibodies against ~20 targets)

Competitive Product Pipeline with Global Rights



	Product Candidate ¹	Target	Indication	Pre-clinical	Phase I	Phase II/III ²	BLA/ NDA
Autologous CAR-T	Zevor-cel (CT053) ³	BCMA	R/R MM (4L+) R/R MM	LUMMICAR 1 (China)	On Market		
				LUMMICAR 2 (US, Canada)			
	Satri-cel (CT041)	Claudin18.2	G/GEJA (3L+) GC/PC PC (adjuvant) G/GEJA, PC, etc. G/GEJA (adjuvant)	ST-01 (China)			
				ST-02 (US, Canada)			
				ST-05 (China)			
				IIT (China)			
Allogeneic CAR-T	CT071	GPRC5D	R/R MM, R/R pPCL R/R MM, R/R PCL NDMM	(US)			
				IIT (China)			
				IIT (China)			
	CT011	GPC3	HCC (adjuvant)	(China)			
	CT0590	BCMA	R/R MM, R/R PCL	IIT (China)			
	CT0596	BCMA	R/R MM, R/R PCL	IIT (China)			
	KJ-C2219	CD19/CD20	B-cell malignancies SLE, SSc	IIT (China)			
	KJ-C2320	CD38	AML	IIT (China)			
	KJ-C2114	Undisclosed	Solid tumors				
	KJ-C2526	NKG2DL	AML, other malignancies, senescence				

for hematologic malignancies
 for solid tumors
 for autoimmune diseases

R/R MM: Relapsed/Refractory Multiple Myeloma; G/GEJA: Gastric/Gastroesophageal Junction Adenocarcinoma; GC: Gastric Cancer; PC: Pancreatic Cancer; HCC: Hepatocellular Carcinoma; R/R pPCL: Relapsed/Refractory Primary Plasma Cell Leukemia; NDMM: Newly Diagnosed Multiple Myeloma; SLE: Systemic Lupus Erythematosus; SSc: Systemic Sclerosis; AML: Acute Myeloid Leukemia

¹ All product candidates are self-developed with global rights

² Phase II trials of some indications are pivotal studies

³ Core Product Candidate. Commercial rights in mainland China have been granted to Huadong Medicine (SZ: 000963). Rights in the South Korean market have been licensed out to HK Inno.N (KOSDAQ: 195940)

CAR T 生产区
CAR T Production Area



Autologous CAR-T Against Hematologic Malignancies



Zevor-cel: Differentiated Fully-human BCMA CAR-T for R/R MM



EHA2024

Zevor-cel Highlights



- Optimized scFv
 - Enhanced binding affinity
 - High stability
 - Enhanced anti-tumor activity
 - Excellent safety profile
 - Co-stimulatory domain: 4-1BB
 - Low immunogenicity
-
- ✓ Designations: RMAT (FDA), Orphan Drug (FDA)
 - ✓ NDA approved by China NMPA (February 23, 2024)

China Pivotal Phase II (LUMMICAR-1) ¹ N=102

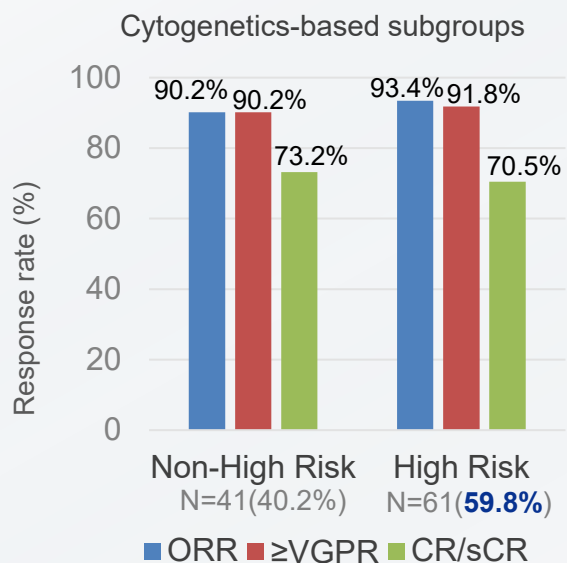
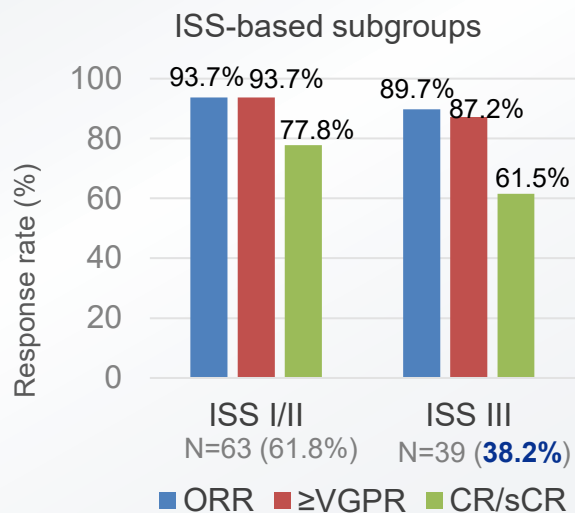
Follow-up, median (range), Month	20.3 (0.4-27)
ISS stage III, No. (%)	39 (38.2%)
High risk Cytogenetic, No. (%)	61 (59.8%)
EMD+ , No. (%)	11 (10.8%)
Prior lines of therapies, median (range)	4 (3-15)
Double-class refractory*, No. (%)	91 (89.2%)
Triple-class refractory**, No. (%)	23 (22.5%)
ORR, No. (%)	94 (92.2%)
CR/sCR, No. (%)	73 (71.6%)
≥VGPR, No. (%)	93 (91.2%)
mDoR, Month	Not mature
mPFS, Month	Not mature
MRD Negativity***, No. (%)	73 (100%)
≥Grade 3 CRS, No. (%)	7 (6.9%)
≥Grade 3 NT, No. (%)	0
Treatment related death, No.	1

*Double-class refractory: Refractory to a proteasome inhibitor and immunomodulatory drug; **Triple-class refractory: Refractory to a proteasome inhibitor, immunomodulatory drug and anti-CD38 antibody; ***In the patients achieved CR/sCR

Zevor-cel: Outstanding Efficacy and Manageable Safety



ASH 2024 



Long-term survival with deep response

It has been reported that ISS-III and high risk cytogenetics could impact the efficacy of BCMA CAR-T. Although, zevor-cel treated a high percentage of patients at ISS III stage or high risk cytogenetics in pivotal phase II, it showed competitive efficacy (left figures).

◆ Overall Superior efficacy

- IIT¹: ORR of 87.5%, sCR/CR rate of 79.2%.
- Phase I²: **2-year OS rate of 100%, 3-year OS rate of 92.9%.**
- Pivotal phase II^{3,4}: ORR of 92.2%, predicted **30-month OS rate of 87.7%** (in patients who achieved CR/sCR) .

ISS: International Staging System; ORR: Objective Response Rate; CR: Complete Response; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; IIT: Investigator-initiated Trial; OS: Overall Survival; SAE: Serious Adverse Event

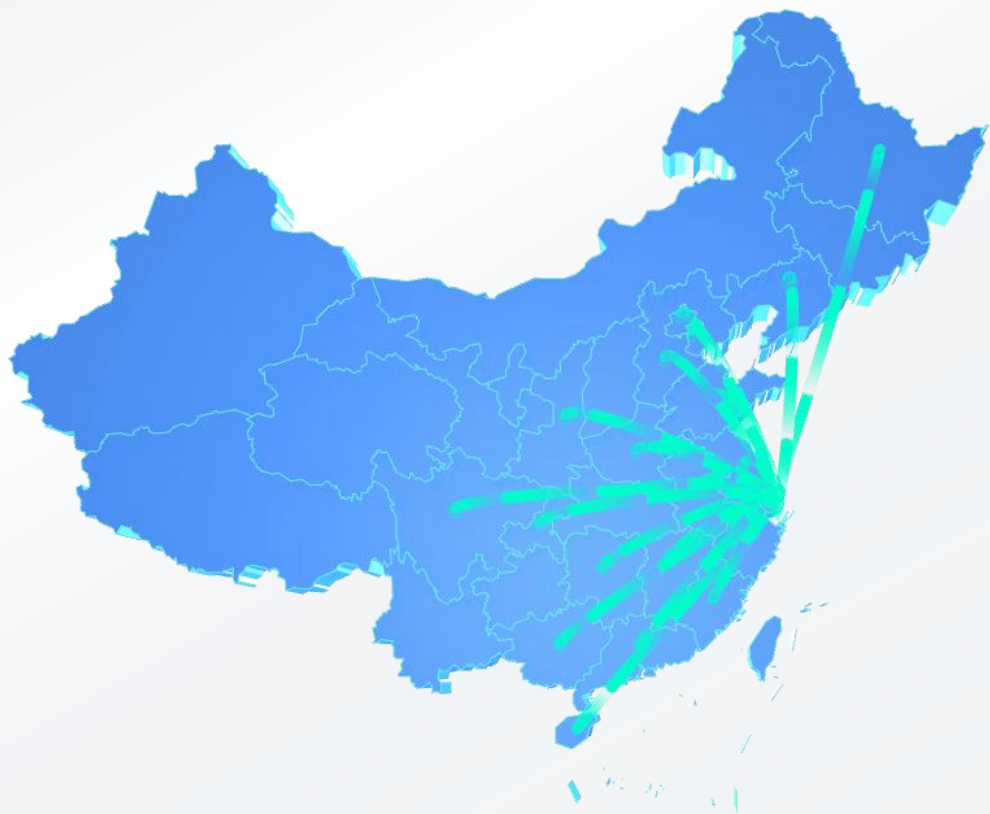
Higher safety, lower incidence of SAE

◆ In IIT, Phase I, and Phase II studies

- ≥Grade 3 CRS incidence: 0%, 0%, 6.9%, respectively.
- ≥Grade 3 neurotoxicity incidence: 4.2%, 0%, 0%, respectively.
- Treatment-related death: 0%, 0%, 1%, respectively.
- ◆ **Low incidence of ≥Grade 3 infections or prolonged hematologic toxicity**
- Low incidence of ≥Grade 3 infections.
- Significantly low incidence of ≥Grade 3 prolonged (>30 days) cytopenia.

1. Yang M, et. al. *Haematologica*. 2022 Aug 1;107(8):1960-1965
2. Fu C, et. al. ASH 2023. 2023 Dec; Poster #4845
3. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209
4. Chen W, et al. ASH 2024. 2024 Dec; Poster #4762

Zevor-cel: Commercialization in China



- Zevor-cel was approved by the NMPA in 2024 for the treatment of R/R MM.
- Exclusive commercialization partner in mainland China:



certification and regulatory filings
completed in

100+

healthcare institutions

20+

provinces / cities

154

valid orders in 2024
(Mar-Dec)

CT071: Differentiated GPRC5D CAR-T with CARcelerate® Platform




Product

- Fully-human scFV generated by CARsgen
- For relapsed R/R Multiple Myeloma or R/R Primary Plasma Cell Leukemia
- Proprietary **CARcelerate®** platform

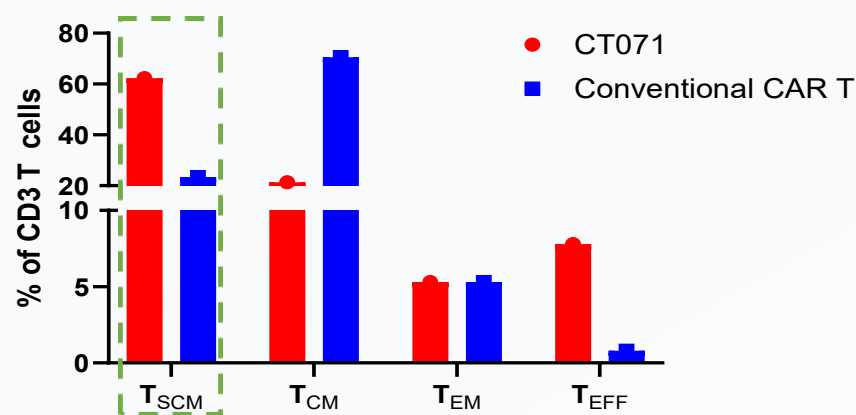
Manufacturing Time:

 **CARcelerate®: ~30 hours**

 **Conventional: > 7 days**

*Younger,
healthier,
possibly
more potent
CAR-T*

T cells phenotype



Clinical Development Status



- China investigator-initiated trial for R/R MM and PCL (NCT05838131) **Enrollment Completed**
- China investigator-initiated trial for NDMM (NCT06407947) **Enrollment Completed**



- IND cleared:** R/R MM or R/R pPCL

R/R MM: Relapsed/Refractory Multiple Myeloma; R/R pPCL: Relapsed/Refractory Primary Plasma Cell Leukemia; NDMM: Newly Diagnosed Multiple Myeloma

CT071 in R/R MM: Deep Response with Promising Safety Profile in China IIT

ASH 2024



	0.1 × 10 ⁶ cells/kg (n=8)	0.3 × 10 ⁶ cells/kg (n=9)	All Patients (n=17)
R-ISS Stage, No. (%)			
II	4 (50.0)	8 (88.9)	12 (70.6)
III	4 (50.0)	0	4 (23.5)
Extramedullary Disease, No. (%)	2 (25.0)	2 (22.2)	4 (23.5)
High-risk Cytogenetics, No. (%)	6 (75.0)	6 (66.7)	12 (70.6)
Prior Lines of Therapy, median (range)	4 (1, 12)	5 (3, 7)	5 (1, 12)
ORR, No. (%)	8 (100)	8 (88.9)	16 (94.1)
CR/sCR rate, No. (%)	5 (62.5)	4 (44.4)	9 (52.9)
VGPR or better rate, No. (%)	5 (62.5)	5 (55.6)	10 (58.8)
MRD Negativity (<10 ⁻⁶) with CR/sCR subjects*, No. (%)	5 (100)	4 (100)	9 (100)
CRS, No. (%)	6 (75.0)	5 (55.6)	11 (64.7)
Grade 1, No. (%)	5 (62.5)	3 (33.3)	8 (47.1)
Grade 2, No. (%)	1 (12.5)	2 (22.2)	3 (17.6)
ICANS, No. (%)	0	0	0
AE leading to death, No. (%)	0	0	0

R/R MM: Relapsed/Refractory Multiple Myeloma; IIT: Investigator-initiated Trial; R-ISS: Revised International Staging System; ORR: Objective Response Rate; CR: Complete Response; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; MRD: Minimal Residual Disease; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome; AE: Adverse Event

*Percentages were calculated based on CR/sCR patients (n=9)

Cut-off date: Jun 21, 2024

1. Du J, et al. ASH 2024. 2024 Dec; Poster #3451

CT071 in High-risk NDMM: Deep Response and Favorable Safety Profile in China IIT



EHA2025

	China investigator-initiated trial (N=10)
R2-ISS Stage, No. (%)	
I	1 (10)
II	2 (20)
III	4 (40)
IV	3 (30)
Extramedullary Disease, No. (%)	3 (30)
ECOG PS, No. (%)	
1	10 (100)
High-risk Cytogenetics, No. (%)	6 (60)

	China investigator-initiated trial (N=10)
ORR, No. (%)	10 (100)
sCR, No. (%)	7 (70)
VGPR, No. (%)	2 (20)
PR, No. (%)	1 (10)
MRD Negativity (<10 ⁻⁶) at Week 4, No. (%)	10 (100)
CRS, No. (%)	7 (70)
Grade 1, No. (%)	7 (70)
ICANS, No. (%)	0
Dose Limiting Toxicity	0
Death due to TRAE	0

NDMM: Newly Diagnosed Multiple Myeloma; IIT: Investigator-initiated Trial; ECOG PS: Eastern Cooperative Oncology Group Performance Status; ORR: Objective Response Rate; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; PR: Partial Response; MRD: Minimal Residual Disease; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome; TRAE: Treatment-related Adverse Event

Cut-off date: Jan 2, 2025

1. Du J, et al. EHA 2025. 2025 Jun; Poster #PF1164



Autologous CAR-T Against Solid Tumors

Unmet Medical Needs in Solid Tumors, Including Gastric and Pancreatic Cancers

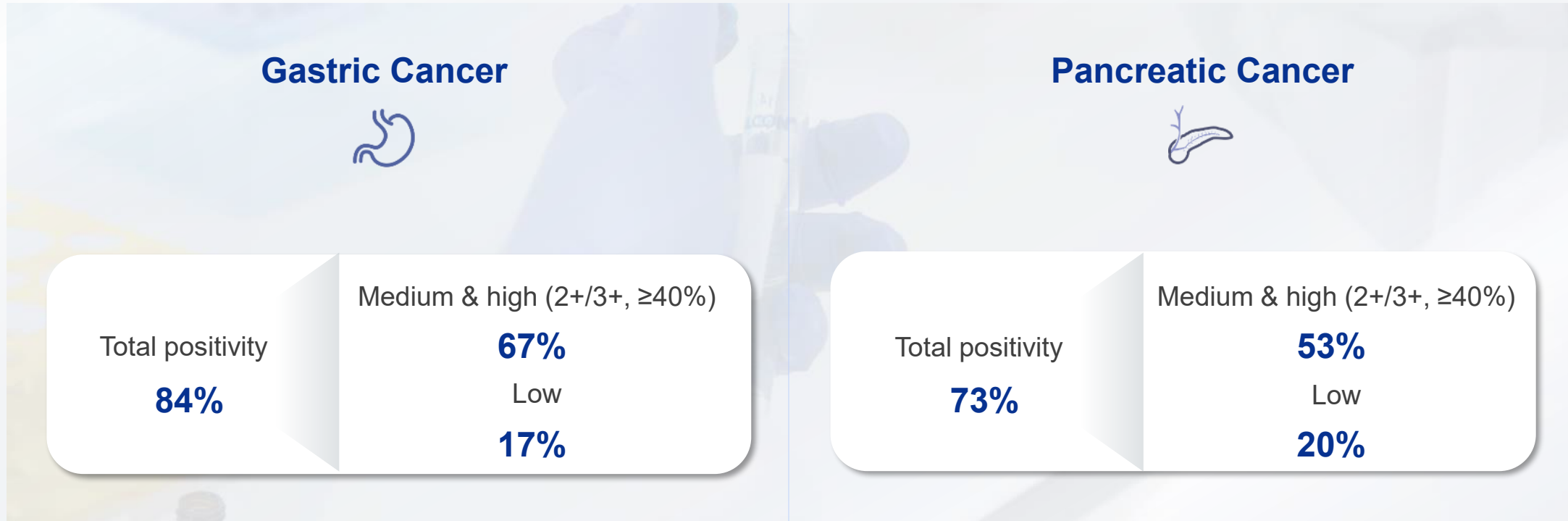
<div>  </div> <div> <p>Gastric Cancer</p>  </div> <div> <p>Incidence ~25.6K¹</p> <ul style="list-style-type: none"> • Resectable ~10.0K <p>Mortality ~11.0K¹</p> <p>5-year survival rate of advanced GC is 5-20%; For advanced GC (3L+), ORR is 4.5%, mPFS < 2 months, mOS < 6 months (TAGS study)²</p> </div>	<div>  </div> <div> <p>Incidence ~358.7K¹</p> <ul style="list-style-type: none"> • Resectable ~300.0K <p>Mortality ~260.4K¹</p> </div>
<div> <p>Pancreatic Cancer</p>  </div> <div> <p>Incidence ~60.1K¹</p> <p>Mortality ~49.5K¹</p> <p>5-year survival rate of PC is about 10%; No effective SOC for PC (2L+)</p> </div>	<div> <p>Incidence ~118.7K¹</p> <p>Mortality ~106.3K¹</p> </div>

1. International Agency for Research on Cancer. Population factsheets. 2022

2. Shitara K, et al. *Lancet Oncol.* 2018 Nov;19(11):1437-1448

CARsgen Proprietary Claudin18.2 IHC Test




Claudin18.2 IHC test kit with high sensitivity



*Claudin18.2 expression is also observed in other solid tumors, e.g. in bile duct cancer, 24% of samples exhibit medium & high positivity (2+/3+, ≥40%).

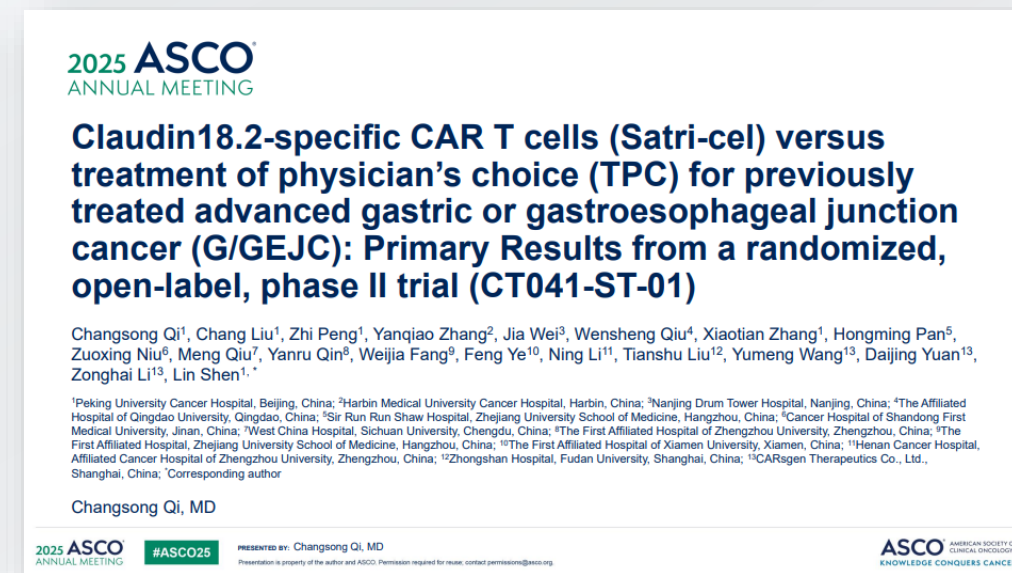
Satri-cel (CT041): Global First-in-Class CAR-T for Claudin18.2-Positive Solid Tumors



Product 	Designations 	Clinical Development Plan 
<ul style="list-style-type: none"> • Optimized scFv¹ <ul style="list-style-type: none"> ✓ High binding affinity ✓ High stability 	<ul style="list-style-type: none"> • Breakthrough Therapy (NMPA) • RMAT (FDA) • Orphan Drug (FDA) 	 <ul style="list-style-type: none"> • GC (3L+) confirmatory Phase II trial in China achieved positive results; NDA submitted; Priority Review granted • PC adjuvant therapy Phase I trial in China: Ongoing • GC adjuvant therapy IIT in China: Ongoing
<ul style="list-style-type: none"> • Innovative FNC (FC + low-dose Nab-Paclitaxel) preconditioning regimen to enhance penetration and anti-tumor effect of CAR-T cells 	Collaboration  <p>Collaboration with Moderna, Inc. (Nasdaq: MRNA) to investigate satri-cel in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine</p>	<p>Expansion of clinical development in</p> <ul style="list-style-type: none"> • earlier lines of therapy • additional Claudin18.2 positive cancers

1. Jiang H, et al. *J Natl Cancer Inst.* 2019;111(4):409-418

Satri-cel China Pivotal Phase II Results — Published in *The Lancet*, Orally Presented at 2025 ASCO

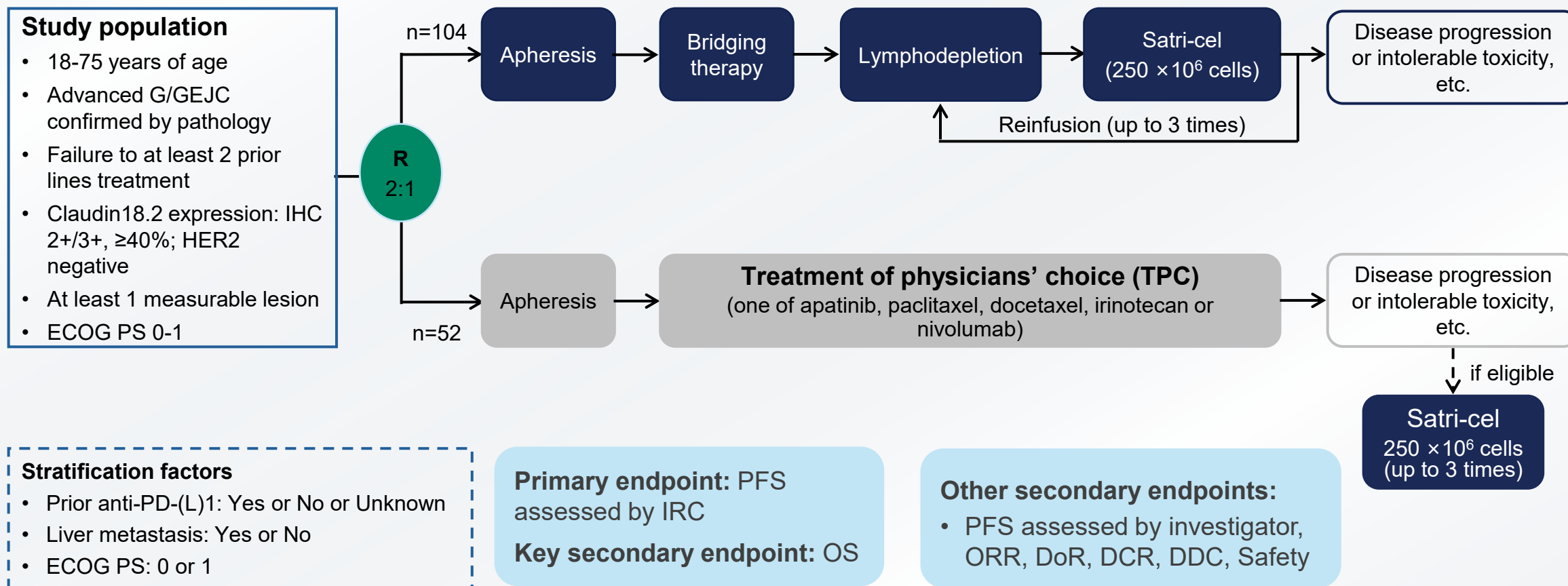


1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Trial Design



An open-label, multicenter, randomized controlled trial conducted in China (CT041-ST-01).

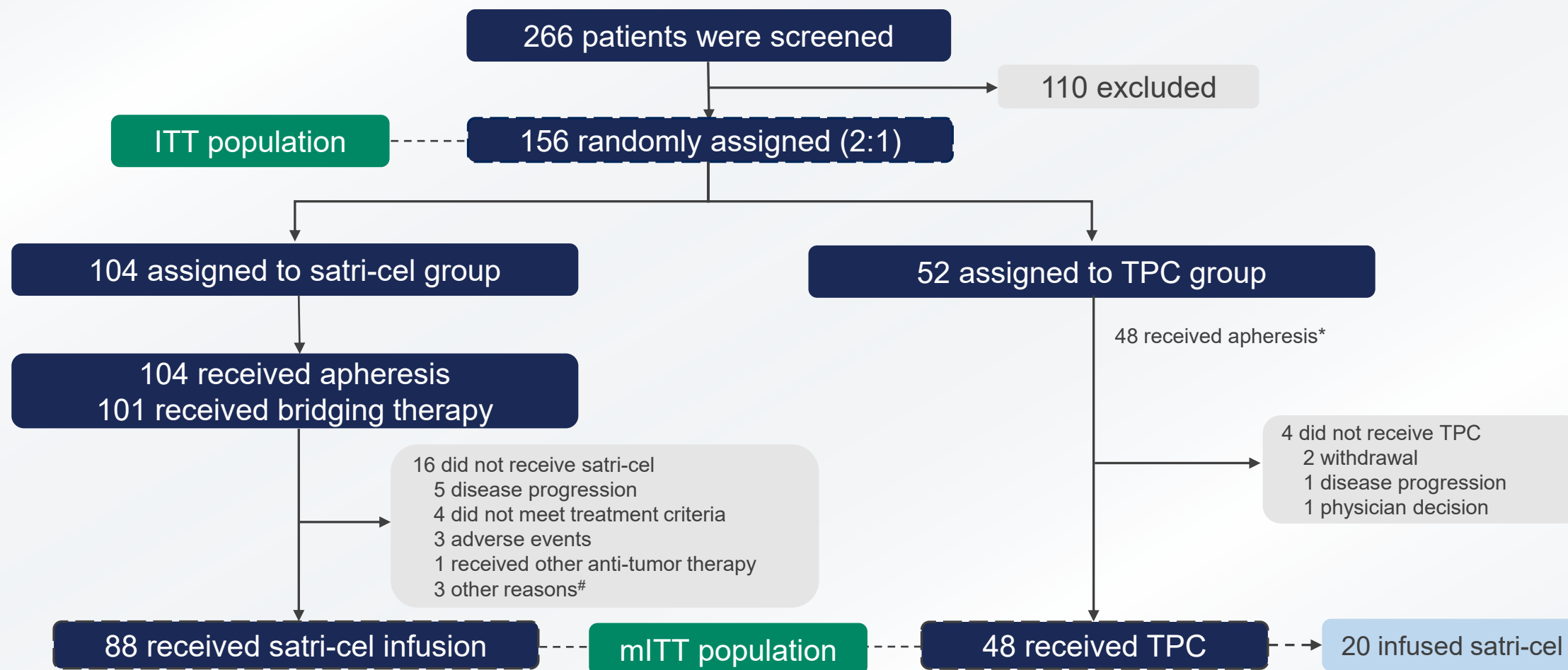


G/GEJC: Gastric or Gastroesophageal Junction Cancer; ECOG PS: Eastern Cooperative Oncology Group Performance Status; PFS: Progression-Free Survival; IRC: Independent Review Committee; OS: Overall Survival; ORR: Objective Response Rate; DoR: Duration of Response; DCR: Disease Control Rate; DDC: Duration of Disease Control

Cut-off date: Oct 18, 2024

1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Patient Disposition



*One was not apheresed per physician's decision and received TPC

#Three patients requested to withdraw from study treatment.

Cut-off date: Oct 18, 2024

1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Baseline Characteristics



Characteristics	Satri-cel group (n=104)	TPC group (n=52)
Age, median (IQR), years	53.5 (45.0, 60.0)	50.5 (43.0, 58.0)
Sex, n (%)		
Male	56 (53.8)	31 (59.6)
Female	48 (46.2)	21 (40.4)
Ethnicity, n (%)		
Chinese	104 (100%)	52 (100%)
ECOG, n (%)		
0	17 (16.3)	8 (15.4)
1	87 (83.7)	44 (84.6)
Primary tumor site, n (%)		
Gastric	88 (84.6)	48 (92.3)
Gastroesophageal junction	16 (15.4)	4 (7.7)
Signet ring cell carcinoma*	41 (39.4)	27 (51.9)
Lauren type, n (%)		
Intestinal type	21 (20.2)	12 (23.1)
Diffuse type	45 (43.3)	26 (50.0)
Mixed type	29 (27.9)	8 (15.4)
Unknown	9 (8.7)	6 (11.5)
Previous gastrectomy, n (%)	49 (47.1)	31 (59.6)

Characteristics	Satri-cel group (n=104)	TPC group (n=52)
Claudin18.2 expression, n (%)†		
Medium expression	24 (23.1)	10 (19.2)
High expression	80 (76.9)	42 (80.8)
Number of prior lines, n (%)‡		
2	76 (73.1)	42 (80.8)
≥3	28 (26.9)	10 (19.2)
Previous systemic therapies, n (%)		
Fluorouracil/analogues and derivatives§	101 (97.1)	52 (100)
Taxanes	96 (92.3)	47 (90.4)
Platinum	103 (99.0)	50 (96.2)
Prior anti-PD-(L)1	81 (77.9)	42 (80.8)
Number of metastatic organs, n (%)		
≤2	53 (51.0)	25 (48.1)
≥3	51 (49.0)	27 (51.9)
Metastatic organs, n (%)		
Peritoneal	72 (69.2)	31 (59.6)
Liver	21 (20.2)	10 (19.2)
Lung	9 (8.7)	7 (13.5)
Bone	8 (7.7)	9 (17.3)

* Inclusion of signet ring cell carcinoma components includes those with WHO classification of signet ring cell carcinoma or those accompanied by signet ring cell carcinoma.

† Claudin18.2 expression classification: High expression is defined as the sum of the percentages of tumor cells with 3+ and 2+ Claudin18.2 expression being ≥ 70%; medium expression is defined as the sum being ≥ 40% but < 70%.

‡ Second-line treatment includes all second-line treatments and first-line treatments that concurrently used three chemotherapeutic drugs, namely taxane [or anthracycline], platinum, and fluorouracil.

IQR=interquartile range. ECOG =Eastern Cooperative Oncology Group. Claudin18.2=claudin-18 isoform 2.

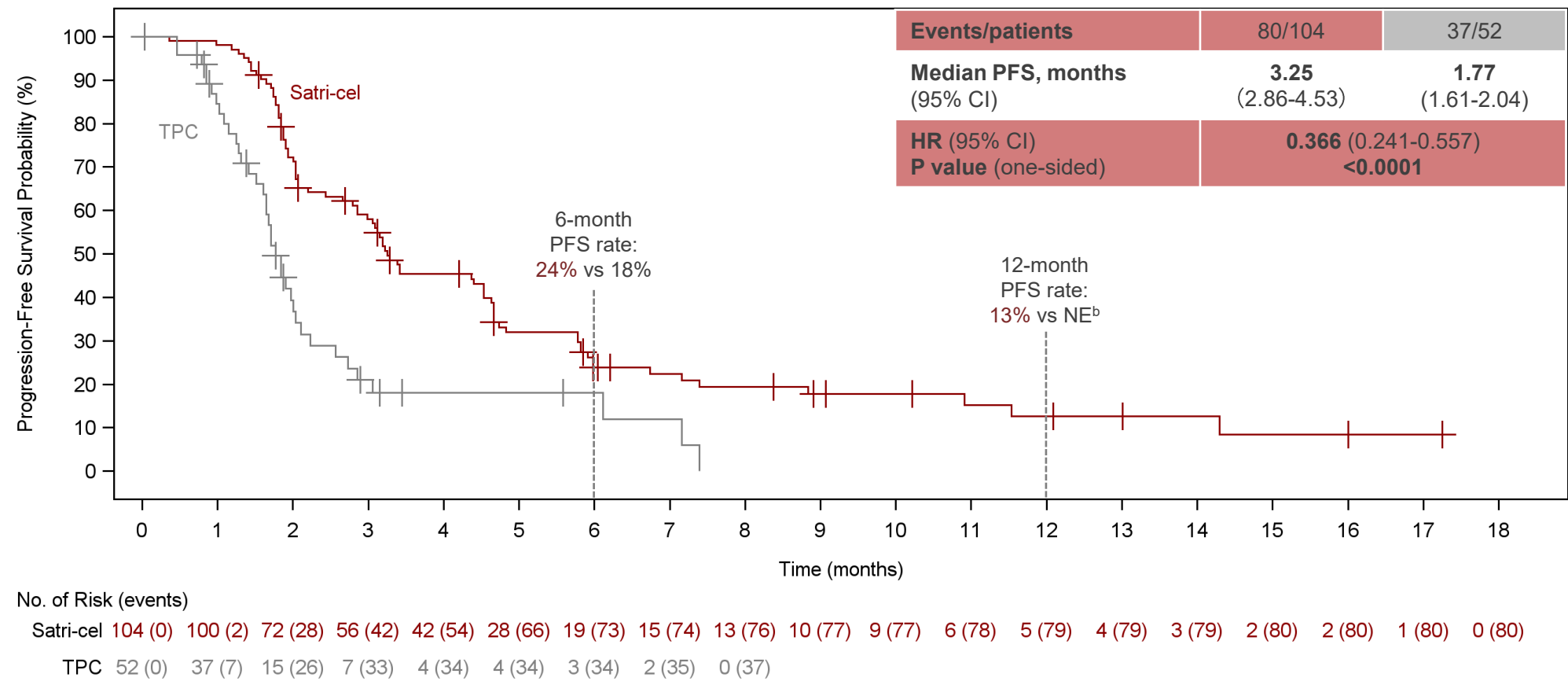
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Cut-off date: Oct 18, 2024

Satri-cel China Pivotal Phase II: Primary Endpoint—PFS by IRC^a



Satri-cel demonstrated statistically significant PFS improvement



a: Per RECIST v1.1.
b: 12-month PFS rate could not be estimated in the TPC group.

Cut-off date: Oct 18, 2024
Median follow-up: 9.07 months (satri-cel group) vs 3.45 months (TPC group).

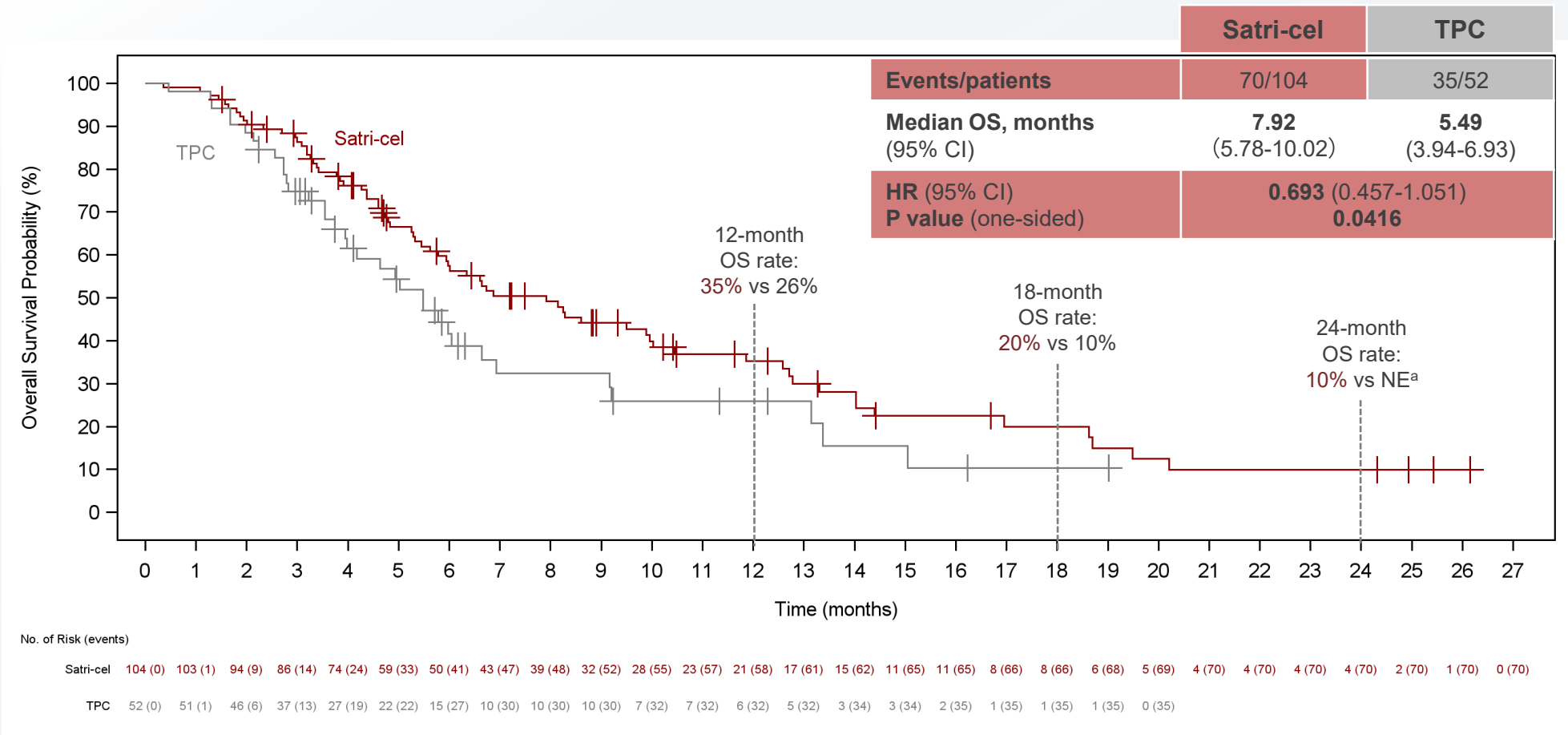
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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Satri-cel China Pivotal Phase II: Key Secondary Endpoint OS



Satri-cel demonstrated clinically meaningful OS benefit



a: 24-month OS rate could not be estimated in the TPC group.

Cut-off date: Oct 18, 2024
Median follow-up: 14.42 months (satri-cel group) vs 11.33 months (TPC group).

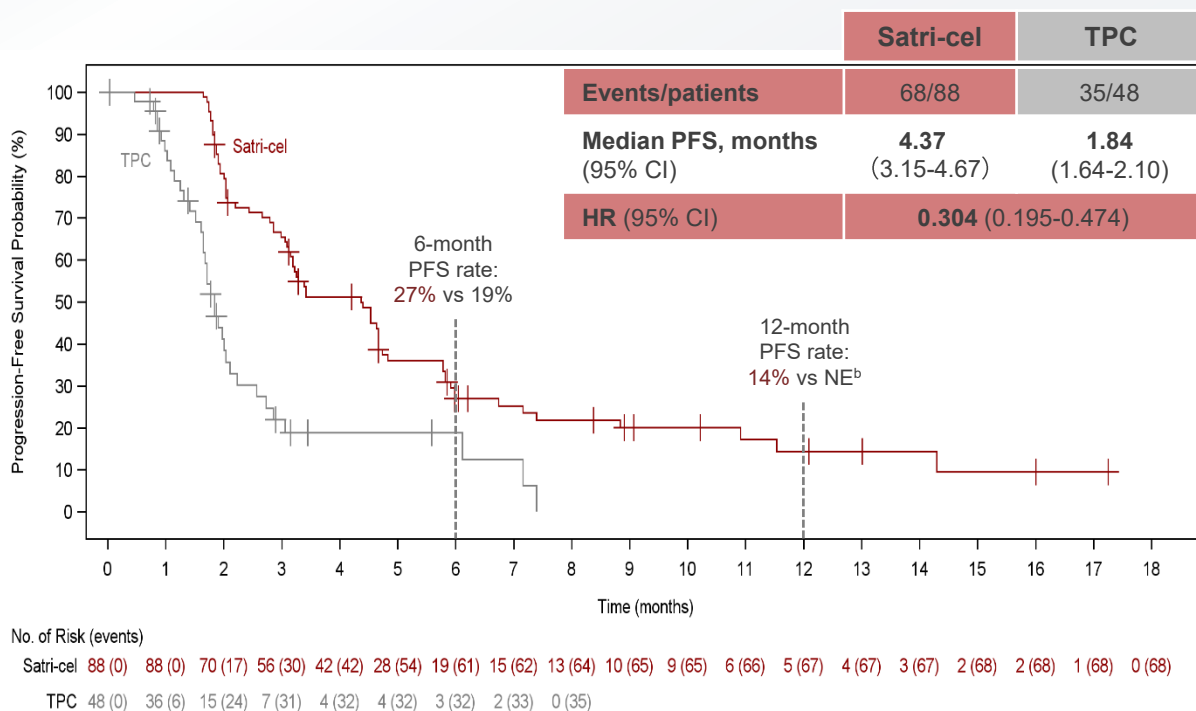
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: PFS and OS in Treated Population

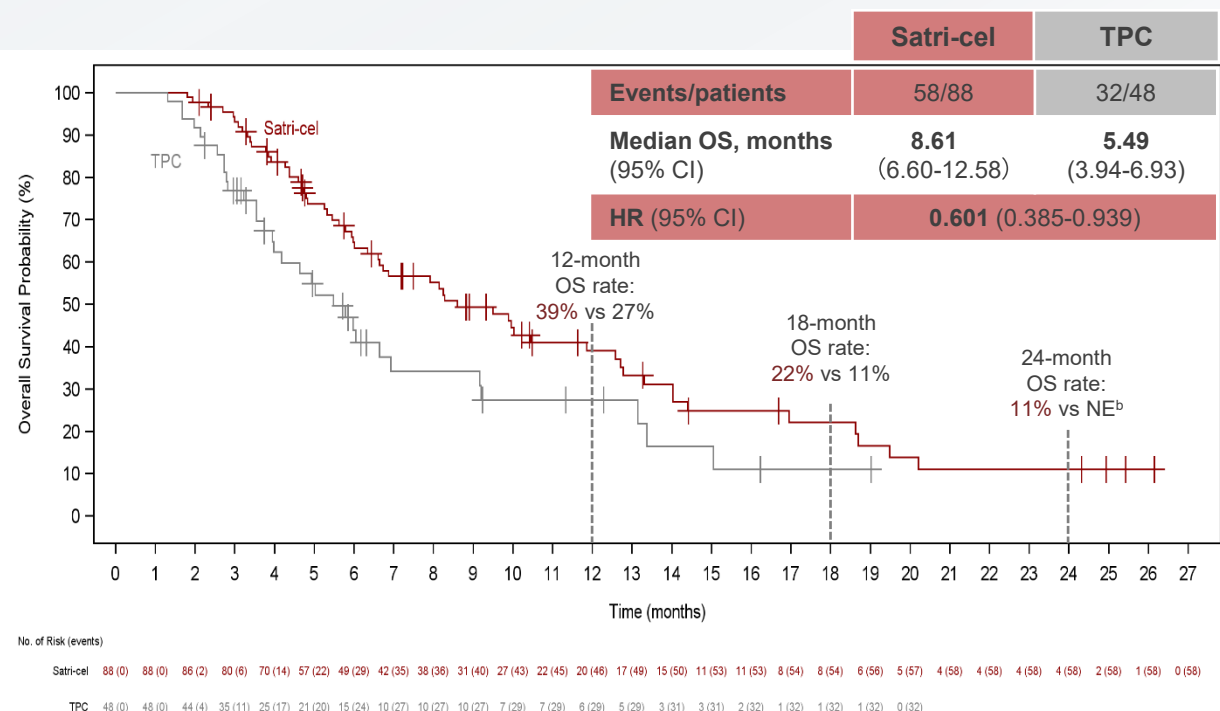


In treated population (mITT), PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

PFS assessed by IRC^a



OS in mITT population



Cut-off date: Oct 18, 2024

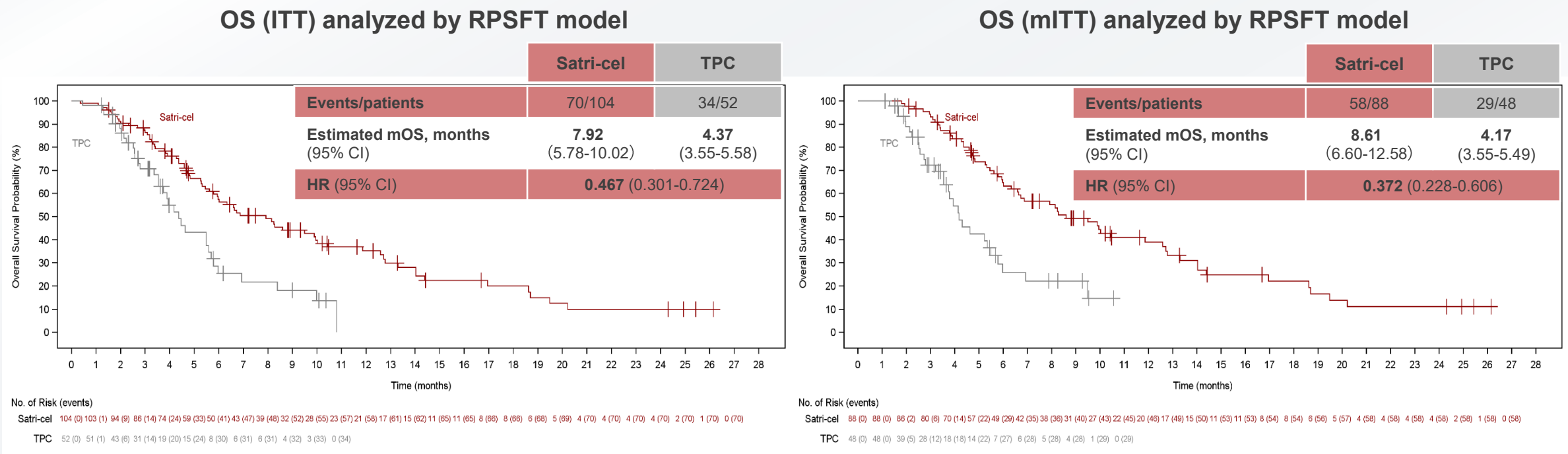
a: Per RECIST v1.1. b: the rate could not be estimated in the TPC group.

1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Adjusting OS for Treatment Switching in TPC



The estimated mOS was 1.81-2.06 fold longer with satri-cel vs TPC by RPSFT model, providing a 53% and 63% reduction in risk of mortality in the ITT and mITT populations, respectively.



- 42% (20/48) of patients in the TPC group subsequently received satri-cel infusion.
- Among all 108 patients (88 in satri-cel group, 20 in TPC group) treated with satri-cel, mOS reached **9.17 months** (95% CI 6.64–12.58).

Satri-cel China Pivotal Phase II: Manageable Safety



Safety, n (%)	Satri-cel group (n=88)		TPC group (n=48)	
	All grade	Grade ≥3	All grade	Grade ≥3
All treatment-emergent adverse events (TEAEs)	88 (100%)	87 (98.9%)	44 (91.7%)	30 (62.5%)
TEAEs related to treatment (TRAEs)	88 (100%)	87 (98.9%)	44 (91.7%)	27 (56.3%)
TRAEs leading to discontinuation	0	0	2 (4.2%)	1 (2.1%)
TRAEs leading to death	1 (1.1%) ^[1]	1 (1.1%)	1 (2.1%) ^[2]	1 (2.1%)
Cytokine release syndrome (CRS)	84 (95.5%)	4 (4.5%) ^[3]	0	0
Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	0	0	0	0

Treatment was defined as bridging therapy, lymphodepletion and Satri-cel infusion in Satri-cel group and treatment of physician's choice in TPC group.

[1] disseminated intravascular coagulation; [2] coagulopathy; [3] all grade 3.

Cut-off date: Oct 18, 2024

1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Conclusions



- ✓ It is the world's **first** confirmatory randomized controlled trial (RCT) of a CAR-T cell therapy in solid tumors. It is also the **first** RCT in this field to demonstrate statistically superior efficacy on its primary endpoint.
- ✓ Satri-cel demonstrated **statistically significant PFS improvement and clinically meaningful overall survival benefit** in patients with Claudin18.2-positive, advanced G/GEJC (3L+) compared to standard of care.
- ✓ This trial expanded the percentage of Claudin18.2-positive patients with G/GEJC.
- ✓ We observed a **manageable safety profile** alongside **long-term benefit** in many patients.
- ✓ These data suggest that satri-cel could become **a new treatment option** and provide a strong rationale for continued investigation of satri-cel in earlier lines of treatment for patients with advanced G/GEJC.

1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel: Clinical Data from China and the US (Single-arm Study)



	China investigator-initiated trial (NCT03874897) ^{1,2}	Phase Ib in China (NCT04581473) ³	Phase 1b in the US (NCT04404595) ⁴	
	ASCO 2024, <i>Nature Medicine</i>	ASCO 2022	ASCO GI 2024	
Sample size, No.	51 G/GEJA*	14 G/GEJA	7 G/GEJA	12 PC
Median follow-up, Month	32.4*	8.8	8.9	
ORR	54.9%*	57.1%	42.9%	16.7%
mPFS, Month	5.8**	5.6	5.7	2.7
mDoR, Month	6.4*	Not reported	6.9	3.4
mOS, Month	9.0**	10.8	8.9	8.9
≥Grade 3 CRS, No.	0	1***	0	2
≥Grade 3 ICANS, No.	0	0	0	
Treatment related death, No.	0	0	0	
*51 G/GEJA patients with target lesions at baseline received satri-cel monotherapy.				
**59 G/GEJA patients received satri-cel monotherapy.				
***One patient was related to the investigational disease (lung metastasis of GC) and fully recovered after corticosteroids treatment.				

1. Qi C, et al. ASCO 2024. 2024 Jun; Oral presentation #2501

2. Qi C, et al. *Nat Med* (2024). DOI: 10.1038/s41591-024-03037-z2

3. Qi C, et. al. ASCO 2022. 2022 Jun; Poster #4017

4. Botta G, et. al. ASCO GI 2024. 2024 Jan; Poster #356

G/GEJA: Gastric/Gastroesophageal Junction Adenocarcinoma; PC: Pancreatic Cancer; ORR: Objective Response Rate; mPFS: Median Progression-Free Survival; mDoR: Median Duration of Response; mOS: Median Overall Survival; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome

Satri-cel: Extension to GC/PC Earlier Line / Adjuvant Settings



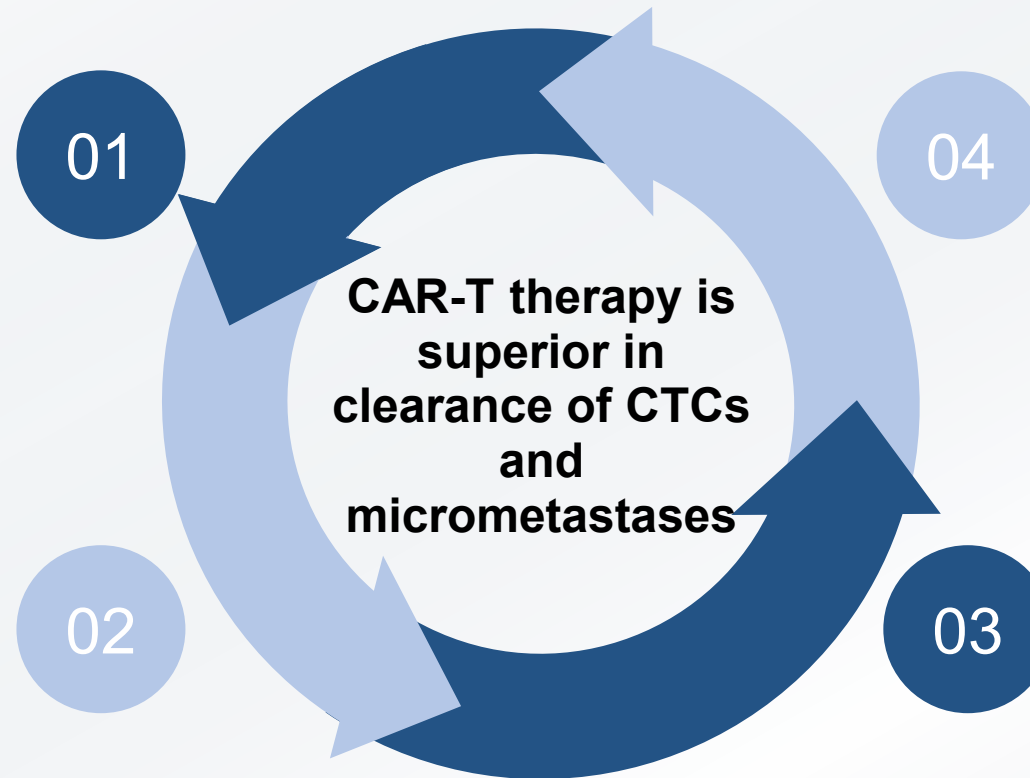
Promising greater clinical value in earlier line / earlier disease stage and providing better chances of cure for a much broader patient population

More Accessible Tumor

- Low disease burden & aggressiveness
- Easier tissue penetration

Preserved Immune System

- Better quality of T cells
- More durable responses are expected



Better Tolerability

- Mild CRS
- Good hematopoietic and organ function

Favorable TME

- ECM & normal fibroblasts not affected by previous anti-cancer therapy

Satri-cel as 1L Consolidation Delivered 100% Response Rate



No.	Age/Gender	BOR of 1 st line	BOR of Satri-cel	TTR
1	50/F	SD	PR	W4
2	55/F	PR	PR	W4
3	30/F	SD	PR	W4
4	48/M	SD	NN	No target lesion
5	53/F	NE (intolerable to chemo, myelosuppression)	PR	W4

Satri-cel Efficacy Highlights

- **ORR 100%** in 4 patients with target lesions, TTR (Time to Response) Week 4
- 1 NN patient remained stable **beyond 15 months**
- 2 pts subsequently underwent **surgical resection** after satri-cel infusion, and **remain alive until now.**

ORR: Objective Response Rate; BOR: Best of response; SD: Stable Disease; PR: Partial Response; NE: Non-Evaluable; NN: Non-Complete Response/Non-Progressive Disease

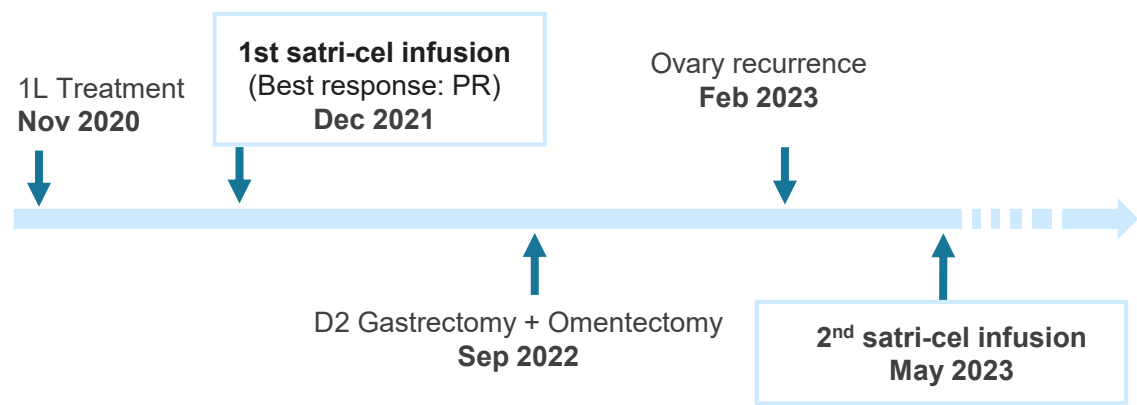
Following Satri-cel Infusion, Two Patients Underwent Surgical Resection, and Remain in Long-term Survival at the Latest Follow-up



Case 1

1L Treatment

- Regimen: POS regimen (6 cycles) + S-1/Paclitaxel/TNF intraperitoneal perfusion (4 cycles)
- 1L BOR : SD

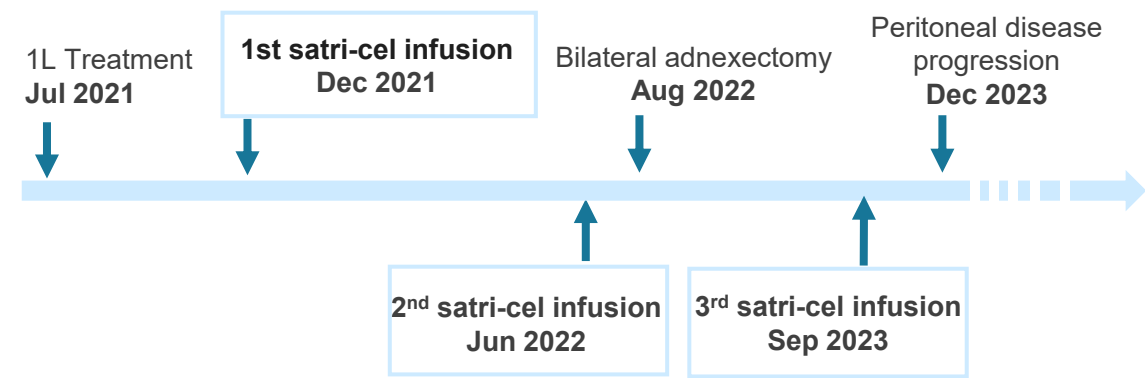


OS: 36.0+ months (last FU: Dec 2024)

Case 2

1L Treatment

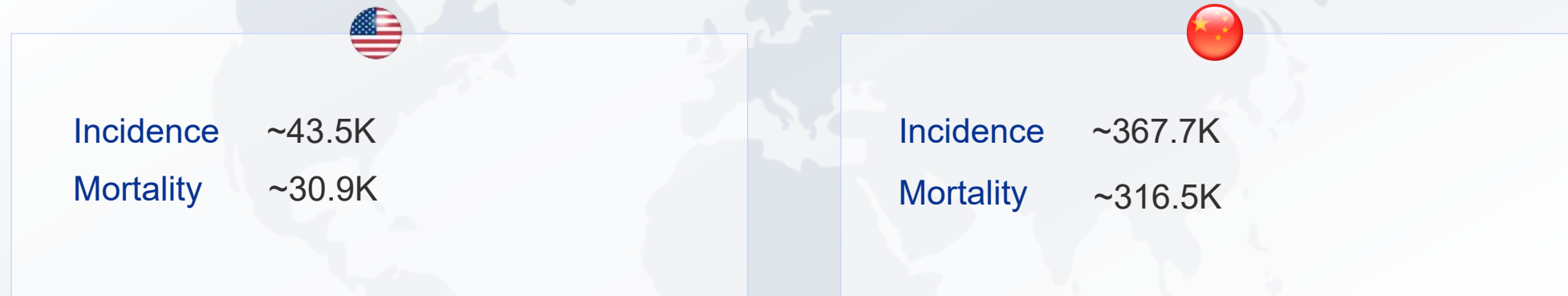
- **Regimen:** SOX regimen (4 cycles)
- **BOR :** PR



OS: 39.0+ months (last FU: Mar 2025)

Liver Cancer: The Third Leading Cause of Cancer Mortality Worldwide

2022 Liver Cancer Epidemiology in the US and China¹



Liver Cancer 5-year survival rate

	Global ²	US ³	China ⁴
Liver Cancer, all stages	18%	20%	12%

1. International Agency for Research on Cancer. Population factsheets. 2022

2. Lin L, et al. *Liver Cancer*. 2020 Sep;9(5):563-582

3. 2022 American Cancer Society medical information

4. Zheng R, et al. *Chinese Journal of Cancer Research*, 2018 Dec;30(6):571-579

CT011: First-in-class CAR-T in Hepatocellular Carcinoma with PoC Clinical Results



GPC3: high expression and specificity

- Overexpression in hepatocellular carcinomas (HCC), and is associated with poor disease prognosis

CARsgen's GPC3 IHC test kit

Expression* in HCC:

70.7%

- overexpressed in other cancer types, e.g. >60% of lung squamous cell carcinoma (SCC)

CT011

Product

- ✓ an autologous GPC3 CAR-T product

Clinical Development



- Phase I trial **Completed**
- Phase I trial for stage IIIa HCC at high risk of recurrence after surgical resection **Ongoing**

*CARsgen internal data

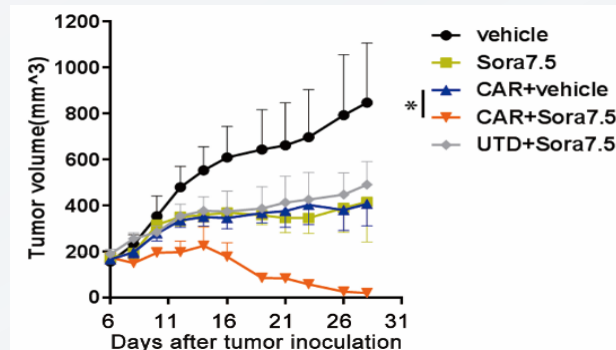
GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*



> Mol Ther. 2019 Aug 7;27(8):1483-1494. doi: 10.1016/j.ymthe.2019.04.020. Epub 2019 Apr 29.

Combined Antitumor Effects of Sorafenib and GPC3-CAR T Cells in Mouse Models of Hepatocellular Carcinoma

Xiuqi Wu¹, Hong Luo², Bizhi Shi¹, Shengmeng Di¹, Ruixin Sun¹, Jingwen Su¹, Ying Liu¹, Hua Li¹, Hua Jiang³, Zonghai Li⁴



Molecular Therapy Commentary

Alliance of the Titans: An Effective Combination of a TKI with CAR T Cells

Andras Heczey¹

<https://doi.org/10.1016/j.ymthe.2019.07.008>



TYPE Case Report
PUBLISHED 17 August 2022
DOI 10.3389/fimmu.2022.963031

Long term complete response of advanced hepatocellular carcinoma to glypican-3 specific chimeric antigen receptor T-Cells plus sorafenib, a case report

As of Dec 2021 (last follow-up at publication)

- CR status has been over 24 months and continues



(Photo taken in Jun 2023)

1. Wu X, Mol Ther. 2019 Aug 7;27(8):1483-1494

CAR-T in Combination with Local Therapy Against HCC: Cover Story in *Cancer Communications*; Both Patients Achieved Disease-free Survival around 9 Years



Patients stayed tumor free till latest follow-up on Apr 11, 2025

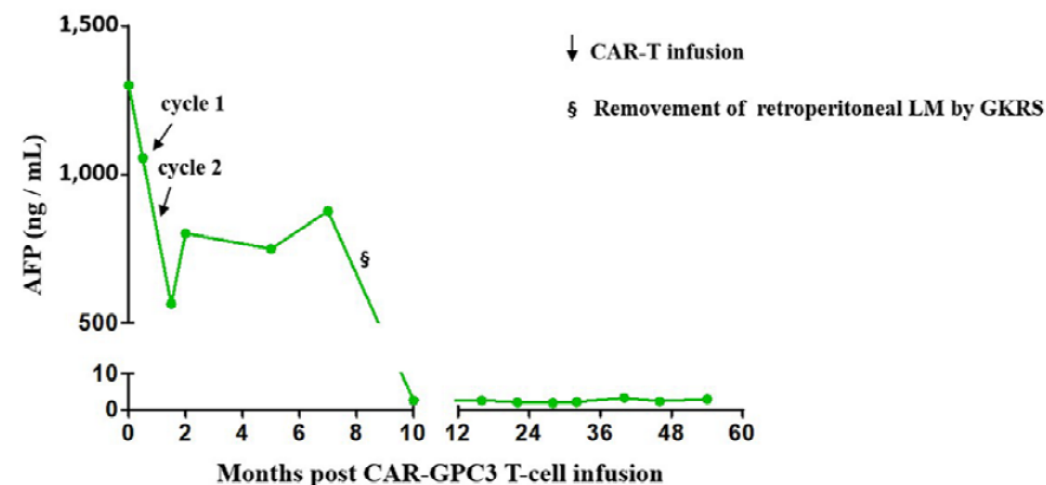
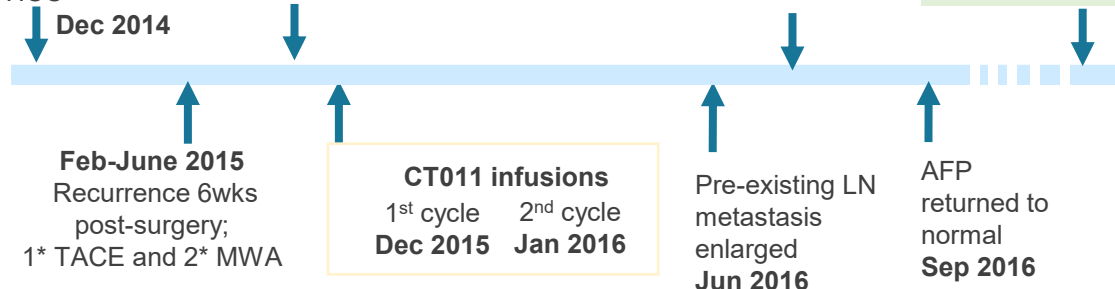
• Case: a 54-year-old male

Diagnosed with Ib-stage HCC. Liver resection of primary HCC

Multiple Metastasis; GKRS and 2* MWA July - Oct 2015

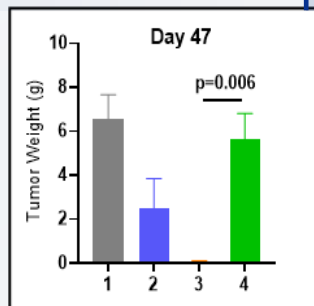
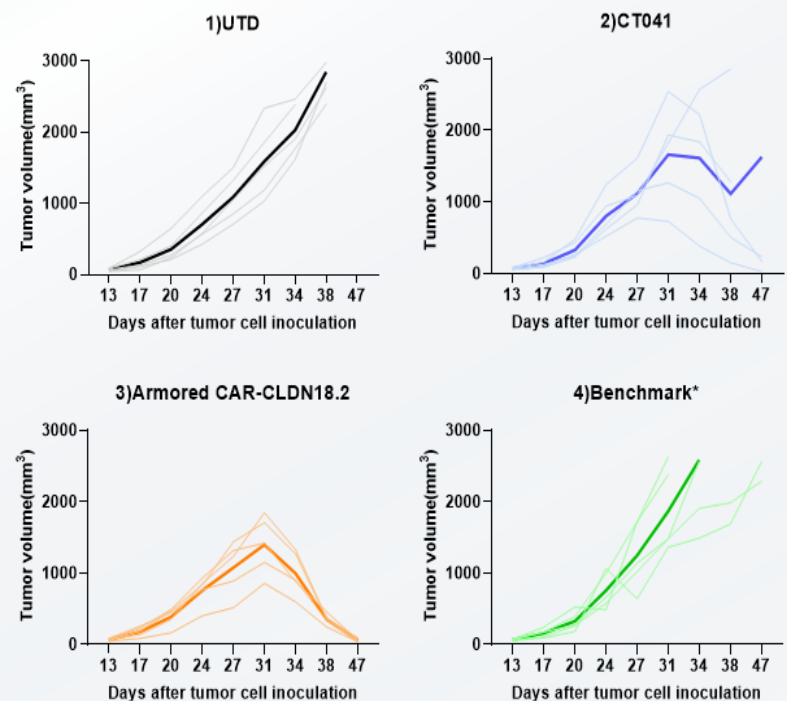
GKRS July 2016

tumor free survival (> 5 years) Nov 2021

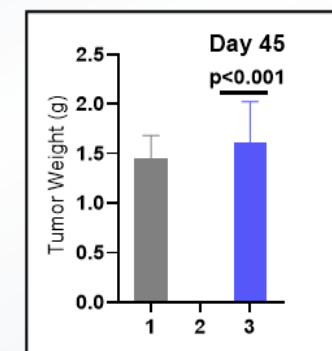
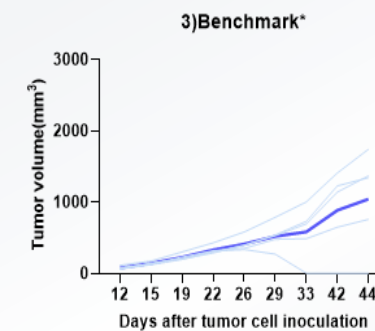
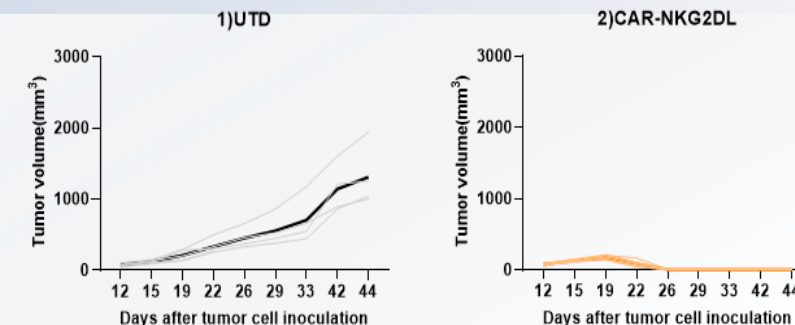


Next-Gen CAR-T Development: Tackling Key Challenges in Solid Tumors

Next-gen Claudin18.2 CAR-T shows enhanced anti-tumor activity in GC models



Next-gen NKG2DL CAR-T shows robust anti-tumor activity in HCC models



Satri-cel-derived Armored CAR-T demonstrates enhanced therapeutic efficacy

Proprietary CAR-NKG2DL T cells achieve 100% clearance in HCC



Allogeneic CAR-T Platforms and Pipeline Products

Existing Efficacy Gap between Allogeneic CAR-T and Autologous CAR-T



Treatment and outcomes	Allogeneic BCMA CAR-T			Autologous BCMA CAR-T
	ALLO-715 3.2 x10 ⁸ cells, N=24 ¹	P-BCMA-ALLO1 ²		cilta-cel 0.5-1 x10 ⁶ cells/kg, N=97 ³
		All Arm ^{**} : 0.25-6 x10 ⁶ cells/kg, N=72	Arm C ^{**} : 2 x10 ⁶ cells/kg N=23	
Enrolled	48	72	23 (including 2 retreatment)	113
Days to treatment initiation*	5	1	1	32
Required bridging therapy	0%	0%	0%	75%
ORR (mITT)	71%	54%	91%	98%
CR/sCR rate (mITT)	25%	11%	22%	80%
≥VGPR rate (mITT)	71%	33%	48%	95%
mDoR	8.3 months	7.7 months ^{***}	Not reported	Not reached ^{****}

*For ALLO-715, time is calculated from enrollment to lymphodepletion; for P-BCMA-ALLO1, time is calculated from enrollment to the start of study treatment.

**Four arms in total, Arm C (cy 750 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10⁶ and Arm B (cy 1000 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10⁶, Arm S (cy 300 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose Range of 0.25-6×10⁶, and Arm A (cy 500 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10⁶.

***The median duration of response (DoR) was 232 days for study Arms A and B – the cohorts with six or more months of follow-up at the time of data cut-off.

****Based on a median duration of follow-up of 18 months, mDOR=21.8 months.

1. Allogene Therapeutics. 2021. ASH 2021 Presentation. Accessed Nov 5, 2024

2. Poseida website news releases of phase 1 early results; Poseida Therapeutics. 2024. International Myeloma Society (IMS) 21st Annual Meeting and Exposition

3. ciltacabtagene autoleucel [Prescribing Information]. Janssen Biotech

Relatively Limited Expansion of Allogeneic CAR-T in Patients



- In allogeneic CAR-T, donor T cells will be recognized and rapidly eliminated by the host immune system (HvGR), which impacts CAR-T cell survival and results in limited expansion.
- Compared to autologous CAR-T, in vivo persistence of allogeneic CAR-T is significantly reduced.

Autologous and Allogeneic BCMA CAR-T in Multiple Myeloma			
	Allogeneic CAR-T ALLO-715 UNIVERSAL Phase I ^{1*}	Autologous CAR-T cilta-cel CARTITUDE-1 ²	Autologous CAR-T zevor-cel LUMMICAR-1 Phase 1 ³
Median C _{max} (copies/ug gDNA)	6,419*	47,806	202,543
Lymphodepletion Regimen	<ul style="list-style-type: none">• Fludarabine: 30 mg m²*3 days;• Cyclophosphamide: 300 mg m²*3days;• ALLO-647 mAb^{**}: 13mg/20mg/30mg*3days	<ul style="list-style-type: none">• Fludarabine: 30 mg m²*3 days;• Cyclophosphamide: 300 mg m²*3 days;	<ul style="list-style-type: none">• Fludarabine: 25 mg m²*3 days;• Cyclophosphamide: 300 mg m²*3 days

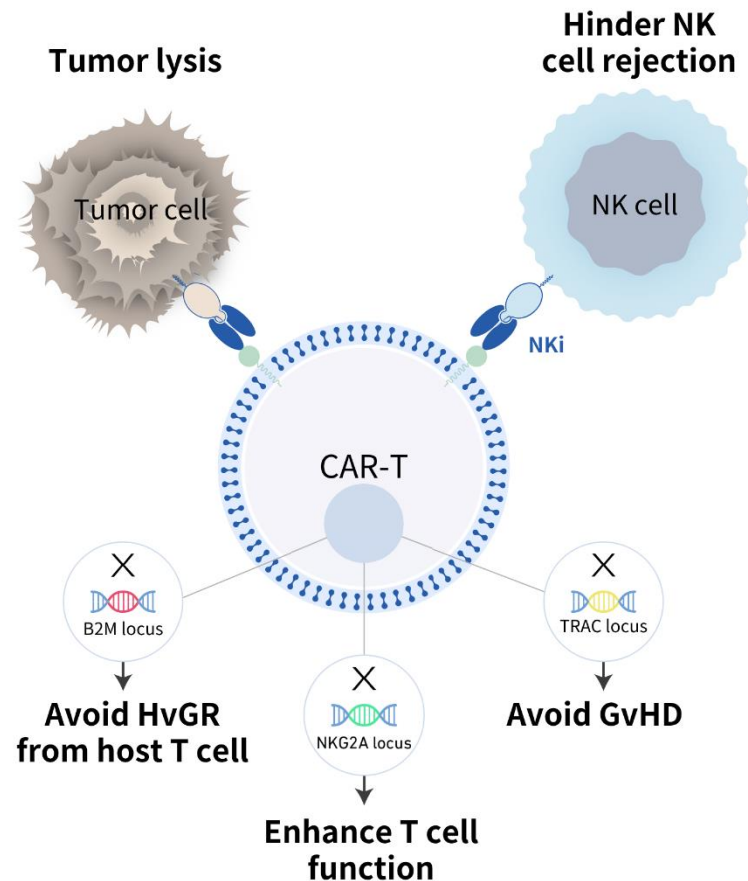
*Data from all patients (N=24) receiving the FCA regimen with 3.2 x10⁸ cells.
**ALLO-647: A humanized anti-CD52 monoclonal antibody for the depletion of CD52-positive host lymphocytes.

1. Mailankody S, et al. *Nat Med* 29, 422–429 (2023)
2. cilta-cel autoleucl [Prescribing Information]. Janssen Biotech
3. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209

THANK-uCAR® : Innovative Allogeneic CAR-T Platform Aimed to Address Immune Rejection



Target and **H**inder the **A**ttack of **NK** cells on **U**niversal **C**AR-T cells (**THANK-uCAR®**)



HvGR is the major challenge faced by Allogeneic CAR-T

- B2M knockout to overcome HvGR from host T cells, but NK cells attack uCAR-T cells without B2M.

THANK-uCAR® to better address HvGR

- Anti-NKG2A CAR protects the uCAR-T cells from NK cell lysis.
- NK cells could act as “feeder cells” for uCAR-T cells, thereby enhancing the expansion of uCAR-T cells.
- NKG2A knockout can further enhance T cell functionality.

CT0590 (BCMA CAR-T, THANK-uCAR®): Baseline Characteristics and Outcomes from the IIT

ASH 2024 



- An open-label, single-arm, phase 1, first-in-human trial in China (NCT05066022).
- Lymphodepletion: F: Fludarabine (30mg/m²/day×3days), C: Cyclophosphamide (500 mg/m²/day × 3 days).
- Doses: 50×10⁶, 150×10⁶, 300×10⁶, 450×10⁶ CT0590 cells.

Patient (Diagnosis)	High risk cytogenetics Y/N	ISS stage	# of prior lines	Refractoriness to PI/ IMiD*	% Baseline NKG2A expression NK cells	Best overall response	DoR (mo)	TTR (mo)	Peak CAR copy number (copies/μg gDNA)
PT 1 (MM)	Y	I	2	1	23	SD	NA	NA	BLQ
PT 1-reinf (MM)									5,102
PT 2 (MM)	Y	I	2	2	38	sCR	23	1.1	482,749
PT 3 (MM)	Y	III	3	2	12	SD	NA	NA	BLQ
PT 4 (MM)	Y	III	3	2	NA	PR	4	2.3	BLQ
PT 4-reinf (MM)						PR	6.9	2.4	
#PT 5 (pPCL)	N	NA	3	2	46	sCR	20	1.2	280,863

Cut-off date: Apr 22, 2024

This patient was treated under compassionate use
 * 2 indicates double class refractoriness (to a PI and an IMiD), 1 indicates PT 1 patient refractory to a PI.

IIT: Investigator-initiated Trial; PI: Protease Inhibitor; IMiD: Immunomodulatory Drug; DoR: Duration of Response; TTR: Time to Response; MM: Multiple Myeloma; pPCL: Primary Plasma Cell Leukemia; SD: Stable Disease; sCR: Stringent Complete Response; PR: Partial Response

1. Fu C, et al. ASH 2024. 2024 Dec; Poster #4843

CT0590: Manageable Safety Profile, Deep and Durable Responses



Safety

- Two patients experienced CRS
 - ✓ One patient each at Grade 1 and Grade 2; **no** \geq Grade 3 CRS;
 - ✓ Time to onset was 8-10 days post-infusion;
 - ✓ Duration was 3-4 days.
- **No** cases of ICANS or GvHD were observed.
- **No** DLTs, **no** withdrawals due to AE, **no** deaths due to AE.

Efficacy

- 3 subjects achieved confirmed responses including 2 with sCR and 1 with PR. 1 Patient achieved PR but it could not be confirmed due to COVID-19.
- CAR copies could be detected in 3 out of the 5 patients:
 - ✓ Patient 2 remained in response at the time of data cut-off (DoR > 23 months) ; achieved substantial peaks CAR copy numbers of 482,749 copies/ μ g gDNA at Day 19;
 - ✓ Patient 5 with pPCL achieved sCR and was in response for 20 months; achieved substantial peaks CAR copy numbers of 280,863 copies/ μ g gDNA at Day 15.

CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome; GvHD: Graft versus Host Disease; DLT: Dose-Limiting Toxicity; AE: Adverse Event; sCR: Stringent Complete Response; PR: Partial Response; DoR: Duration of Response; pPCL: Primary Plasma Cell Leukemia

1. Fu C, et al. ASH 2024. 2024 Dec; Poster #4843

A Case of CT0590 to Treat R/R MM

Baseline Characteristics

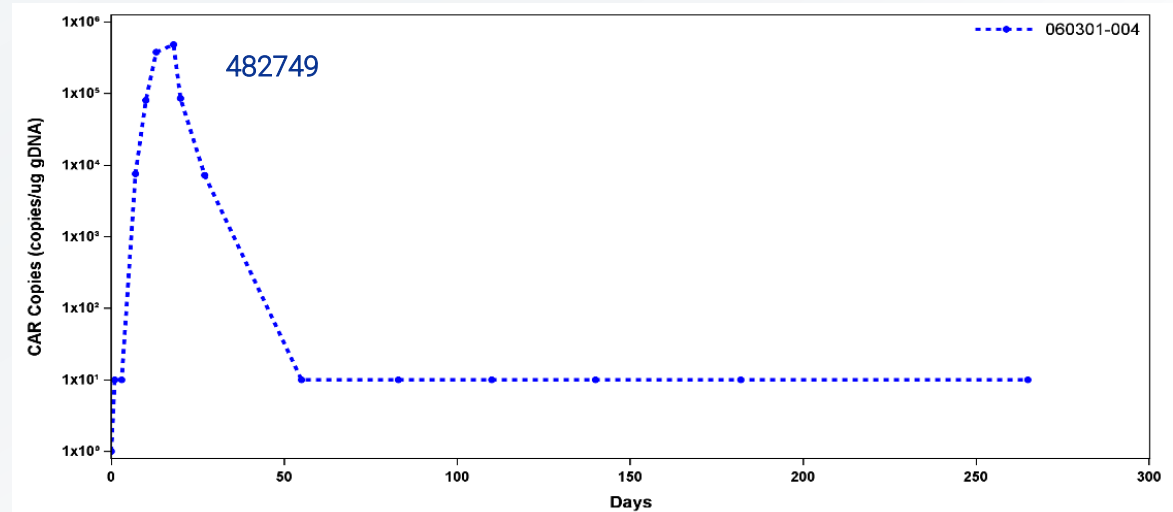
- A 71-year-old male diagnosed with MM,
- Double-refractory, with 94.5% plasma cells in bone marrow.
- 2 prior lines of therapies, including 3 regimens.
- Received 3×10^8 CT0590 CAR-T cells infusion.

Safety

- 1 Grade CRS
- Only 1 subject had Grade 3 treatment-related infection (pneumonia) on Day 12, which fully resolved.
- No ICANS

Efficacy

- W12: achieved sCR, with a DoR of ≥ 23 months (ongoing)



R/R MM: Relapsed/Refractory Multiple Myeloma; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome; sCR: Stringent Complete Response; DoR: Duration of Response

1. Fu C, et al. ASH 2024. 2024 Dec; Poster #4843

A Case of CT0590 to Treat R/R pPCL



Baseline Characteristics

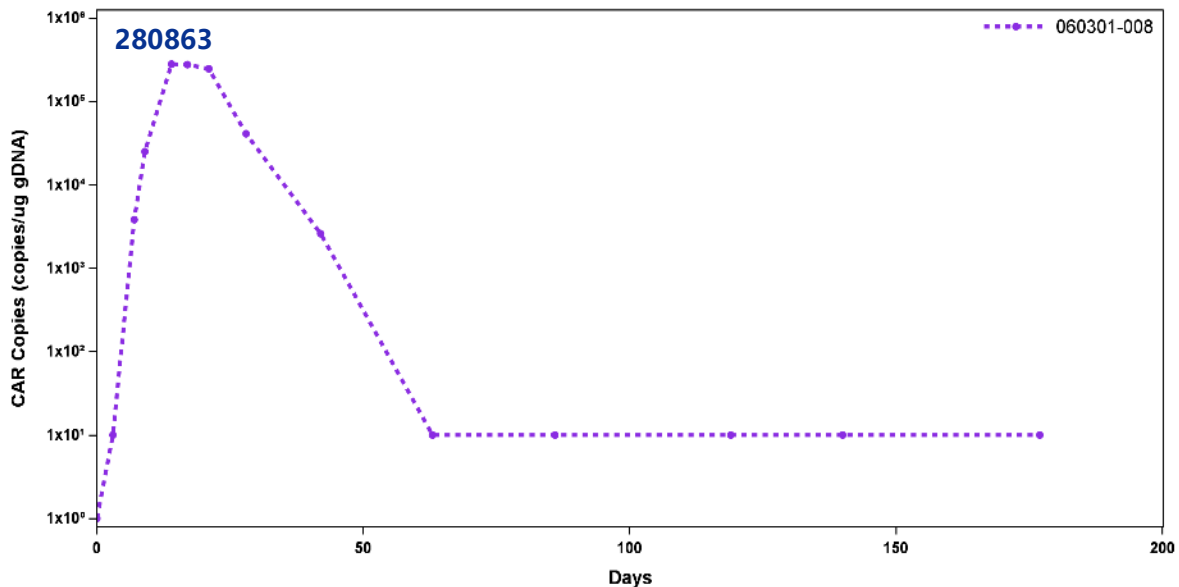
- A 52-year-old male diagnosed with pPCL
- Double-refractory
- 3 prior lines, including 3 regimens (ASCT, etc.)
- Received an infusion of 3×10^8 CT0590 CAR-T cells.

Safety

- 1 Grade CRS
- Grade 1 infection (pneumonia), unrelated to treatment.
- No ICANS

Efficacy

- sCR with a DoR of 20 months.
- The DoR is more than double the duration reported for autologous BCMA CAR-T treatments in PCL.



Best response	Duration of response	References
1 VGPR	117days (PFS)	Li, C, et al. Clin Transl Med. 2021;11(3):e346.
1 CR	307 days (PFS)	Li, C, et al. Clin Transl Med. 2021;11(3):e346.
1 sCR	7months (DoR)	Deng J, et al. Front Oncol. 2022; 12: 901266.

Previous reports of autologous BCMA CAR-T therapy for multiple myeloma show that the DoR is less than 10 months.

R/R pPCL: Relapsed/Refractory Primary Plasma Cell Leukemia; ASCT: Autologous Stem Cell Transplantation; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome; sCR: Stringent Complete Response; DoR: Duration of Response; VGPR: Very Good Partial Response; CR: Complete Response; PFS: Progression-Free Survival

Baseline NKG2A Expression on NK cells may be Predictive of CT0590 Responses



- 4 patients had baseline NKG2A data available.
- Both patients who attained sCR, Patient 2 and Patient 5, had relatively higher NKG2A expression levels on NK cells at 38% and 46% respectively.
- A relatively weak expansion of CT0590 CAR-T cells in vitro in the presence of NK cells with lower NKG2A expression was observed (data not shown here).
- Baseline NKG2A expression levels on NK cells may predict treatment outcomes with CT0590.

Patient (Diagnosis)	Dose (cells)	% Baseline NKG2A expression NK cells	Best overall response
PT 1 (MM)	50 × 10 ⁶	23	SD
PT 1-reinf (MM)	300 × 10 ⁶		
PT 2 (MM)	300 × 10 ⁶	38	sCR
PT 3 (MM)	300 × 10 ⁶	12	SD
PT 4 (MM)	450 × 10 ⁶	NA	PR
PT 4-reinf (MM)	450 × 10 ⁶		PR
PT 5 (pPCL)	300 × 10 ⁶	46	sCR

sCR: Stringent Complete Response; MM: Multiple Myeloma; pPCL: Primary Plasma Cell Leukemia; SD: Stable Disease; PR: Partial Response

1. Fu C, et al. ASH 2024. 2024 Dec; Poster #4843

CT0596: Allogeneic BCMA-Targeted CAR-T (THANK-u Plus™)



THANK-u Plus™ Platform

- THANK-u Plus™ exhibits significantly improved expansion compared to THANK-uCAR®
- THANK-u Plus™ demonstrates sustained expansion regardless of varying NKG2A expression levels on NK cells

CT0596

- Based on THANK-u Plus™, **CT0596**—an allogeneic BCMA-targeted CAR-T therapy—was developed for the treatment of **R/R MM or R/R PCL**.

Clinical Development

- CT0596 is under evaluation in an IIT for the treatment of R/R MM or R/R PCL:
 - ✓ As of May 6, 2025, 8 patients with R/R MM have been infused.
- Further exploration is planned in plasma cell malignancies and autoimmune diseases.
- IND submission is planned in the H2, 2025.

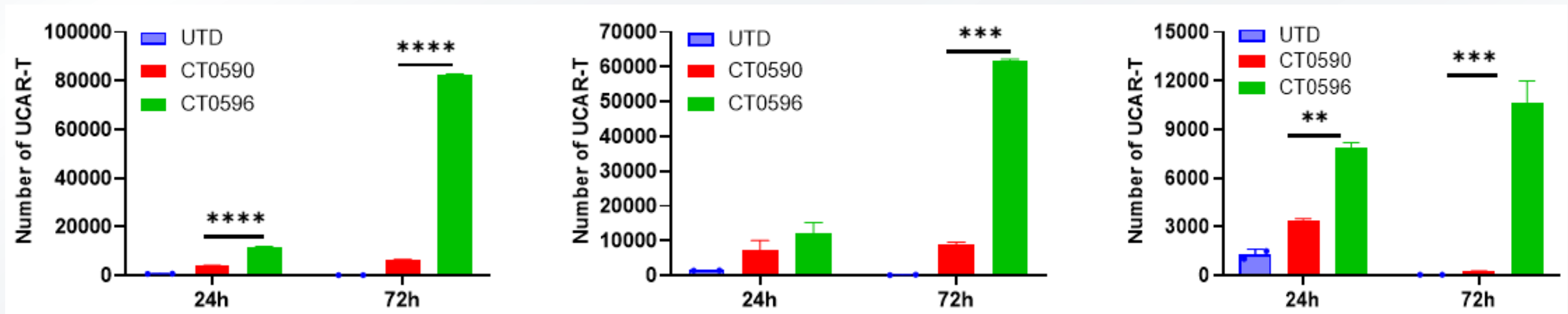
CT0596: Enhanced and Sustained Allogeneic CAR-T Expansion Across Different NKG2A Expression Levels



NKG2A expression: High

Medium

Low



- CT0590 (THANK-uCAR®): exhibits a decrease in expansion within 72 hours in NK cells with relatively low NKG2A expression.
- CT0596 (THANK-u Plus™):**
 - ✓ In the presence of NK cells with high/medium/low levels of NKG2A expression, **CT0596 expanded significantly within 72 hours.**
 - ✓ In the presence of NK cells with medium/high levels of NKG2A expression, **CT0596 expanded significantly better than CT0590.**

CT0596 IIT Preliminary Data: Favorable Safety and Efficacy



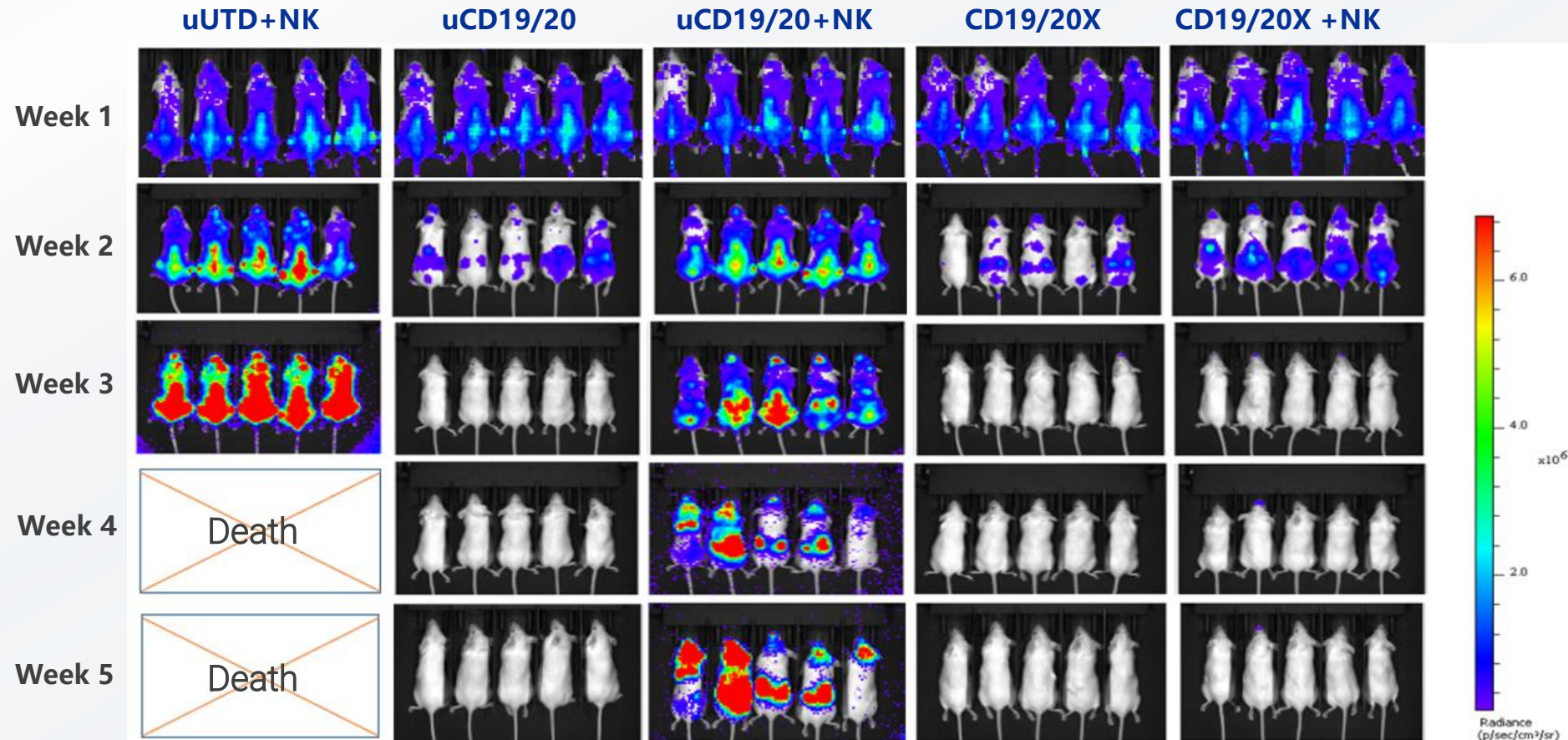
Safety

- **CT0596 demonstrated favorable tolerability:**
 - ✓ **NO** \geq Grade 3 CRS
 - ✓ **NO** ICANS or GvHD
 - ✓ **NO** DLTs, **no** patients discontinuing treatment due to AE

Efficacy

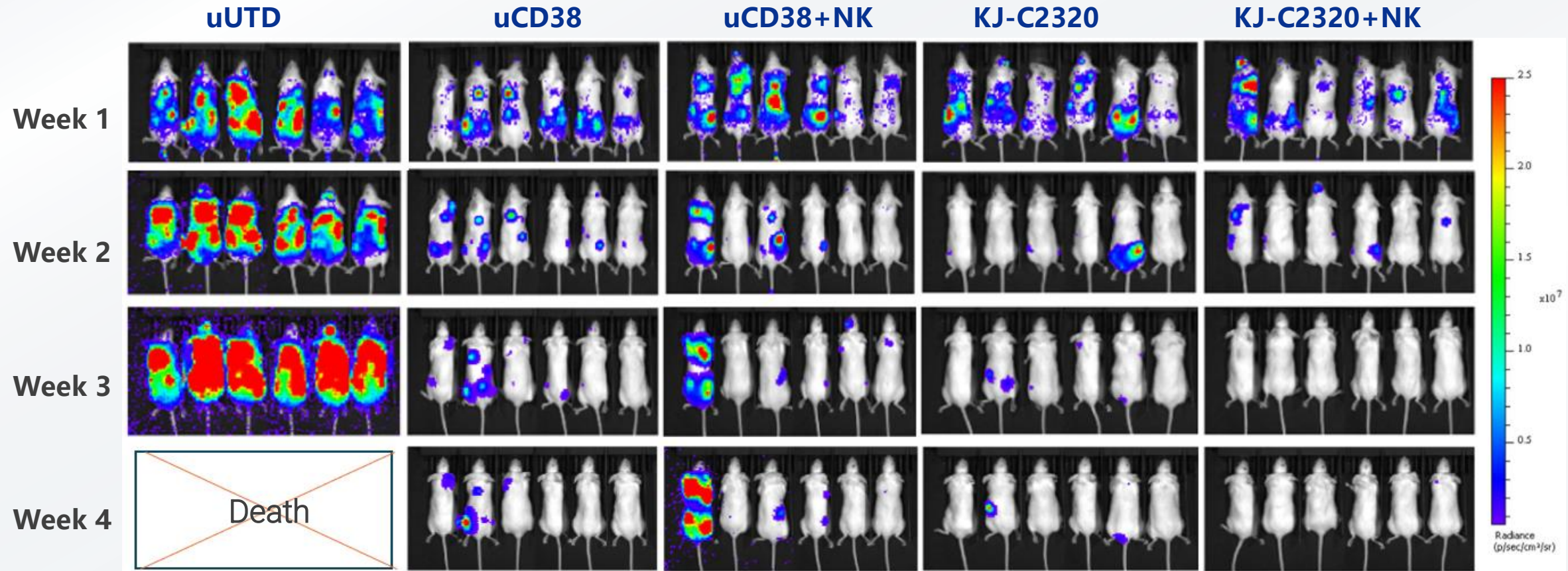
- As of May 6, 2025, 8 R/R MM patients (3L+) received infusion (Lymphodepletion: **fludarabine 22.5-30 mg/m² and cyclophosphamide 350-500 mg/m²**). Key findings from up to four months of follow-up include:
 - ✓ 5 patients completed the first efficacy assessment at Week 4:
 - **3 patients (60%) achieved sCR/CR; all are in ongoing response.**
 - **4 patients (80%) attained MRD-negativity in the bone marrow.**
 - ✓ 2 patients at Day 14 showed reductions in measurable lesions by **$\geq 92\%$** and **$\geq 65\%$** , respectively.
 - ✓ 1 patient had not yet reached the protocol-specified efficacy assessment timepoint.
 - ✓ **CAR-T expansion was observed across all predefined dose levels.**

Allogeneic CD19/20X CAR-T (THANK-u Plus™) Exhibits Robust Anti-lymphoma Activity in the Presence of NK Cells



In the presence of NK cells, allogeneic CD19/20X CAR-T (THANK-u Plus™ platform) demonstrates much better anti-tumor efficacy than conventional allogeneic CD19/20 CAR-T.

KJ-C2320, Allogeneic CD38 CAR-T (THANK-uCAR®) Exhibits Enhanced Antitumor Activity in Mice in the Presence of NK Cells



In the presence of NK cells, allogeneic CD38 CAR-T (THANK-uCAR® platform) demonstrates much better anti-tumor efficacy than conventional allogeneic CD38 CAR-T.

Summary of CARsgen's Allogeneic CAR-T Platform



- Allogeneic CAR-T products are currently in development:
 - CT0596 – targeting BCMA, for R/R MM and R/R PCL, an IIT is ongoing.
 - KJ-C2219 – targeting CD19/CD20, for B-cell malignancies, an IIT is ongoing; for SLE and SSc, an IIT is ongoing.
 - KJ-C2320 – targeting CD38, for AML, an IIT is ongoing.
 - KJ-C2114 – for solid tumors.
 - KJ-C2526 – targeting NKG2DL, for AML, other malignancies, senescence.
- **Collaboration with Zhuhai SB Xinchuang**
 - Zhuhai SB Xinchuang-managed fund investment: RMB80M for 8% stake of **UCARsgen Biotech** (post-dilution: CARsgen retains 92%)
 - UCARsgen owns mainland China exclusive rights (covering R&D, manufacturing, and commercialization) of **BCMA CAR-T, for MM & PCL; CD19/CD20 CAR-T, for B-cell malignancies (excl. autoimmune diseases)**

Multiple Value Inflection Milestones in the Near Future



- **H2 2025:** Anticipated data release for satri-cel in pancreatic cancer adjuvant therapy.
- **H2 2025:** Anticipated IND application for CT0596. Anticipated disclosure of CT0596 clinical data at academic conferences.
- Multiple allogeneic CAR-T products are under development, with upcoming data updates.

Experienced Senior Management Team



Zonghai Li, MD, PhD
Co-founder, Chairman of
the Board, CEO, CSO



Huamao Wang, PhD
Co-founder and
COO



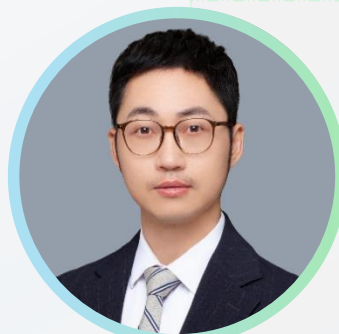
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Making Cancer Curable