

# CARsgen Therapeutics (HKEX: 02171)

December 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 140 issued, as of June 30, 2025)

# 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)



# Advancing a Competitive Pipeline with Global Rights



	Product Candidate <sup>1</sup>	Target	Indication	Pre-clinical	Phase I	Phase II/III <sup>2</sup>	BLA/ NDA
Autologous CAR-T	Zevor-cel (CT053) <sup>3</sup>	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) G/GEJA (1L sequential)	ST-01 (China)			
				ST-02 (US, Canada)			
				ST-05 (China)			
				IIT (China)			
				IIT (China)			
				IIT (China)			
CT071	GPRC5D	R/R MM, PCL R/R MM, PCL NDMM	(US)				
			IIT (China)				
			IIT (China)				
CT011	GPC3	HCC (adjuvant)	(China)				
Allogeneic CAR-T	CT0590	BCMA	R/R MM, PCL	IIT (China)			
	CT0596	BCMA	R/R MM, PCL	IIT (China)			
	KJ-C2219	CD19/CD20	B-cell malignancies SLE, SS <sub>c</sub>	IIT (China)			
				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; PCL: Plasma Cell Leukemia; NDMM: Newly Diagnosed Multiple Myeloma; SLE: Systemic Lupus Erythematosus; SSc: Systemic Sclerosis; AML: Acute Myeloid Leukemia

<sup>1</sup> All product candidates are self-developed with global rights

<sup>2</sup> Phase II trials of some indications are pivotal studies

<sup>3</sup> 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) <sup>1</sup> 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

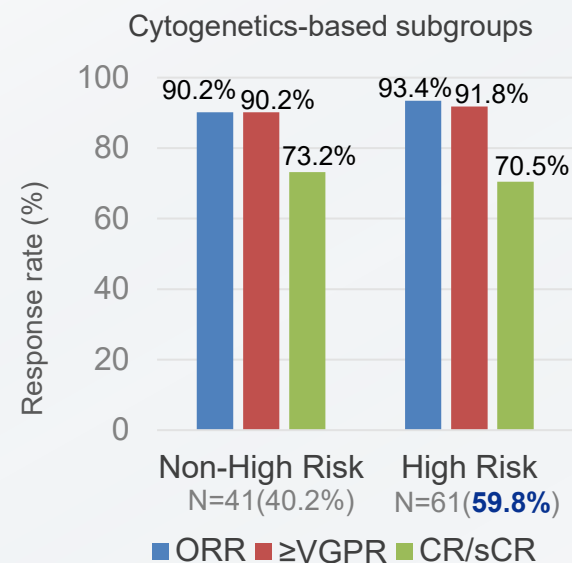
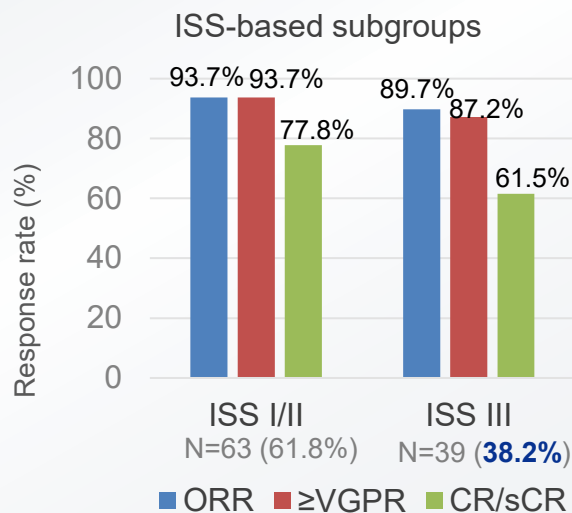
\*Double-class refractory: Refractory to a proteasome inhibitor and immunomodulatory drug; \*\*Triple-class refractory: Refractory to a proteasome inhibitor, immunomodulatory drug and anti-CD38 antibody; \*\*\*In the patients achieved CR/sCR



# 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

- IIT<sup>1</sup>: ORR of 87.5%, sCR/CR rate of 79.2%.
- Phase I<sup>2</sup>: **2-year OS rate of 100%, 3-year OS rate of 92.9%.**
- Pivotal phase II<sup>3,4</sup>: 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.
- Zevor-cel was included in China’s Commercial Health Insurance Innovative Drug Catalogue in 2025.
- Exclusive commercialization partner in mainland China:



certification and regulatory filings  
completed in

100+

healthcare institutions

20+

provinces / cities

170

valid orders from  
January to  
September 2025



# 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

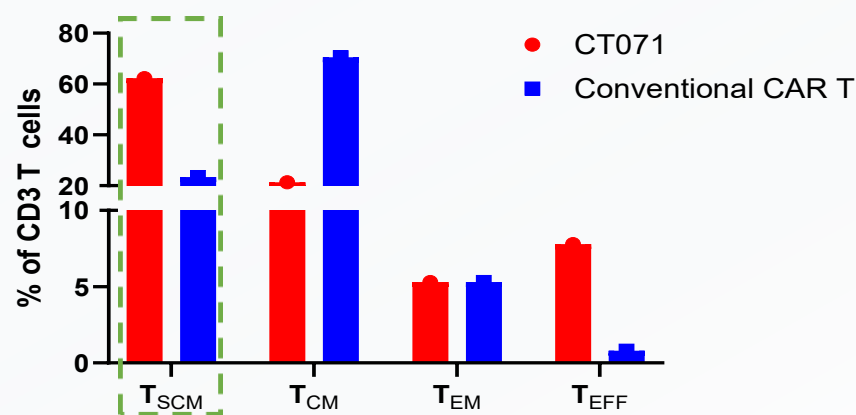
Manufacturing Time:

 **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 <sup>6</sup> cells/kg (n=8)	0.3 × 10 <sup>6</sup> 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 <sup>-6</sup> ) 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 <sup>-6</sup> ) 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><b>Gastric Cancer</b></p>  </div> <div> <p>Incidence ~25.6K<sup>1</sup></p> <ul style="list-style-type: none"> <li>• Resectable ~10.0K</li> </ul> <p>Mortality ~11.0K<sup>1</sup></p> <p>5-year survival rate of advanced GC is 5-20%; For advanced GC (3L+), ORR is 4.5%, mPFS &lt; 2 months, mOS &lt; 6 months (TAGS study)<sup>2</sup></p> </div>	<div>  </div> <div> <p>Incidence ~358.7K<sup>1</sup></p> <ul style="list-style-type: none"> <li>• Resectable ~300.0K</li> </ul> <p>Mortality ~260.4K<sup>1</sup></p> </div>
<div> <p><b>Pancreatic Cancer</b></p>  </div> <div> <p>Incidence ~60.1K<sup>1</sup></p> <p>Mortality ~49.5K<sup>1</sup></p> <p>5-year survival rate of PC is about 10%; No effective SOC for PC (2L+)</p> </div>	<div> <p>Incidence ~118.7K<sup>1</sup></p> <p>Mortality ~106.3K<sup>1</sup></p> </div>

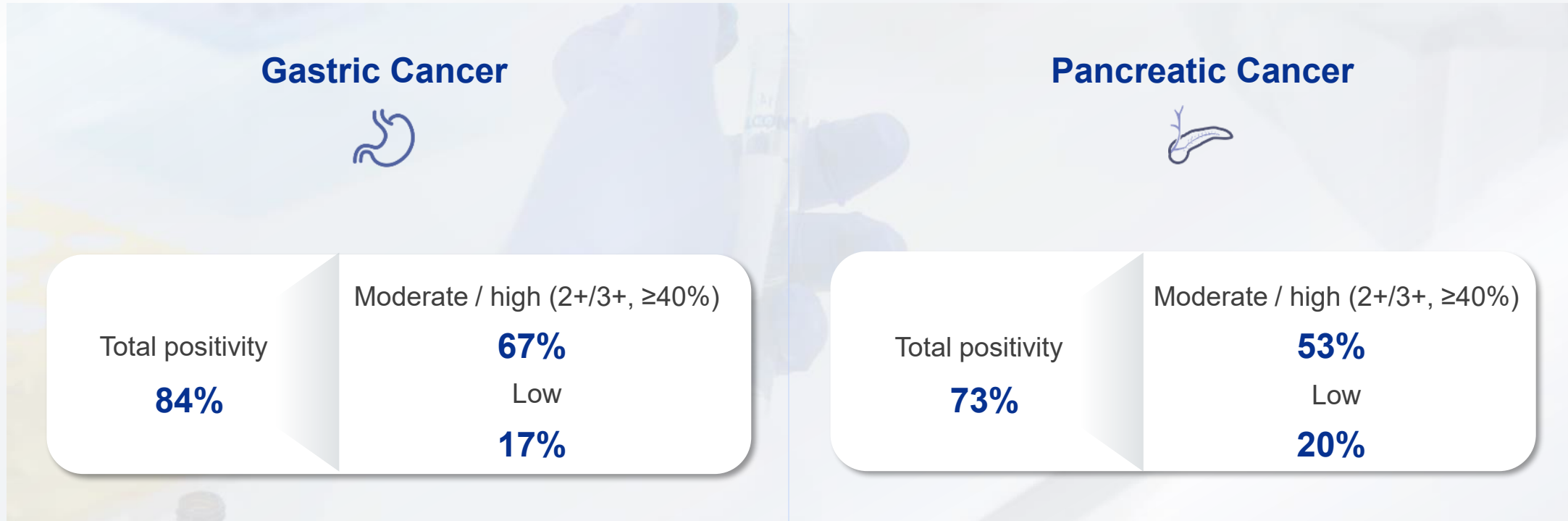
1. International Agency for Research on Cancer. Population factsheets. 2022

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 Moderate / high positivity (2+/3+, ≥40%).



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

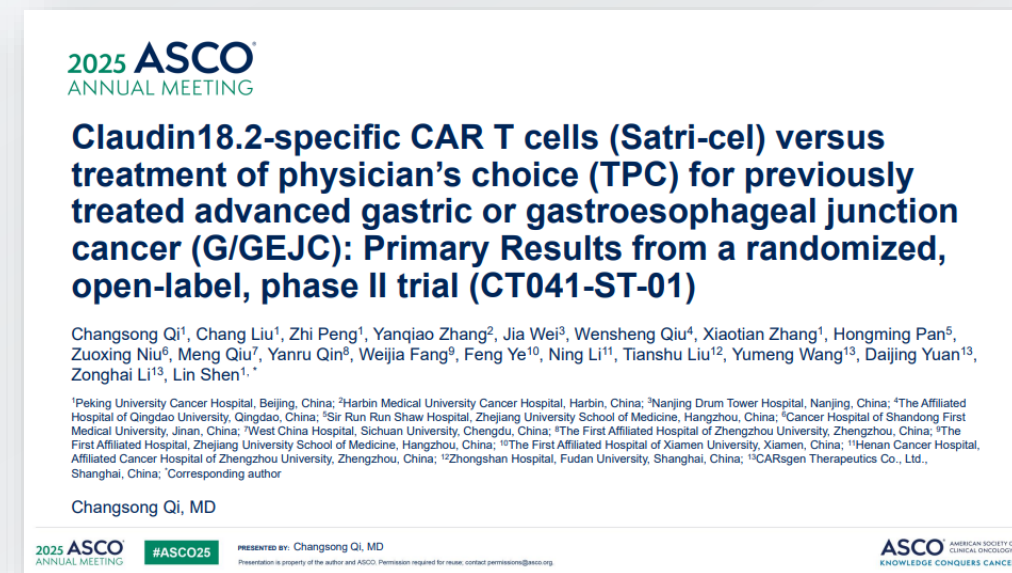


Product 	Designations 	Clinical Development Plan 
<ul style="list-style-type: none"> <li>• <b>Optimized scFv<sup>1</sup></b> <ul style="list-style-type: none"> <li>✓ High binding affinity</li> <li>✓ High stability</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Breakthrough Therapy</b> (NMPA)</li> <li>• <b>RMAT</b> (FDA)</li> <li>• <b>Orphan Drug</b> (FDA)</li> </ul>	 <ul style="list-style-type: none"> <li>• GC (3L+) confirmatory Phase II trial in China achieved <b>positive results</b>; <b>NDA</b> submitted; <b>Priority Review</b> granted</li> <li>• PC adjuvant therapy Phase I trial in China: <b>Ongoing</b></li> <li>• GC adjuvant therapy IIT in China: <b>Ongoing</b></li> </ul>
<ul style="list-style-type: none"> <li>• Innovative FNC (FC + low-dose <b>Nab-Paclitaxel</b>) preconditioning regimen to enhance penetration and anti-tumor effect of CAR-T cells</li> </ul>	<b>Collaboration</b>  <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"> <li>• earlier lines of therapy</li> <li>• additional Claudin18.2 positive cancers</li> </ul>

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



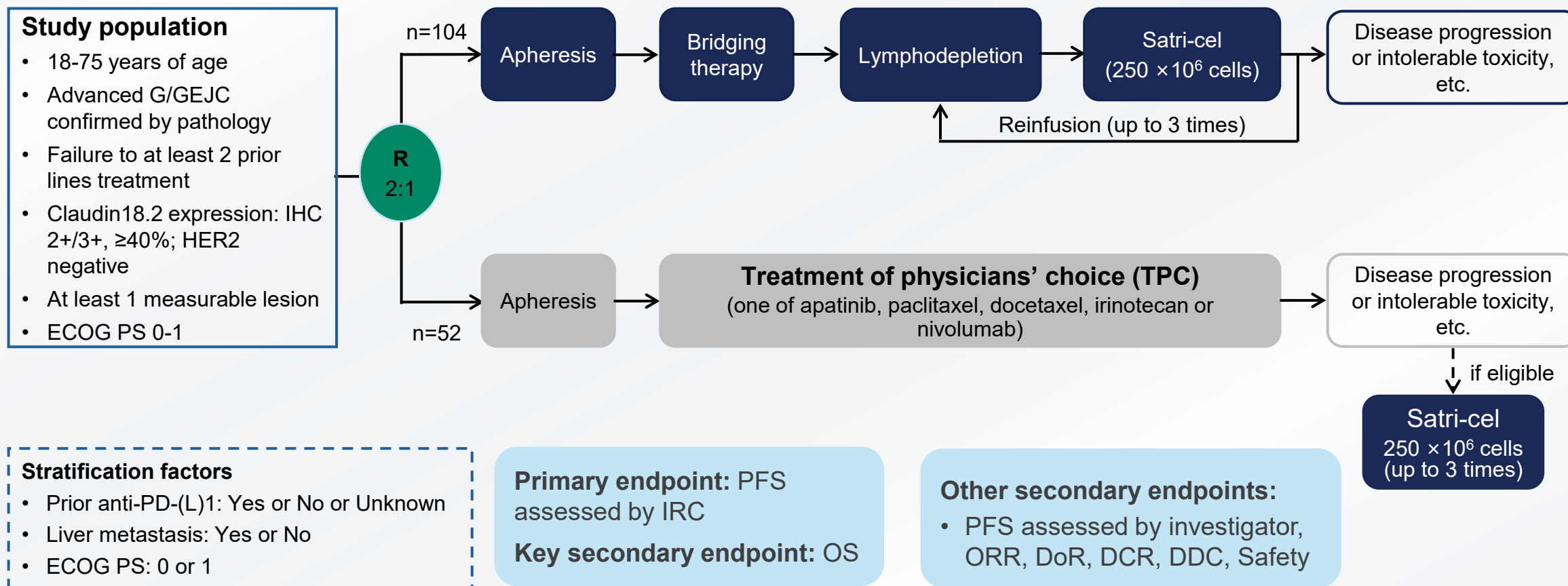
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8



# Satri-cel China Pivotal Phase II: Trial Design



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



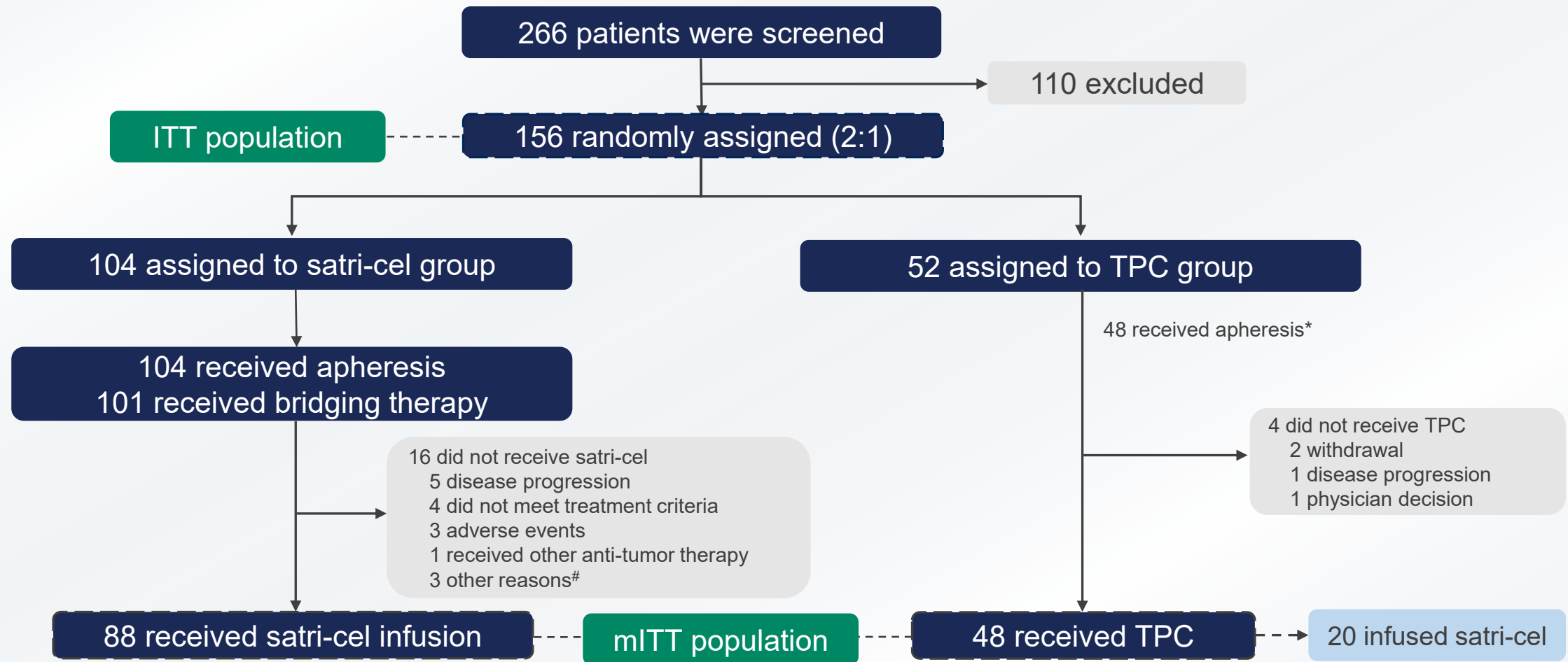
G/GEJC: Gastric or Gastroesophageal Junction Cancer; ECOG PS: Eastern Cooperative Oncology Group Performance Status; PFS: Progression-Free Survival; IRC: Independent Review Committee; OS: Overall Survival; ORR: Objective Response Rate; DoR: Duration of Response; DCR: Disease Control Rate; DDC: Duration 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)
<b>Signet ring cell carcinoma*</b>	<b>41 (39.4)</b>	<b>27 (51.9)</b>
Lauren type, n (%)		
Intestinal type	21 (20.2)	12 (23.1)
<b>Diffuse type</b>	<b>45 (43.3)</b>	<b>26 (50.0)</b>
<b>Mixed type</b>	<b>29 (27.9)</b>	<b>8 (15.4)</b>
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/analogs 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 ( <b>49.0</b> )	27 ( <b>51.9</b> )
Metastatic organs, n (%)		
<b>Peritoneal</b>	<b>72 (69.2)</b>	<b>31 (59.6)</b>
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

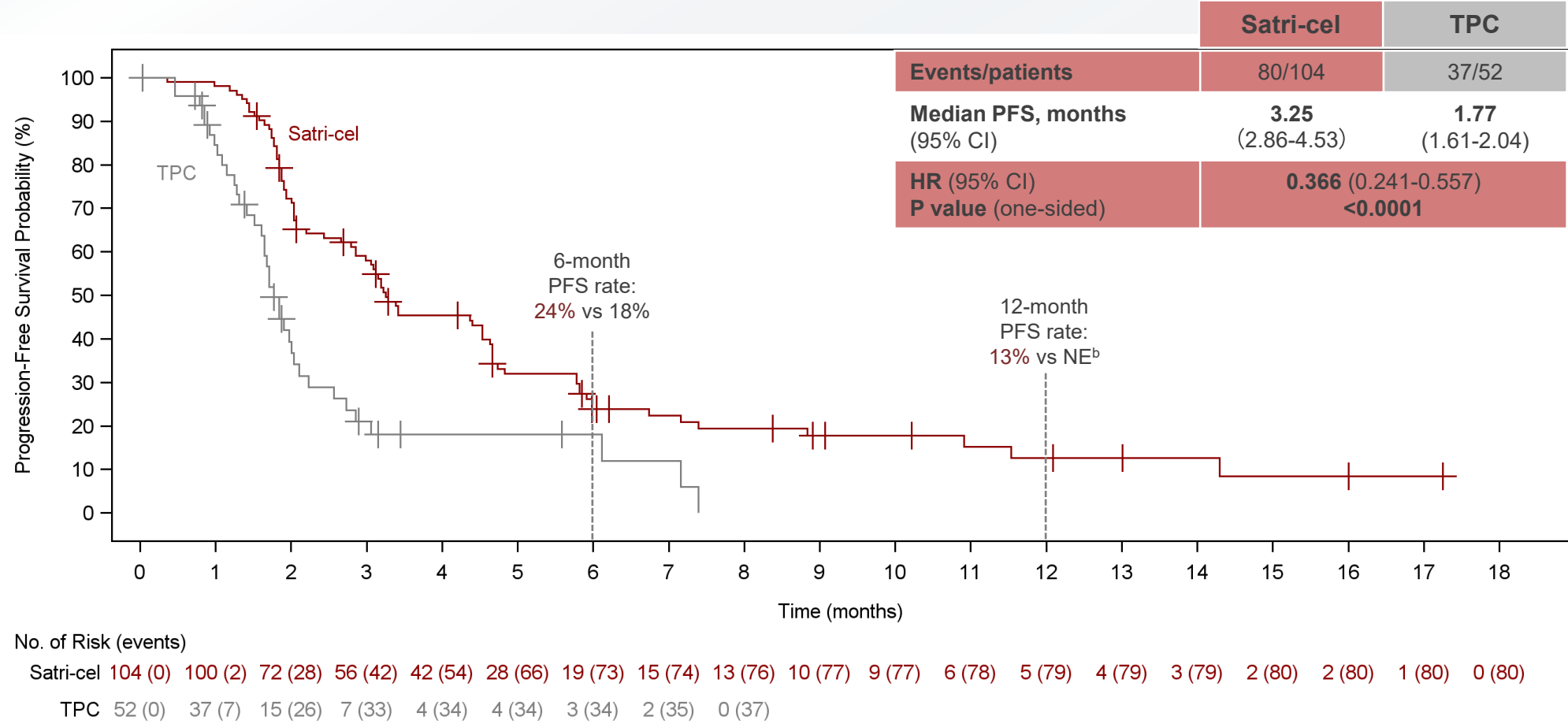
Cut-off date: Oct 18, 2024



# Satri-cel China Pivotal Phase II: Primary Endpoint—PFS by IRC<sup>a</sup>



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

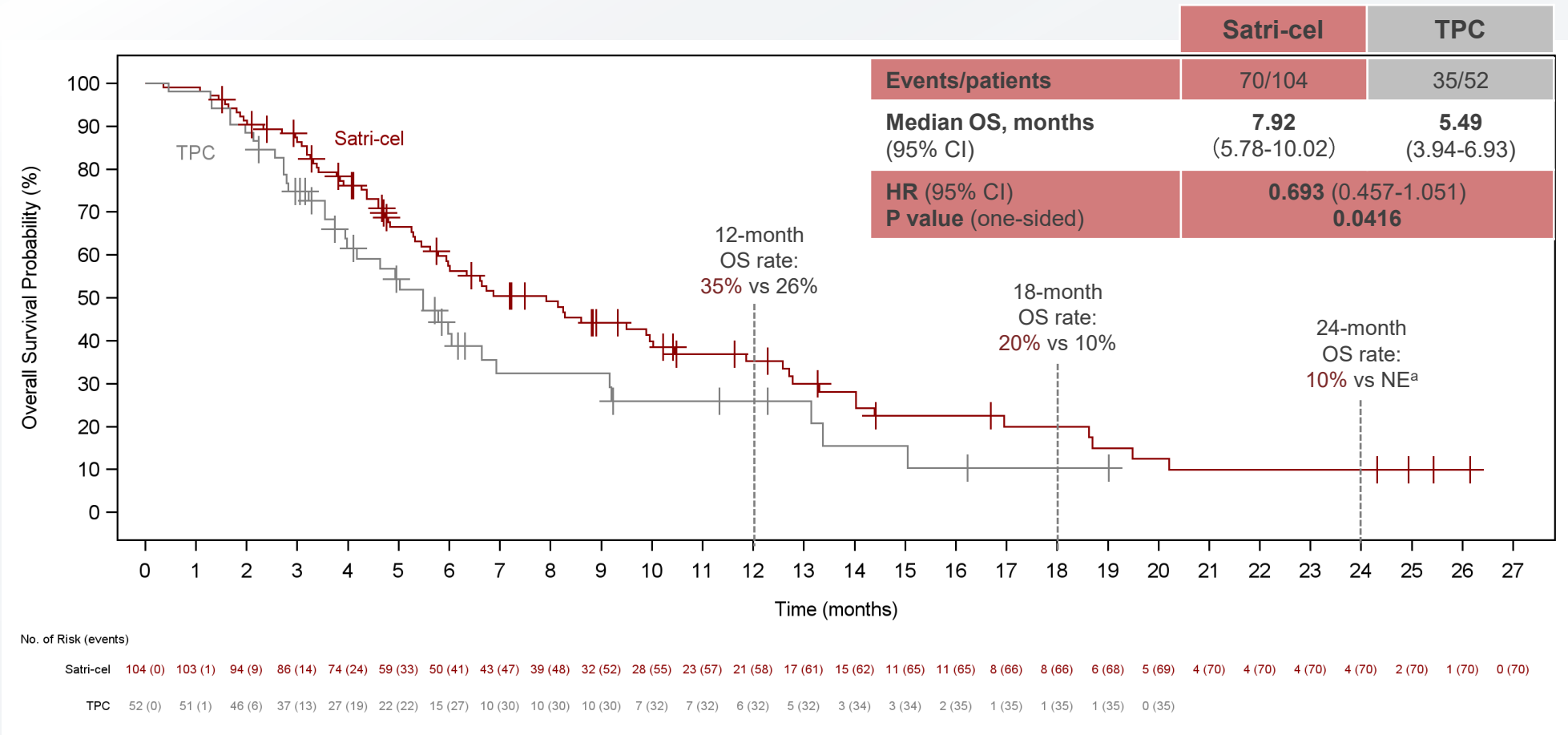
CARSGEN THERAPEUTICS Confidential Copyrights reserved by CARsgen



# 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

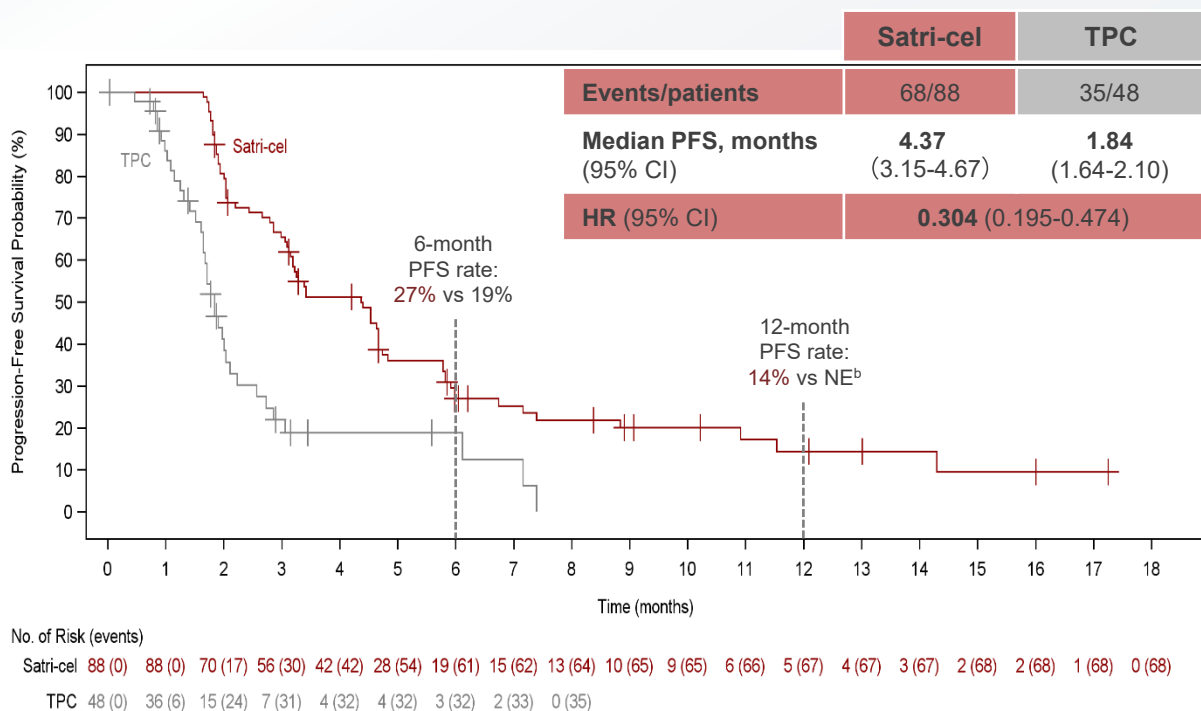


# Satri-cel China Pivotal Phase II: PFS and OS in Treated Population

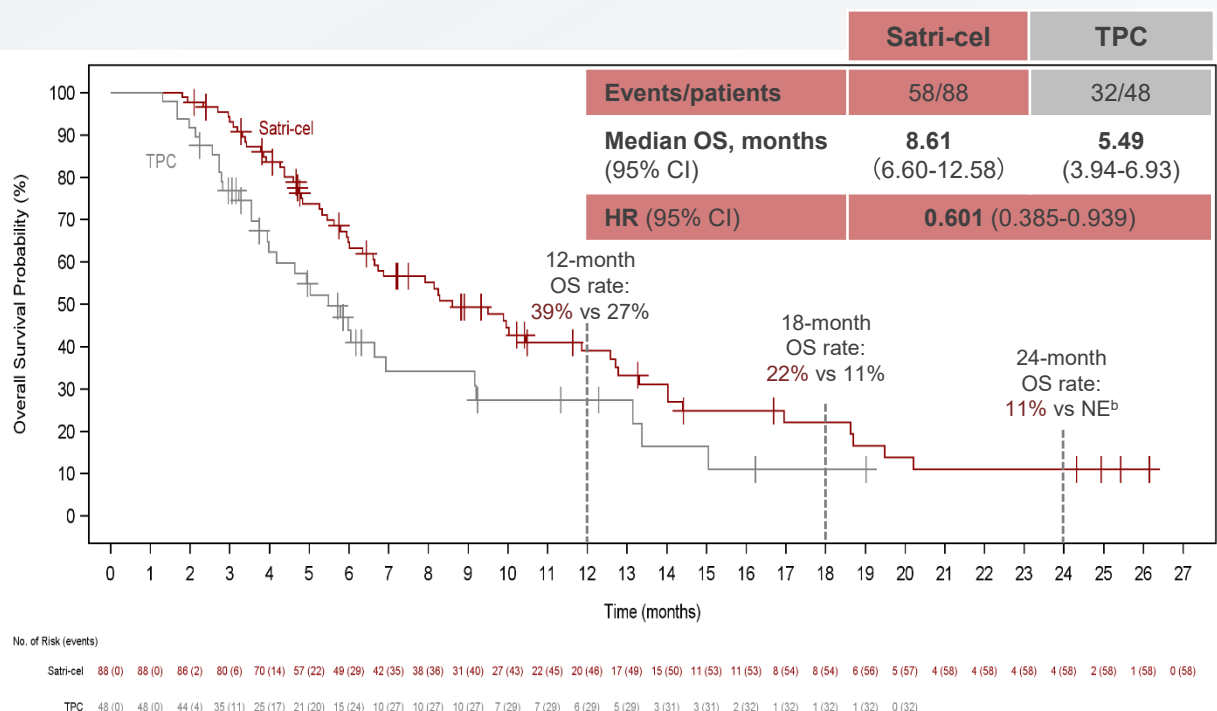


In treated population (mITT), PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

PFS assessed by IRC<sup>a</sup>



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.

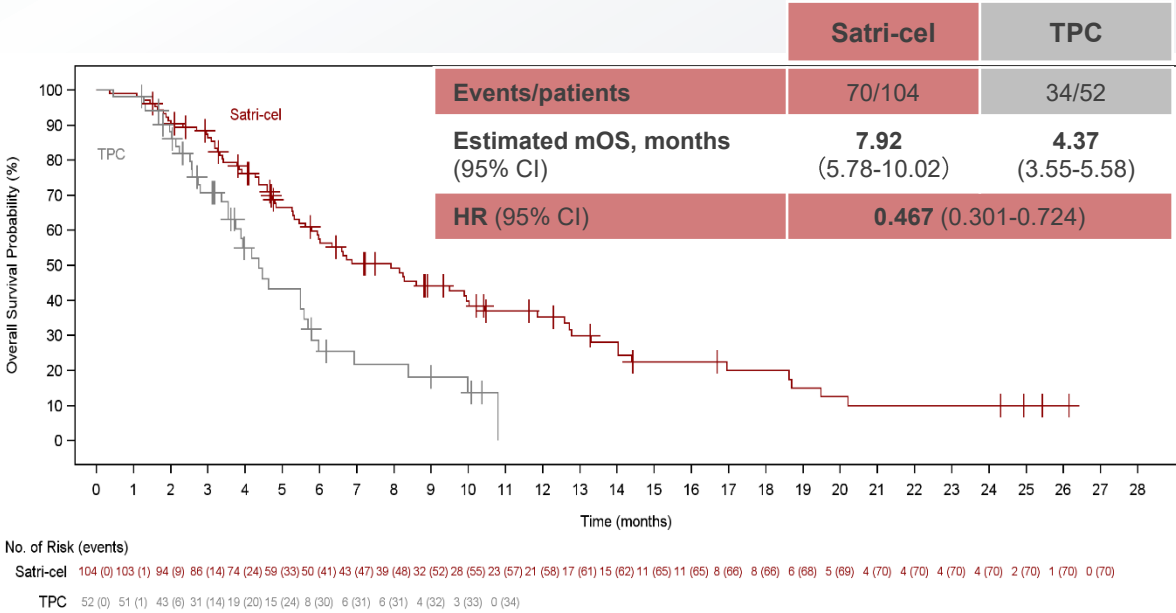


# Satri-cel China Pivotal Phase II: Adjusting OS for Treatment Switching in TPC

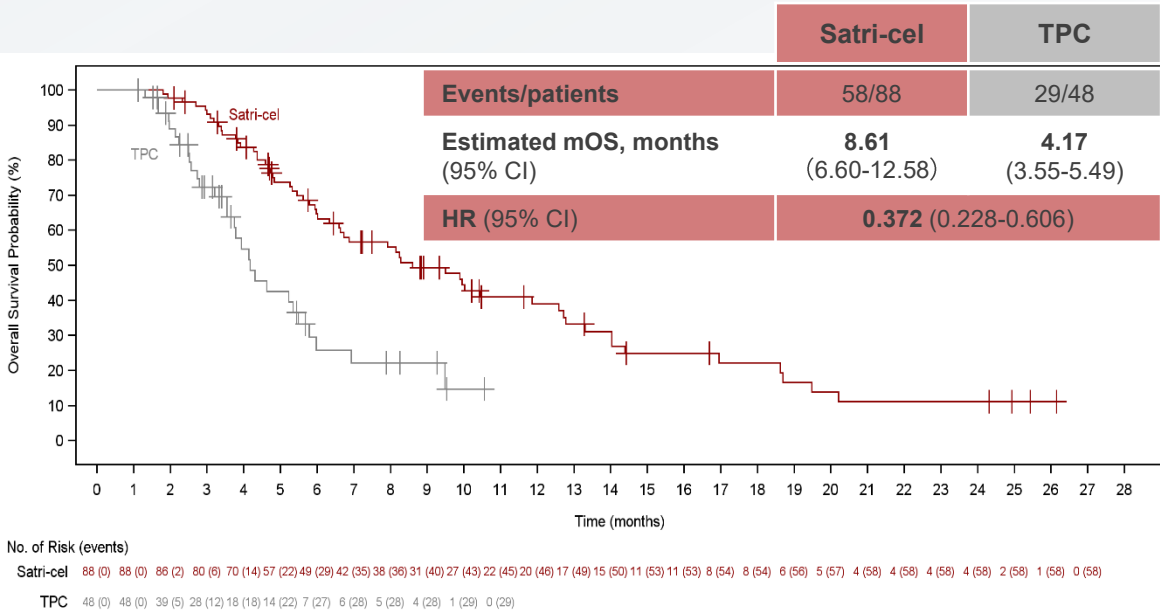


The estimated mOS was 1.81-2.06 fold longer with satri-cel vs TPC by RPSFT model, providing a 53% and 63% reduction in risk of mortality in the ITT and mITT populations, respectively.

OS (ITT) analyzed by RPSFT model



OS (mITT) analyzed by RPSFT model



- 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).

Cut-off date: Oct 18, 2024  
a: RPSFT: Rank Preserving Structural Failure Time. RPSFT model applied to adjust survival time for TPC patients who received satri-cel.

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: 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%) <sup>[1]</sup>	1 (1.1%)	1 (2.1%) <sup>[2]</sup>	1 (2.1%)
Cytokine release syndrome (CRS)	84 (95.5%)	4 (4.5%) <sup>[3]</sup>	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) <sup>1,2</sup>	Phase Ib in China (NCT04581473) <sup>3</sup>	Phase 1b in the US (NCT04404595) <sup>4</sup>	
	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	
<div>*51 G/GEJA patients with target lesions at baseline received satri-cel monotherapy.</div> <div>**59 G/GEJA patients received satri-cel monotherapy.</div> <div>***One patient was related to the investigational disease (lung metastasis of GC) and fully recovered after corticosteroids treatment.</div>				

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



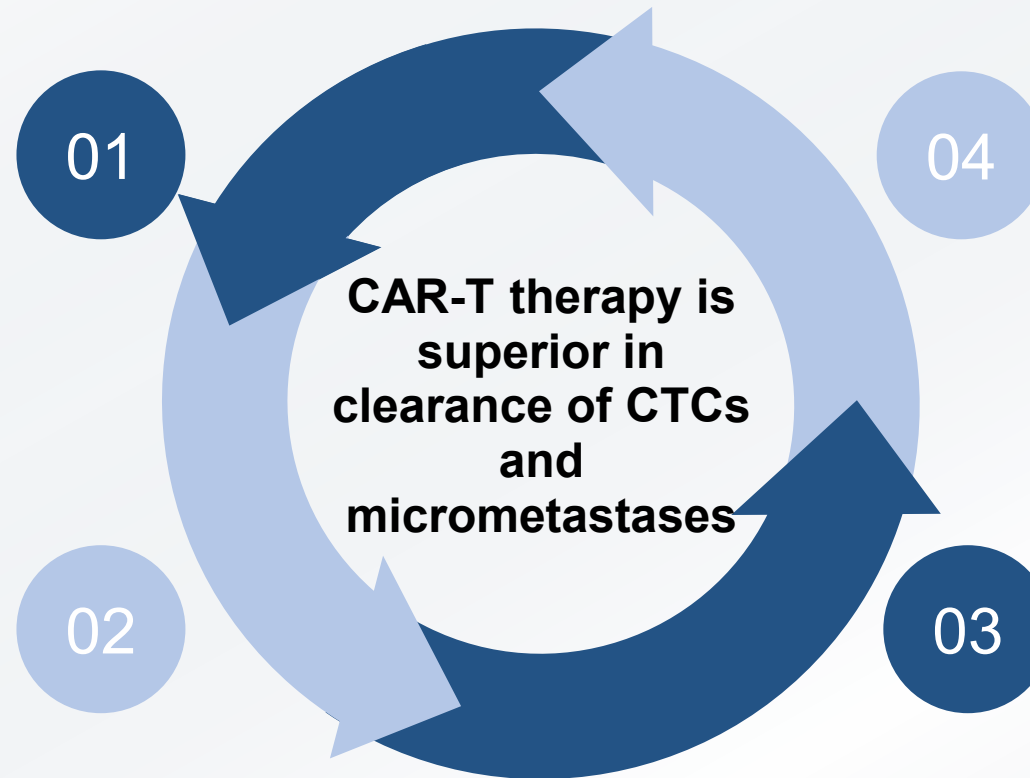
*Promising greater clinical value in earlier line / earlier disease stage and providing better chances of cure for a much broader patient population*

## 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 GC 1L Consolidation Delivered 100% Response Rate



No.	Age/Gender	BOR of 1 <sup>st</sup> 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



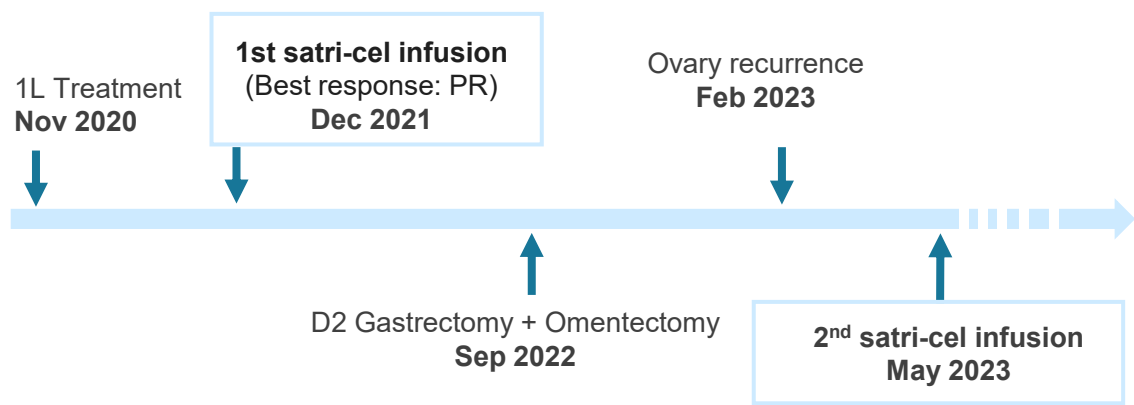
# Following Satri-cel Infusion, Two GC Patients Underwent Surgical Resection, and Remain in Long-term Survival at the Latest Follow-up



## Case 1

### 1L Treatment

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

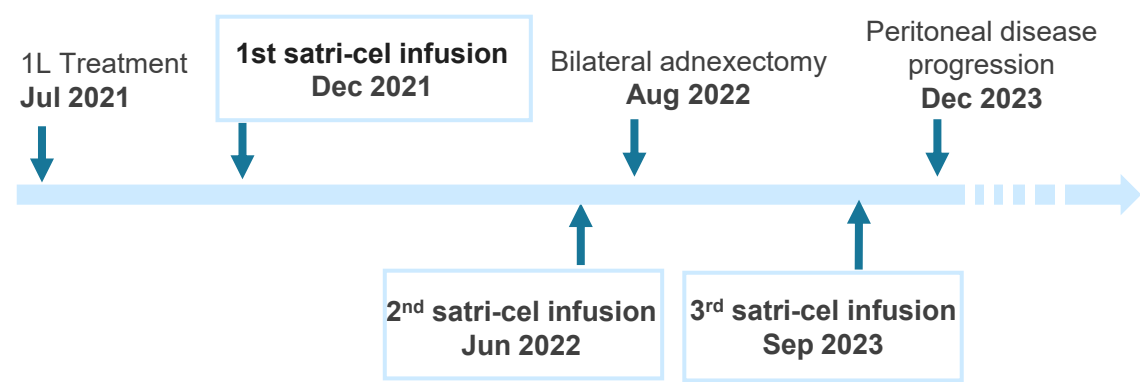


**OS: 40.0+ months (last follow-up: April 2025)**

## Case 2

### 1L Treatment

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



**OS: 42.0+ months (last follow-up: June 2025)**



# Satri-cel in Adjuvant Therapy for Pancreatic Cancer Leads to Significant Decline in CA19-9 Levels



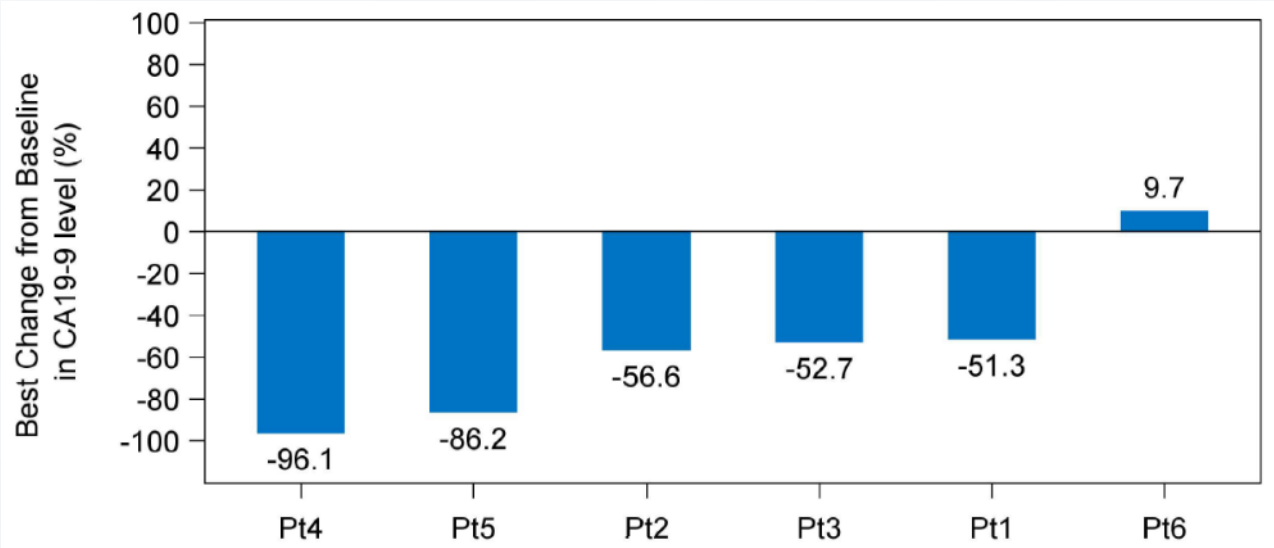
As of April 11, 2025 (data cut-off date), 6 PC patients with median follow-up of 6.05 months:

mDFS, mOS  
**not reached**

9-month DFS  
rate from  
surgery  
**83.3%**

All patients  
developed  
Grade 1 or 2  
CRS

No ICANS  
reported



- **Significant decline in CA19-9 levels** post infusion was observed in **five (83.3%)** patients, with reductions ranging from 51.3% to 96.1%.
- Notably, one patient who has completed **52-week follow-up** post infusion is still under follow-up **without disease recurrence**.

1. Yu X, et al. ESMO 2025. 2025 Oct; Poster #2220P

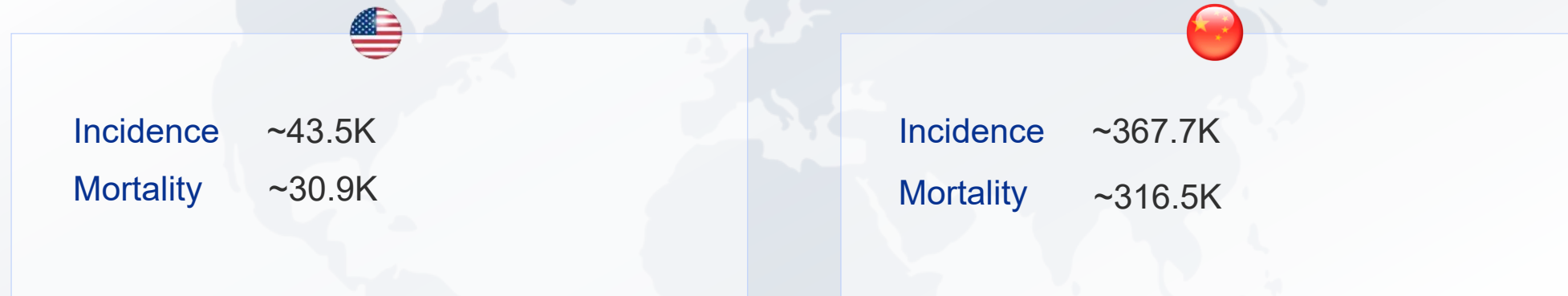
CA19-9: Carbohydrate Antigen 19-9; PC: Pancreatic Cancer; mDFS: Median Disease-free Survival; mOS: Median Overall Survival; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurotoxicity Syndrome





# Liver Cancer: The Third Leading Cause of Cancer Mortality Worldwide

## 2022 Liver Cancer Epidemiology in the US and China<sup>1</sup>



## Liver Cancer 5-year survival rate

	Global <sup>2</sup>	US <sup>3</sup>	China <sup>4</sup>
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



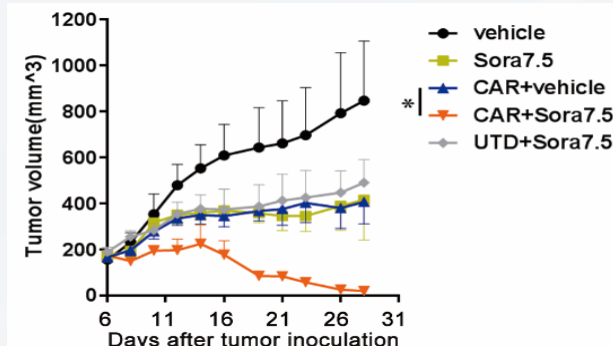
# GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*



> 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 Wu<sup>1</sup>, Hong Luo<sup>2</sup>, Bizhi Shi<sup>1</sup>, Shengmeng Di<sup>1</sup>, Ruixin Sun<sup>1</sup>, Jingwen Su<sup>1</sup>, Ying Liu<sup>1</sup>, Hua Li<sup>1</sup>, Hua Jiang<sup>3</sup>, Zonghai Li<sup>4</sup>



## Molecular Therapy Commentary

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

Andras Heczey<sup>1</sup>

<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

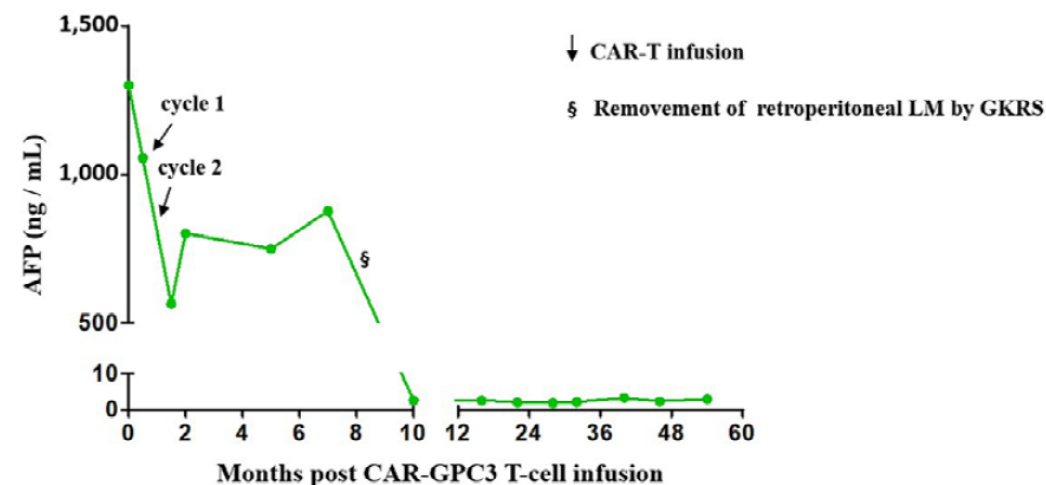
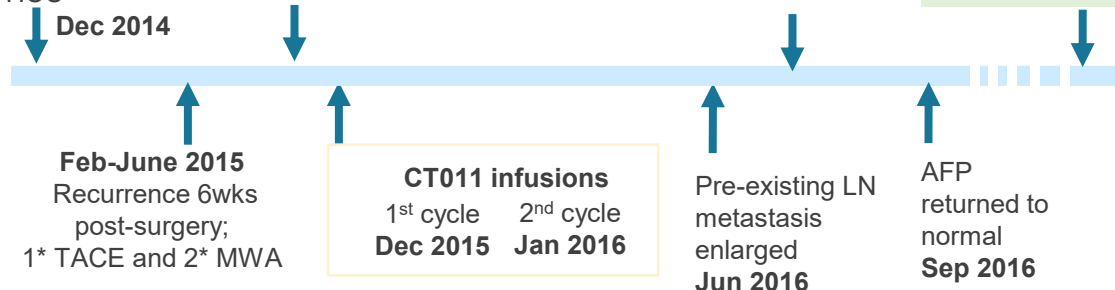
## • Case: a 54-year-old male

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

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

GKRS July 2016

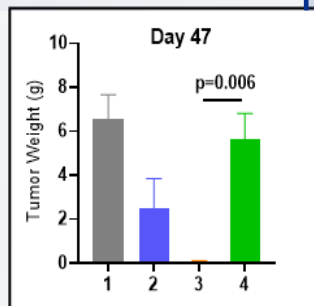
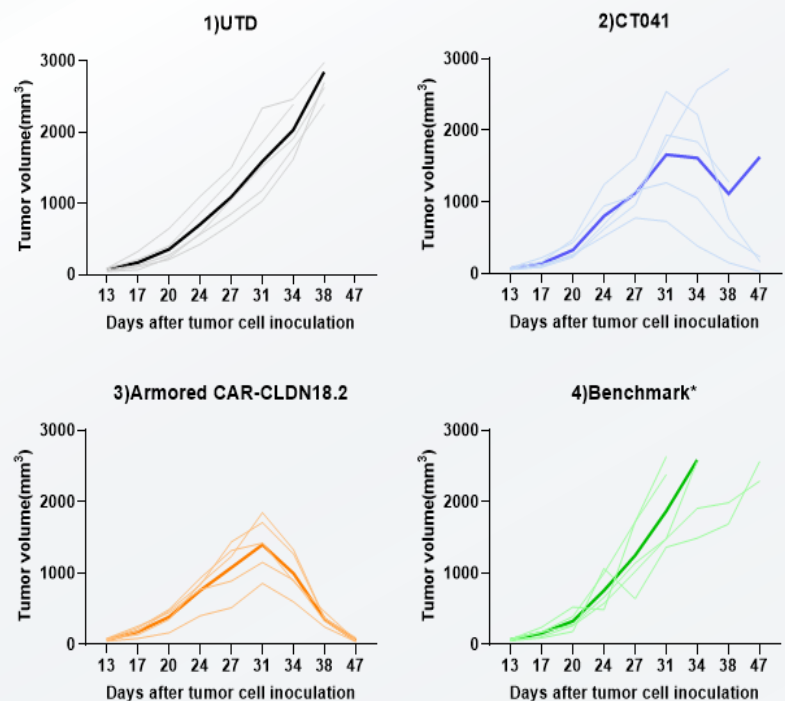
tumor free survival (> 5 years) Nov 2021



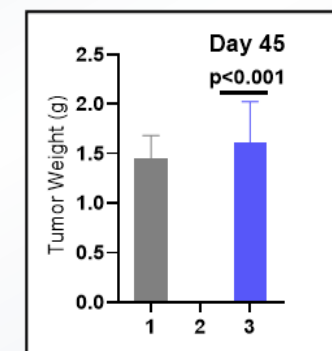
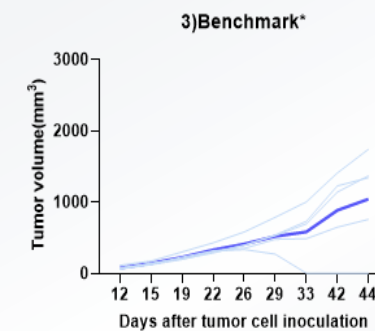
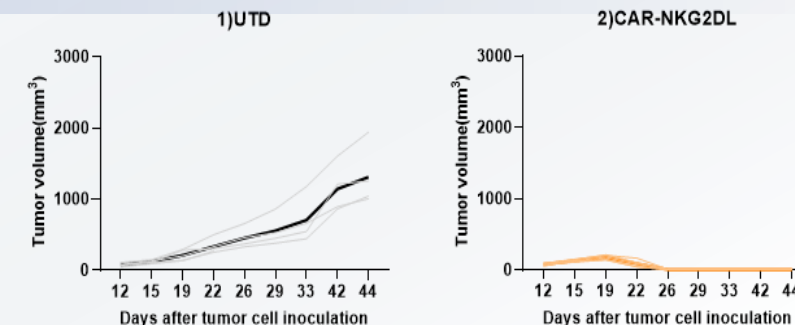


# Next-Gen CAR-T Development: Tackling Key Challenges in Solid Tumors

## 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 <sup>8</sup> cells, N=24 <sup>1</sup>	P-BCMA-ALLO1 <sup>2</sup>		cilta-cel 0.5-1 x10 <sup>6</sup> cells/kg, N=97 <sup>3</sup>
		All Arm <sup>**</sup> : 0.25-6 x10 <sup>6</sup> cells/kg, N=72	Arm C <sup>**</sup> : 2 x10 <sup>6</sup> 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 <sup>***</sup>	Not reported	Not reached <sup>****</sup>

\*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/m<sup>2</sup>/day +Flu 30 mg/m<sup>2</sup>/day) P-BCMA-ALLO1 Dose 2 × 10<sup>6</sup> and Arm B (cy 1000 mg/m<sup>2</sup>/day +Flu 30 mg/m<sup>2</sup>/day) P-BCMA-ALLO1 Dose 2 × 10<sup>6</sup>, Arm S (cy 300 mg/m<sup>2</sup>/day +Flu 30 mg/m<sup>2</sup>/day) P-BCMA-ALLO1 Dose Range of 0.25-6×10<sup>6</sup>, and Arm A (cy 500 mg/m<sup>2</sup>/day +Flu 30 mg/m<sup>2</sup>/day) P-BCMA-ALLO1 Dose 2 × 10<sup>6</sup>.

\*\*\*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 <sup>1*</sup>	Autologous CAR-T cilta-cel CARTITUDE-1 <sup>2</sup>	Autologous CAR-T zevor-cel LUMMICAR-1 Phase 1 <sup>3</sup>
Median C <sub>max</sub> (copies/ug gDNA)	6,419*	47,806	202,543
Lymphodepletion Regimen	<ul style="list-style-type: none"><li>• Fludarabine: 30 mg m<sup>2</sup>*3 days;</li><li>• Cyclophosphamide: 300 mg m<sup>2</sup>*3days;</li><li>• ALLO-647 mAb<sup>**</sup>: 13mg/20mg/30mg*3days</li></ul>	<ul style="list-style-type: none"><li>• Fludarabine: 30 mg m<sup>2</sup>*3 days;</li><li>• Cyclophosphamide: 300 mg m<sup>2</sup>*3 days;</li></ul>	<ul style="list-style-type: none"><li>• Fludarabine: 25 mg m<sup>2</sup>*3 days;</li><li>• Cyclophosphamide: 300 mg m<sup>2</sup>*3 days</li></ul>

\*Data from all patients (N=24) receiving the FCA regimen with 3.2 x10<sup>8</sup> cells.  
\*\*ALLO-647: A humanized anti-CD52 monoclonal antibody for the depletion of CD52-positive host lymphocytes.

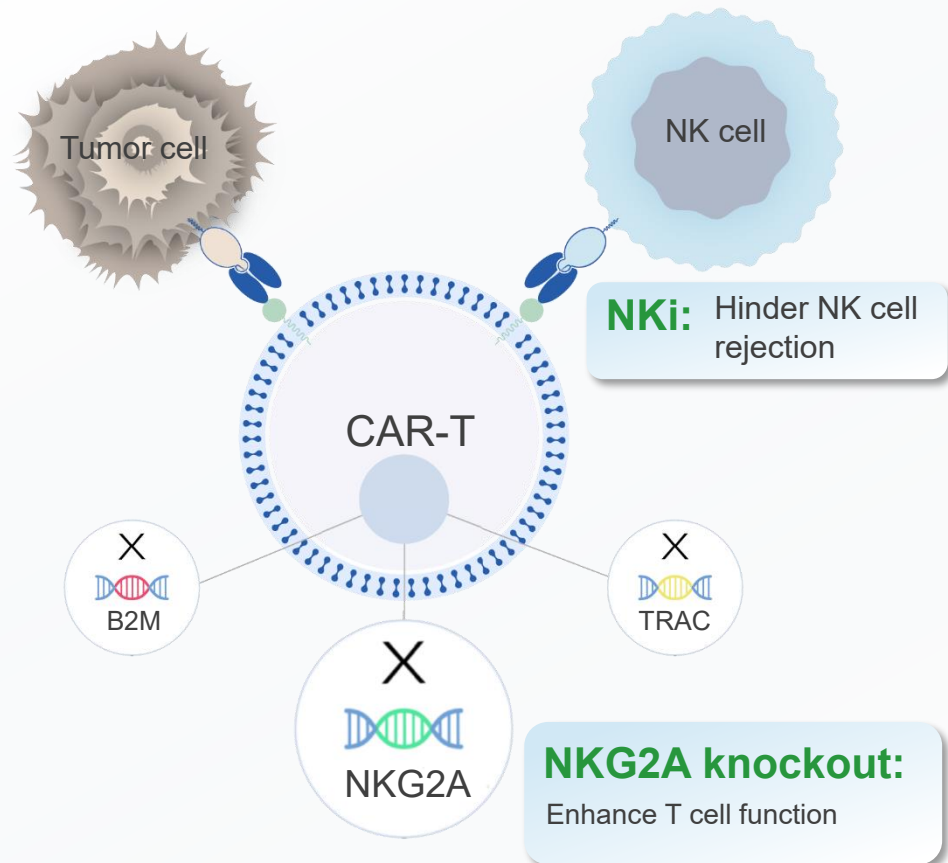
1. Mailankody S, et al. *Nat Med* 29, 422–429 (2023)  
2. cilta-cel autoleucel [Prescribing Information]. Janssen Biotech  
3. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209



# THANK-uCAR® and the Optimized THANK-u Plus™: Innovative Allogeneic CAR-T Platform Aimed to Address Immune Rejection



## Target and Hinder the Attack of NK cells on Universal CAR-T cells (THANK-uCAR®)



## HvGR is the major challenge faced by Allogeneic CAR-T

- Knocking out B2M can mitigate HvGR from host T cells, but it induces killing of uCAR-T cells by host NK cells, thereby limiting therapeutic efficacy.

## THANK-uCAR® to better address HvGR

- Anti-NKG2A CAR (NKi) can help eliminate activated NK cells, thus reducing NK-mediated killing of uCAR-T cells.
- NK cells can serve as "feeder cells" for uCAR-T cells, thereby enhancing the expansion of uCAR-T cells.
- Knockout of NKG2A can further enhance T cell function.

## THANK-u Plus™ improves the ability to resist NK rejection and enhance expansion

- Compared with THANK-uCAR®, THANK-u Plus™ incorporates an NK inhibitory signaling element (NKi binder), strengthening the ability of uCAR-T cells to resist NK cell rejection and broadening its applicability.



# Allogeneic CAR-T CT0590 Reports Outcomes from China IIT in R/R MM



CT0590 is a BCMA-targeting allogeneic CAR-T deploying **THANK-uCAR®** technology.

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

- Both patients who attained sCR had relatively higher NKG2A expression levels on NK cells.
- Baseline NKG2A expression levels on NK cells may predict treatment outcomes with CT0590.

Cut-off date: Apr 22, 2024 (NCT05066022)

# 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; 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



# 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 PCL**.

## Clinical Development

- CT0596 is under evaluation in an IIT for the treatment of R/R MM or PCL:
  - ✓ As of May 6, 2025, 8 patients with R/R MM have been infused.
  - ✓ Infusion has been completed for 2 patients with pPCL.
- Further exploration is planned in plasma cell malignancies and autoimmune diseases.
- IND application for plasma cell neoplasms is planned in the H2, 2025.



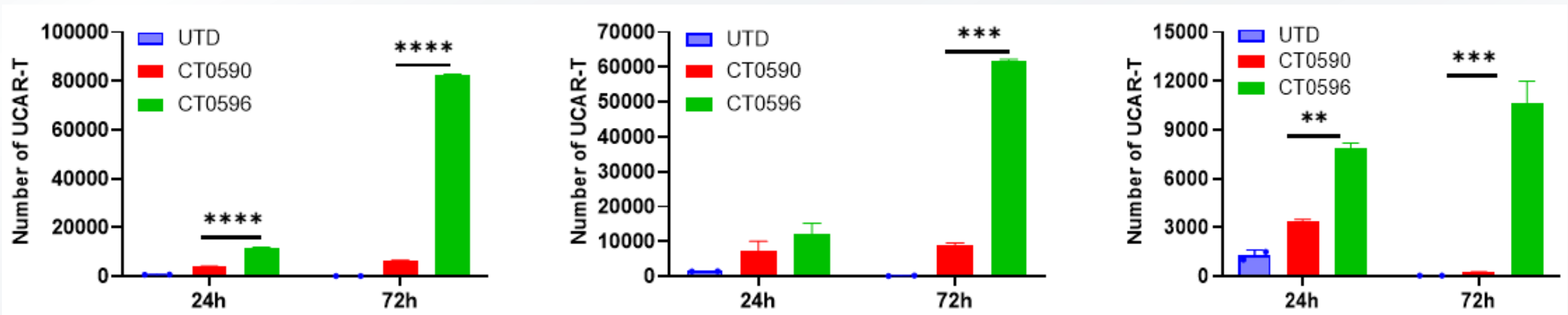
# CT0596: Enhanced and Sustained Allogeneic CAR-T Expansion Across Different NKG2A Expression Levels



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.**



# Patient Baseline Characteristics in IIT

		Patients (N=8)
Multiple Myeloma		8 (100%)
Median Age		63.5
Immunoglobulin Type at Initial Diagnosis, n (%)		
	IgG	2 (25.0%)
	IgA	4 (50.0%)
	κ Light Chain	2 (25.0%)
R-ISS Stage, n (%)		
	I	0
	II	5 (62.5%)
	III	3 (37.5%)
High-Risk Cytogenetics, n (%)		
	Yes	1 (12.5%)
Extramedullary Disease, n (%)		1 (12.5%)
Median Prior Lines of Therapy		4.5
Median Proportion of Plasma Cells, n (%)		22.50 (0.5, 53.5)
Median NKG2A % in NK cells, n (%)		20.75 (5.0, 36.7)
Dose of lymphodepletion	Full	6 (75.0)
	Reduced	2 (25.0)
Dose of CT0596	$1.5 \times 10^8$	1 (12.5)
	$3.0 \times 10^8$	5 (62.5)
	$4.5 \times 10^8$	2 (25.0)

- Lymphodepleting Regimen:
  - 6 patients received the full-dose lymphodepletion regimen (i.e., fludarabine 30mg/m<sup>2</sup>/day and cyclophosphamide 500mg/m<sup>2</sup>/day administered consecutively for 3 days as per protocol).
  - 2 additional patients had their lymphodepletion dose adjusted based on investigator assessment.
- Enrolled patients were not restricted by NKG2A expression level.
- One patient received two infusions.
- Dose exploration is currently ongoing. The lymphodepleting dose has been determined, while the cell dose may be explored at a higher level ( $6 \times 10^8$ ) to identify the recommended dose.



# CT0596 Demonstrated a Manageable Safety Profile

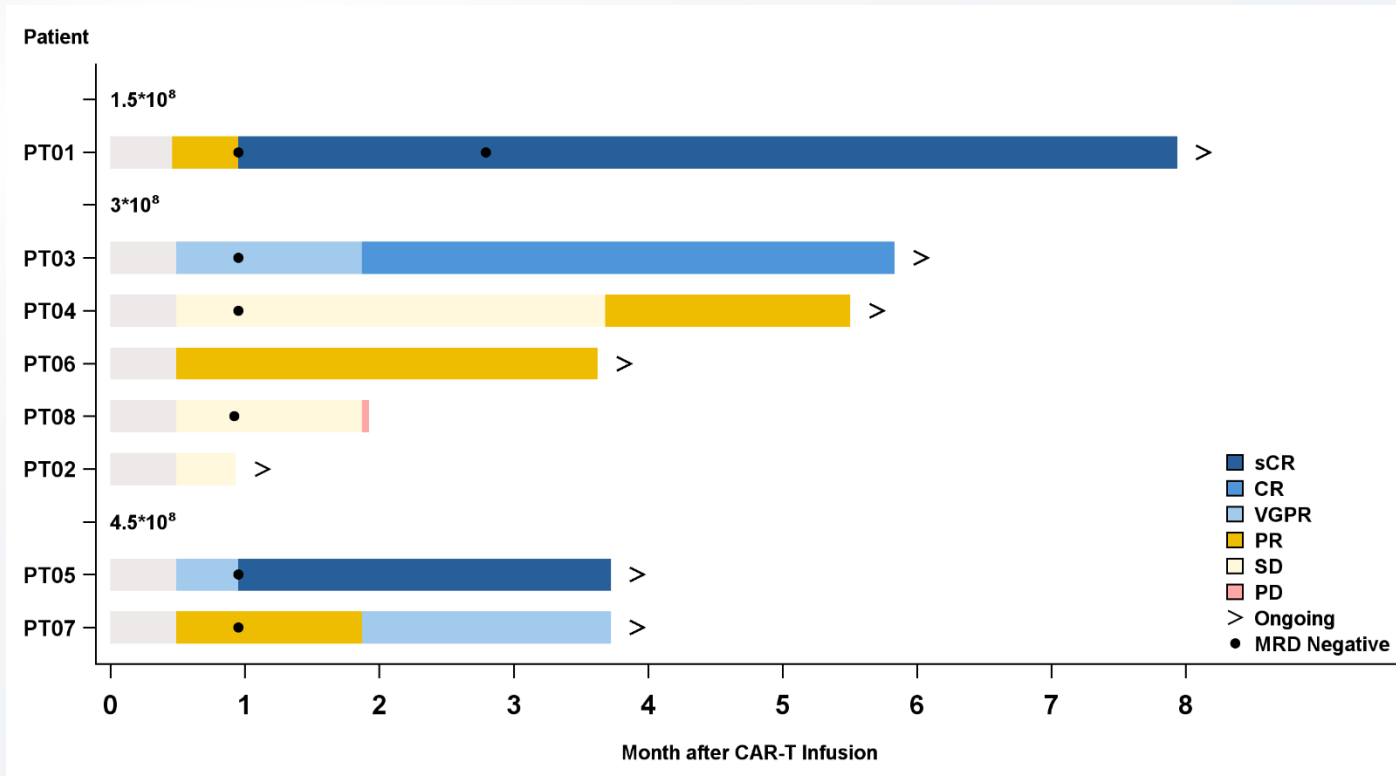


- All 8 patients reported cytopenias.
- 4 patients experienced grade 1 cytokine release syndrome (CRS), with **no grade 2 or higher CRS observed**.
- The time to onset of CRS was 2 (range, 1-8) days after infusion, and the duration was 6 (range, 2-10) days.
- **No ICANS or GvHD was observed.**
- **No** dose-limiting toxicities (DLTs) occurred, **no** patients withdrew from the trial due to adverse events (AEs), and there were **no** deaths caused by adverse events.

	N (%)
TEAEs	8 (100.0)
SAEs	2 (25.0)
≥Grade 3 AEs	8 (100)
Treatment-related TEAEs	
≥Grade 3 Lymphopenia	8 (100)
≥Grade 3 Leukopenia	8 (100)
≥Grade 3 Thrombocytopenia	3 (37.5)
≥Grade 3 Neutropenia	7 (87.5)
≥Grade 3 Anemia	2 (25.0)
≥Grade 3 Infections	0
CRS	4 (50.0)
ICANS	0
GvHD	0
AEs leading to study discontinuation	0
AEs leading to death	0
DLT	0



# CT0596 Induced Deep and Durable Responses



- As of August 31, 2025, all 8 infused patients were evaluable for efficacy, with a median follow-up time of 4.14 months (range: 0.9-7.9 months).
- ✓ **6 patients achieved a response of PR or better:** 3 achieved CR/sCR (all in the full-dose lymphodepletion group), 1 achieved VGPR, and 2 achieved PR. All 6 patients achieved MRD negativity at Week 4.
- ✓ PT01 maintained ongoing **sCR** and MRD-negativity as of **Month 8**.
- ✓ PT04 achieved PR with **resolution of extramedullary disease** following the second infusion.
- ✓ At the dose level of  $4.5 \times 10^8$  cells, PT05 achieved sCR, and PT07's response deepened over time.



# CT0596 Treatment in Two Patients with R/R pPCL Resulting in sCR

As of the data cutoff date (Oct 17, 2025), two patients with relapsed/refractory pPCL had been enrolled.

	pPCL-01	pPCL-02
Patient	62-year-old male, IgG-λ type	70-year-old male, κ light chain type
Prior Therapies	ASCT + triple classes of drugs (PI, IMiD, CD38 mAb)	Triple classes of drugs (PI, IMiD, CD38 mAb)
CAR-T Treatment	Two infusions, ~2 months apart	Single infusion
Safety	Grade 2 CRS, Grade 4 cytopenia, lung infection	Grade 1 CRS, Grade 4 neutropenia and thrombocytopenia
Pharmacokinetics	C <sub>max</sub> : <b>161,971</b> copies/μg gDNA; Maintained at 10 <sup>3</sup> by Week 8	C <sub>max</sub> : <b>151,654</b> copies/μg gDNA
Efficacy	Achieved <b>sCR</b> at Week 4 & 8; bone marrow MRD-negative (<10 <sup>-6</sup> ) at Week 4	Achieved <b>sCR</b> at Week 4, 8, & 12; bone marrow MRD-negative (<10 <sup>-6</sup> ) at Week 4 & 12

- CT0596 has exhibited **robust and rapid efficacy** in heavily pretreated patients with rapidly progressive relapsed/refractory pPCL
- Aside from expected CAR-T-associated toxicities such as CRS and hematologic adverse events, no significant organ toxicities were observed, indicating a **manageable safety profile**.



# CT1190B: An Allogeneic CD19/CD20-Targeting CAR-T Cell Therapy (THANK-u Plus™)



## THANK-u Plus™ Platform

- THANK-u Plus™ demonstrates significantly enhanced expansion compared to THANK-uCAR®
- THANK-u Plus™ sustains expansion regardless of NKG2A expression levels in NK cells

## CT1190B

- Based on the THANK-u Plus™ platform, the allogeneic CD19/CD20 -targeting CAR-T product **CT1190B** has been developed for the treatment of **B-cell malignancies or autoimmune diseases.**

## Clinical Development Progress and Plans

- An Investigator-Initiated Trial (IIT) of CT1190B for relapsed/refractory B-cell non-Hodgkin's lymphoma is ongoing.
- Products based on this platform are also being investigated in autoimmune diseases.



- A total of 14 patients have been enrolled:
  - ✓ 3 with Follicular Lymphoma (FL)
  - ✓ 3 with Mantle Cell Lymphoma (MCL)
  - ✓ 8 with Diffuse Large B-Cell Lymphoma (DLBCL)
- The dose-escalation study has been completed, establishing the lymphodepletion regimen and preliminarily determining the recommended cell dose.

## Lymphodepletion Dose Exploration Phase:

- 3 FL patients (Cell dose:  $3.0 \times 10^8$ : 1 patient;  $4.5 \times 10^8$ : 2 patients)
- 2 DLBCL patients (Cell dose:  $1.5 \times 10^8$ : 1 patient;  $4.5 \times 10^8$ : 1 patient)
- 1 MCL patient (Cell dose:  $4.5 \times 10^8$ : 1 patient)

## Recommended Lymphodepletion Dose: Fludarabine 30 mg/m<sup>2</sup>/day for 3 days + Cyclophosphamide 1000 mg/m<sup>2</sup>/day for 2 days

- 2 MCL patients (Cell dose:  $6.0 \times 10^8$ )
- 6 DLBCL patients (Cell doses:  $3.0 \times 10^8$ : 1 patient;  $4.5 \times 10^8$ : 1 patient;  $6.0 \times 10^8$ : 4 patients)



# CT1190B Demonstrated Efficacy and Safety



Data cut-off: October 17, 2025. The primary safety signals were CRS, cytopenias, and infections. No DLTs were observed, and no other adverse reactions such as ICANS or GvHD were reported.

## ➤ **Lymphodepletion Regimen: Fludarabine 30 mg/m<sup>2</sup> × 3 days + Cyclophosphamide 500 mg/m<sup>2</sup> × 3 days**

- All three FL patients achieved CR, resulting in an ORR of 100% and a CRR of 100%. One FL patient had failed immunochemotherapy, a PI3K inhibitor, chemotherapy + autologous HSCT, and CD3/CD20 bispecific antibody therapy. Another FL patient had failed immunochemotherapy + autologous HSCT and CD19 CAR-T therapy. The peak expansion copy number reached 10<sup>3</sup>-10<sup>4</sup> copies/μg gDNA.

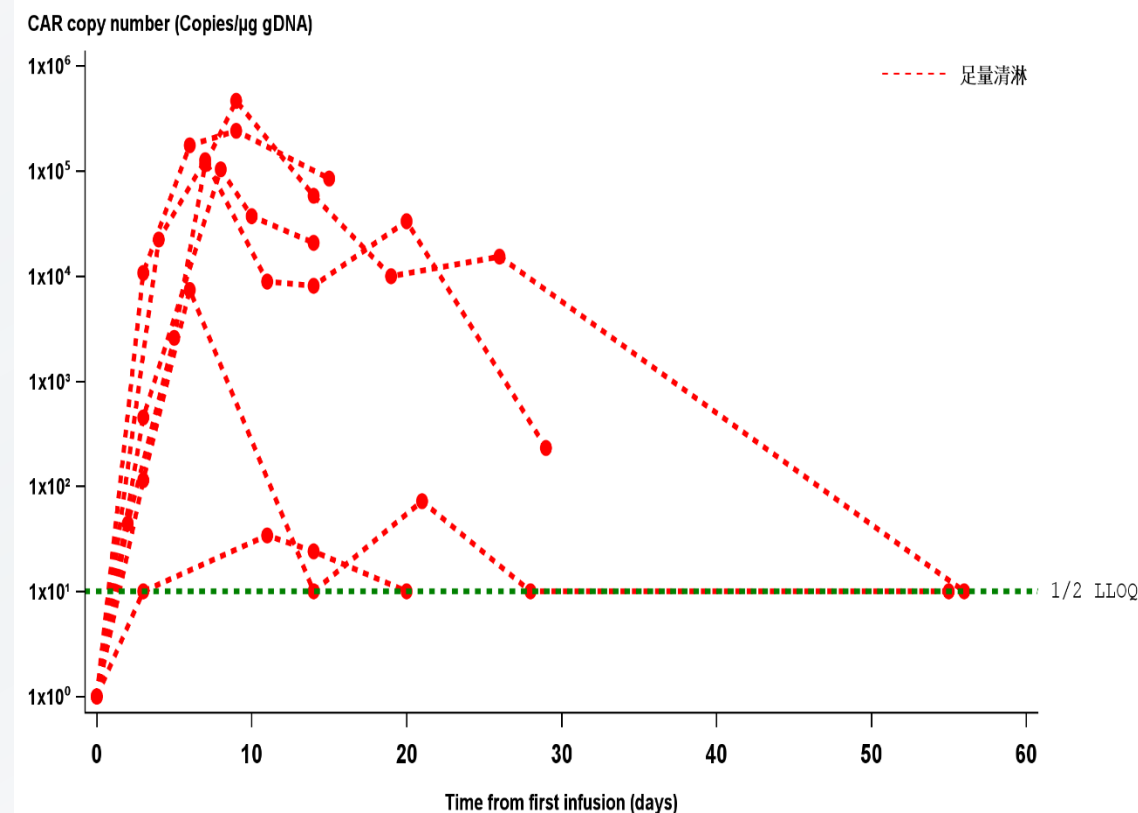
## ➤ **Lymphodepletion Regimen: Fludarabine 30 mg/m<sup>2</sup> × 3 days + Cyclophosphamide 1000 mg/m<sup>2</sup> × 2 days**

- 8 patients were enrolled under this regimen, including 2 MCL patients (cell dose: 6 × 10<sup>8</sup>) and 6 DLBCL patients (cell doses: 3 × 10<sup>8</sup>: 1 patient; 4.5 × 10<sup>8</sup>: 1 patient; 6 × 10<sup>8</sup>: 4 patients).
  - ✓ 6 patients were evaluable for efficacy, showing an ORR of 83.3% and a CRR of 66.6%, including 4 CR and 1 PR. Two DLBCL patients infused with 6 × 10<sup>8</sup> cells had not reached the efficacy assessment timepoint.
  - ✓ Both MCL patients achieved CR. Among the DLBCL patients: 2 achieved CR, 1 achieved PR (this patient had failed autologous CD19 CAR-T manufacturing), and 1 had PD. The two DLBCL patients not yet evaluable for efficacy showed a peak expansion of 10<sup>5</sup> copies/μg gDNA.
  - ✓ In the 6 × 10<sup>8</sup> cell dose cohort (4 patients), 3 achieved CR.



# Pharmacokinetics at the Recommended Dose

Product	Indication	Mean or Median Cmax (copies/ug)
CT1190B (allogeneic)	NHL	114564.5 (RD)
ALL-501 (allogeneic)	LBCL	1688
relma-cel (autologous)	LBCL	25214.5~29693.5
Kymriah (autologous)	LBCL	5210.33~6450



At the recommended dose (full-intensity lymphodepletion and cell dose of  $6 \times 10^8$ ), involving 6 patients (4 DLBCL, 2 MCL), the median Cmax of CT1190B reached  $10^5$  copies/μg gDNA. This significantly exceeds the levels observed with currently approved autologous CAR-T products (typically  $10^3$ - $10^4$ ) and other investigational allogeneic CAR-T products (around  $10^3$ ).



# Registration and Development Plan for CT0596 and CT1190B



We are fully committed to advancing the registration clinical studies for CT0596 and CT1190B, aiming to bring the allogeneic CAR-T products to market as soon as possible.

## CT0596

- Potential Indications: R/R PCL, R/R MM
- Planned initiation of Phase IB registration study in 2026

## CT1190B

- Potential Indications: R/R ALL, R/R DLBCL, R/R MCL, R/R FL
- Planned initiation of Phase IB registration study in 2026

Both CT0596 and CT1190B are planned to consider concurrent IND submissions in both China and the US during 2026-2027.



# Experienced Senior Management Team



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



**Huamao Wang, PhD**  
Co-founder and  
COO



上海锐劲生物技术有限公司



**Hua Jiang, MD, PhD**  
Vice President,  
Early Discovery



上海市肿瘤研究所  
SHANGHAI CANCER INSTITUTE



**Yi Luo, MD, PhD**  
Vice President, Clinical  
Sciences



Innovent  
信达生物制药



**Andy (Peng) Zang, PhD**  
Vice President, Head of  
Business Development  
and Strategic Planning



GSK

Bristol Myers Squibb





# Making Cancer Curable