

# CARsgen Therapeutics (HKEX: 02171)

June 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)

# 3

CAR-T Products at IND stage:

- Satri-cel (Claudin18.2)
- CT011 (GPC3)
- CT071 (GPRC5D)

# 4+

Core technology platforms:

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

# 300+

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

# 2

Manufacturing sites:

- Shanghai, China
- Durham, US

# 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 <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 R/R MM	LUMMICAR 1 (China)	launched		
				LUMMICAR 2 (US, Canada)			
	Satri-cel (CT041)	Claudin18.2	G/GEJA 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				

<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)

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



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 (Approved in China)



## 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 negative***, 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

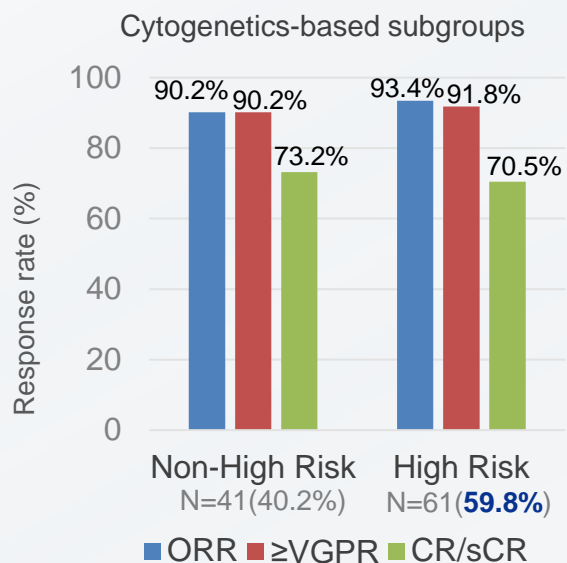
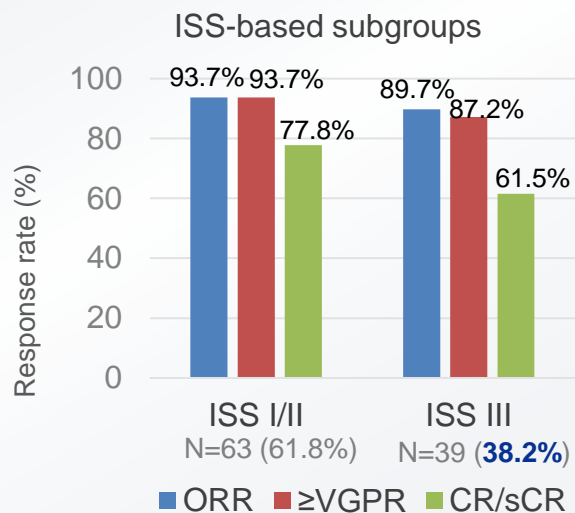
\*\*Triple-class refractory: Refractory to a proteasome inhibitor, immunomodulatory drug and anti-CD38 antibody

\*\*\*In the patients achieved CR/sCR

1. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209



# Zevor-cel: Outstanding Efficacy and Manageable Safety



## 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) .

## 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. [poster]. 2024 ASH. 2024 Dec; Poster 4762

# 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

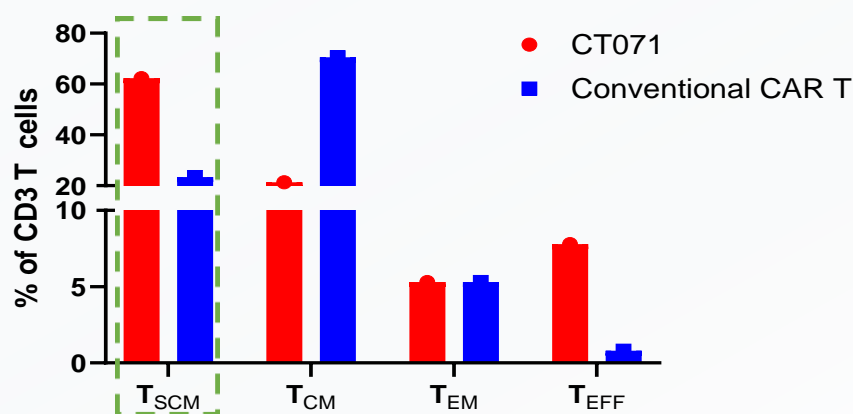
Manufacturing Time:

 **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

# CT071: Baseline Characteristics



Patient Characteristics	$0.1 \times 10^6$ cells/kg (n=8)	$0.3 \times 10^6$ cells/kg (n=9)	All Patients (n=17)
R-ISS disease stage, No. (%)			
II	4 (50.0)	8 (88.9)	12 (70.6)
III	4 (50.0)	0	4 (23.5)
ECOG PS, No. (%)			
1	4 (50.0)	5 (55.6)	9 (52.9)
2	1 (12.5)	0	1 (5.9)
Extramedullary Disease <sup>a</sup> , 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)
Prior CAR T, No. (%)	2 (25.0)	2 (22.2)	4 (23.5)
Prior ASCT, No. (%)	2 (25.0)	7 (77.8)	9 (52.9)
Double-class Refractory <sup>b</sup> , No. (%)	7 (87.5)	9 (100)	16 (94.1)
Triple-class Refractory <sup>c</sup> , No. (%)	4 (50.0)	7 (77.8)	11 (64.7)

Note, a) defined as soft tissue or paramedullary plasmacytomas; b) Double-class: one or more proteasome inhibitor, and one or more immunomodulatory drug; c) Triple-class: one or more proteasome inhibitor, one or more immunomodulatory drug, and one or more anti-CD38 antibody.

Abbreviations: R-ISS, Revised International Staging System; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ASCT, Autologous Stem Cell Transplantation.

\*Cut-off date: June 21, 2024

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



# CT071: Early and Deep Responses with Promising Safety Profile



	0.1 × 10 <sup>6</sup> cells/kg (n=8)	0.3 × 10 <sup>6</sup> cells/kg (n=9)	All Patients (n=17)
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)
Time to CR or better, Median (range), Month	1 (1.0, 1.1)	1.9 (1.0, 4.3)	1 (1.0, 4.3)
MRD Negativity (<10 <sup>-6</sup> ) in BM, No. (%)	8 (100)	7 (77.8)	15 (88.2)
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
Onychomadesis, No. (%)	4 (50.0)	0	4 (23.5)
Skin rash, No. (%)	0	1 (11.1)	1 (5.9)
AE leading to death, No. (%)	0	0	0

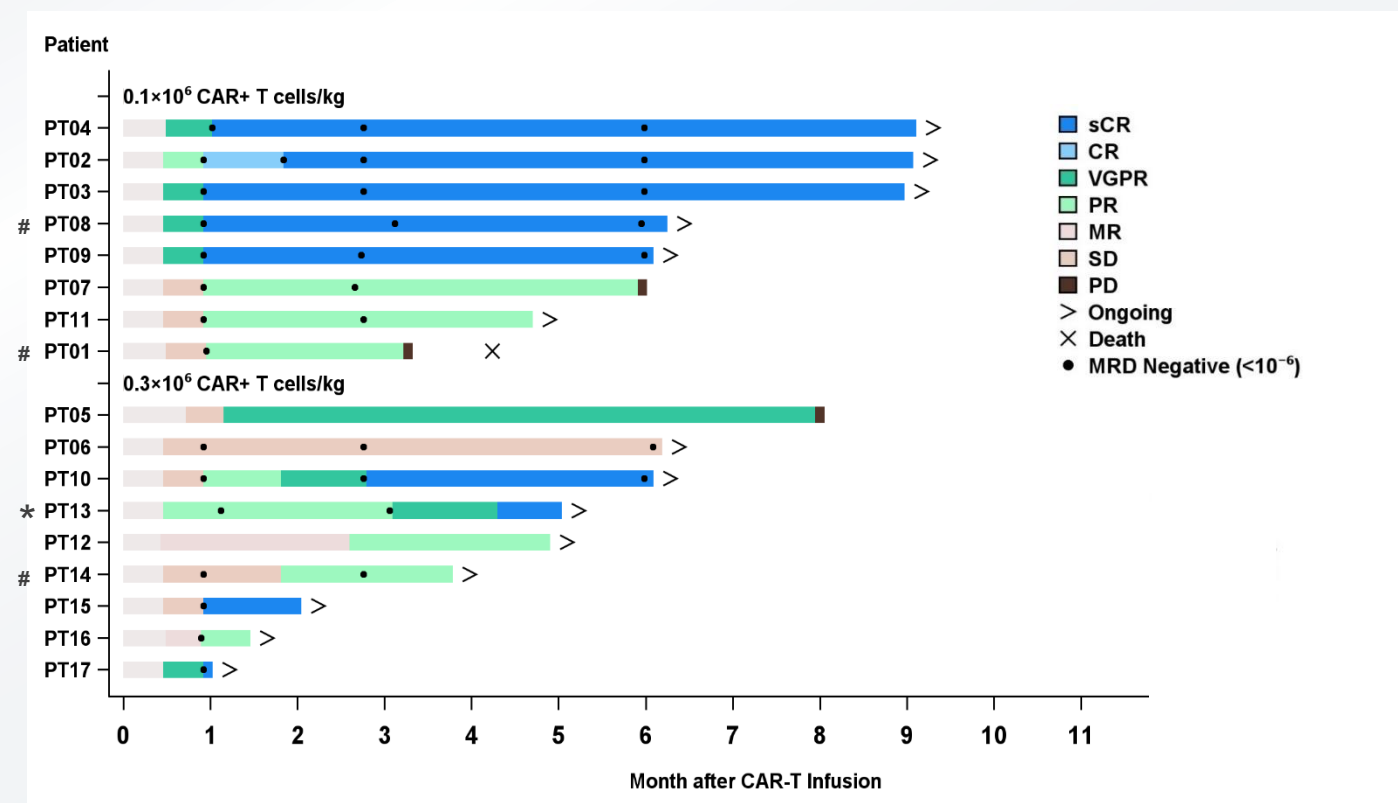
Abbreviations: CI, Confidence Interval; CR, Complete Response; DOR, Duration of Response; MRD, Minimal Residual Disease; NA, Not Applicable; ORR, Objective Response Rate; PR, Partial Response; sCR, Stringent Complete Response; SD, Stable Disease; VGPR, Very Good Partial Response; TRAE, Treatment-related Adverse Event; SAE, Serious Adverse Event; CRS, Cytokine Release Syndrome; ICANS, Immune Effector Cell-associated Neurologic Syndrome.

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

\*Cut-off date: June 21, 2024

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

# CT071: Rapid and Durable Responses



- Seven patients achieved CR or better at week 4.
- All 4 patients with previous exposure to BCMA or BCMA/CD19 CAR-T responded (2 sCR and 2 PR).
- One patient with SD demonstrated ongoing tumor shrinkage of a large EMD (125 mm × 99 mm at baseline) with 38.2% decrease at week 26, along with 93.0% decrease in serum M protein from baseline.

Note:

\* Previous exposure to BCMA CAR-T.

# Previous exposure to BCMA/CD19 CAR-T.

\*Cut-off date: June 21, 2024

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



# **Autologous CAR-T Against Solid Tumors**



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

<div data-bbox="744 254 815 321"></div> <div data-bbox="231 401 392 501">Gastric Cancer</div> <div data-bbox="252 524 346 609"></div> <div data-bbox="529 354 993 538">                     Incidence ~25.6K<sup>1</sup>                      • Resectable ~10.0K                      Mortality ~11.0K<sup>1</sup> </div> <div data-bbox="529 598 2234 704">                     5-year survival rate of advanced GC is 5-20%;                      For advanced GC (3L+), ORR is 4.5%, mPFS &lt; 2months, mOS &lt; 6 months (TAGS study)<sup>2</sup> </div>	<div data-bbox="1753 245 1834 317"></div> <div data-bbox="1538 358 2030 541">                     Incidence ~358.7K<sup>1</sup>                      • Resectable ~300.0K                      Mortality ~260.4K<sup>1</sup> </div>
<div data-bbox="198 803 428 903">Pancreatic Cancer</div> <div data-bbox="262 939 356 1025"></div> <div data-bbox="529 795 993 919">                     Incidence ~60.1K<sup>1</sup>                      Mortality ~49.5K<sup>1</sup> </div> <div data-bbox="529 966 1284 1072">                     5-year survival rate of PC is about 10%;                      No effective SOC for PC (2L+)                 </div>	<div data-bbox="1538 795 2030 919">                     Incidence ~118.7K<sup>1</sup>                      Mortality ~106.3K<sup>1</sup> </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

### Gastric Cancer



Medium & high positivity rate  
( $\geq 2+$ ,  $\geq 40\%$ )

**68%**

### Pancreatic Cancer



Medium & high positivity rate  
( $\geq 2+$ ,  $\geq 40\%$ )

**55%**

### Bile Duct Cancer





Medium & high positivity rate  
( $\geq 2+$ ,  $\geq 40\%$ )

**25%**

# 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></li> <li>✓ High binding affinity</li> <li>✓ High stability</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>plan to submit the NDA in H1, 2025 (Priority Review granted)</b></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>

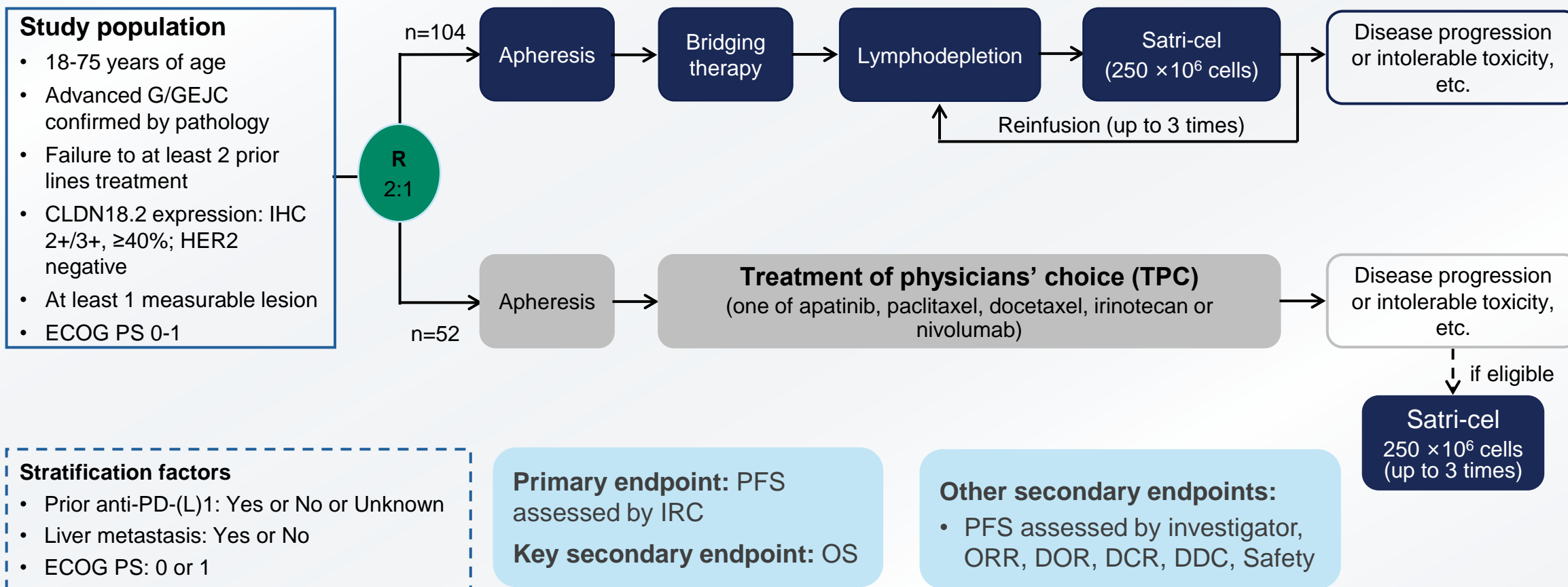
1. Jiang H, et al. *J Natl Cancer Inst.* 2019;111(4):409-418



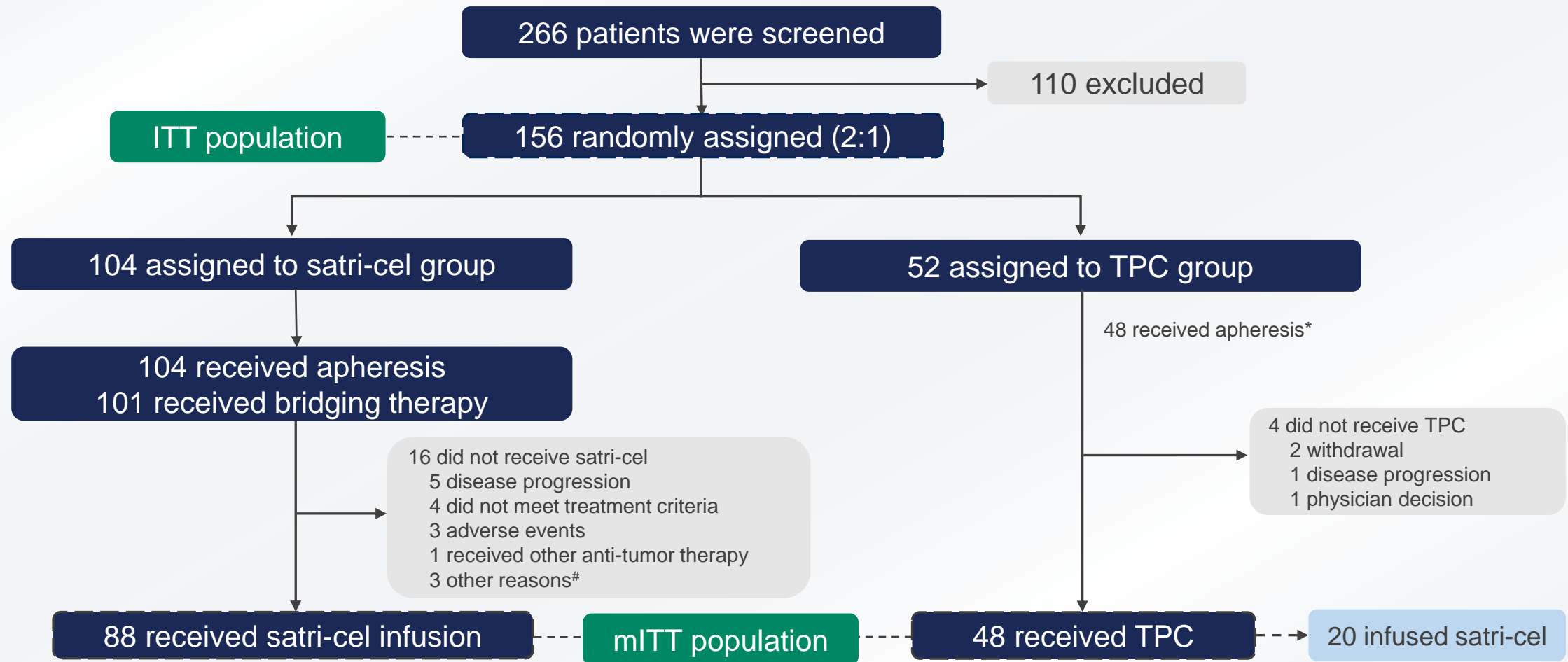
# Satri-cel China Pivotal Phase II: Trial Design



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



# Satri-cel China Pivotal Phase II: Patient Disposition



1. Qi C, et al. 2025 ASCO Abstract #4003

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

#Three patients requested to withdraw from study treatment.

Data cutoff: October 18, 2024

# 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)
CLDN18.2 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)
<b>≥3</b>	<b>51 (49.0)</b>	<b>27 (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.

† CLDN18.2 expression classification: High expression is defined as the sum of the percentages of tumor cells with 3+ and 2+ CLDN18.2 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.

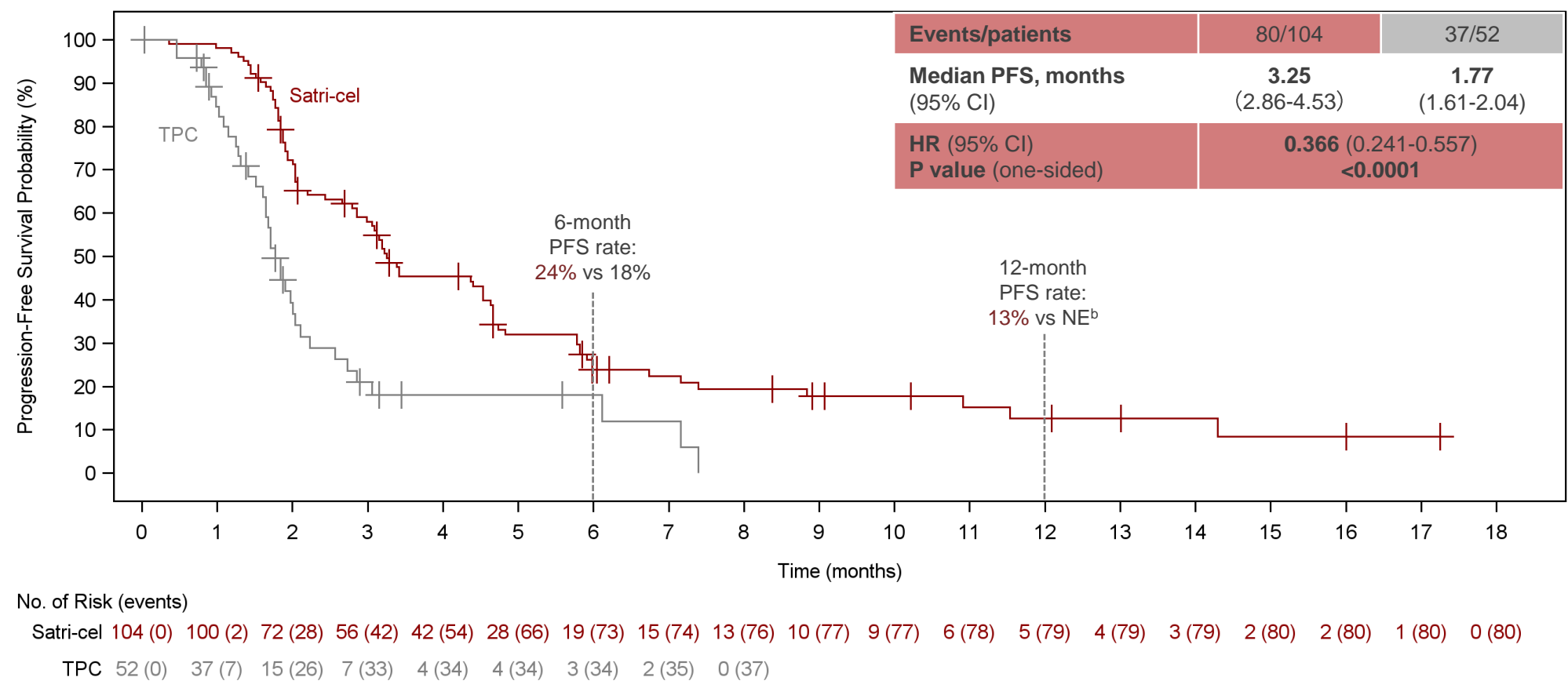
IQR=interquartile range. ECOG =Eastern Cooperative Oncology Group. CLDN18.2=claudin-18 isoform 2.



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



## Satri-cel demonstrated statistically significant PFS improvement



1. Qi C, et al. 2025 ASCO Abstract #4003

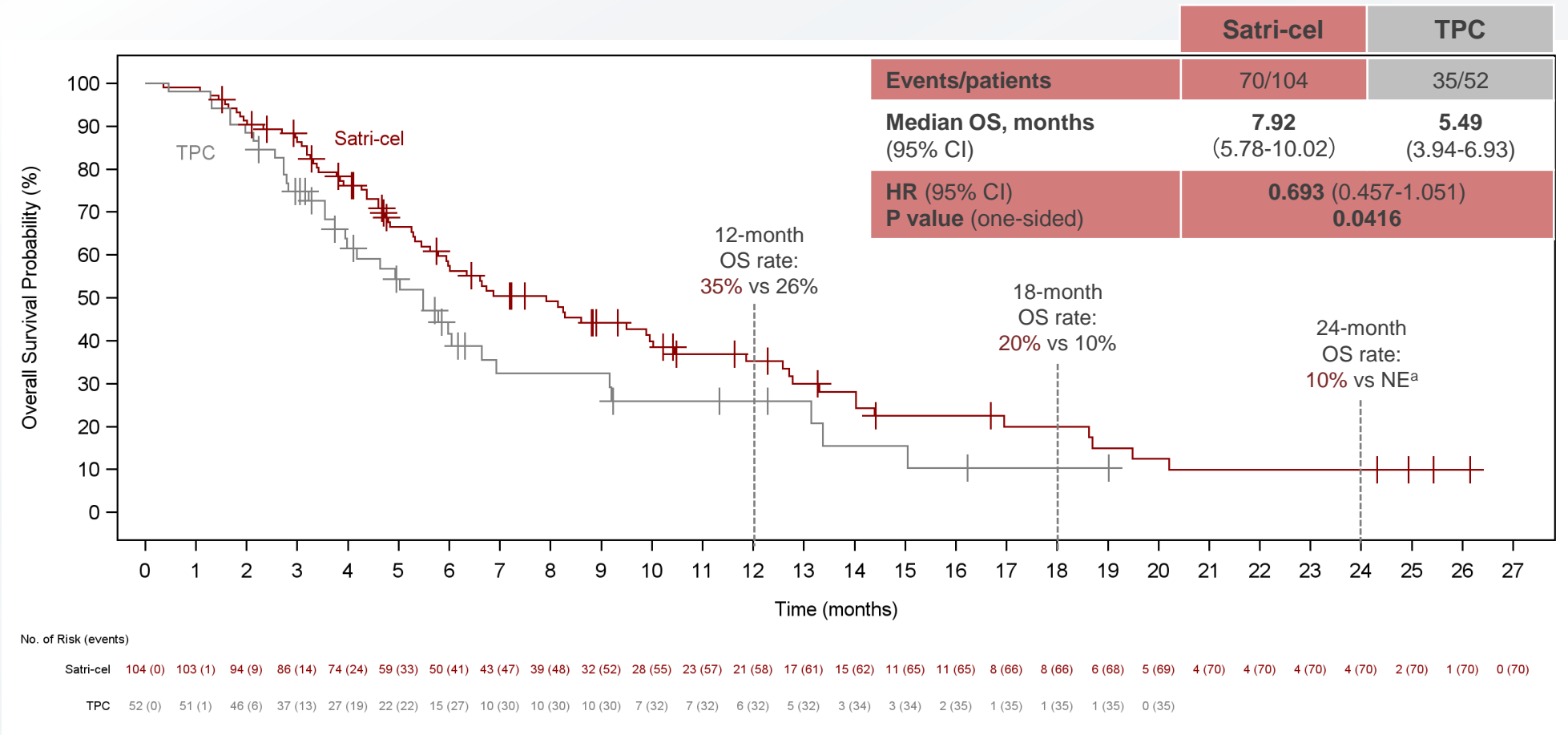
Date cutoff: October 18, 2024.  
Median follow-up: 9.07 months (satri-cel group) vs 3.45 months (TPC group).

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

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



## Satri-cel demonstrated clinically meaningful OS benefit



1. Qi C, et al. 2025 ASCO Abstract #4003

Date cutoff: October 18, 2024.  
Median follow-up: 14.42 months (satri-cel group) vs 11.33 months (TPC group).

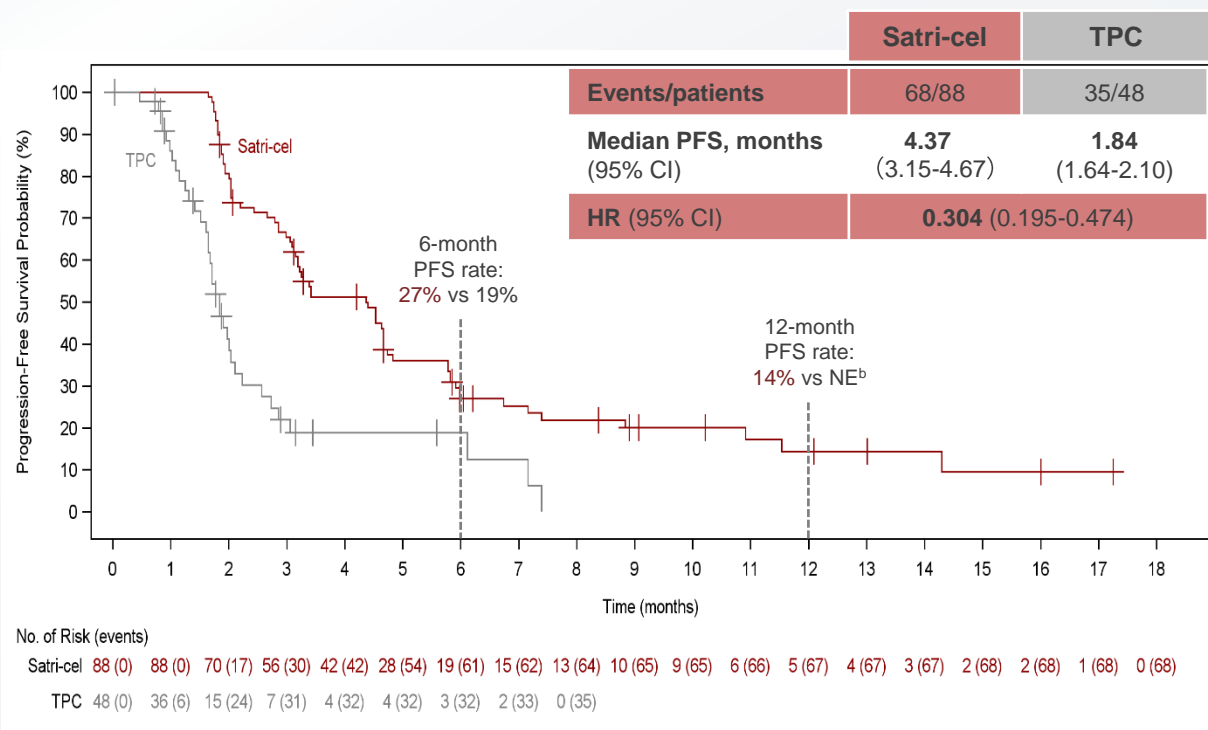
a: 24-month OS rate could not be estimated in the TPC group.

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

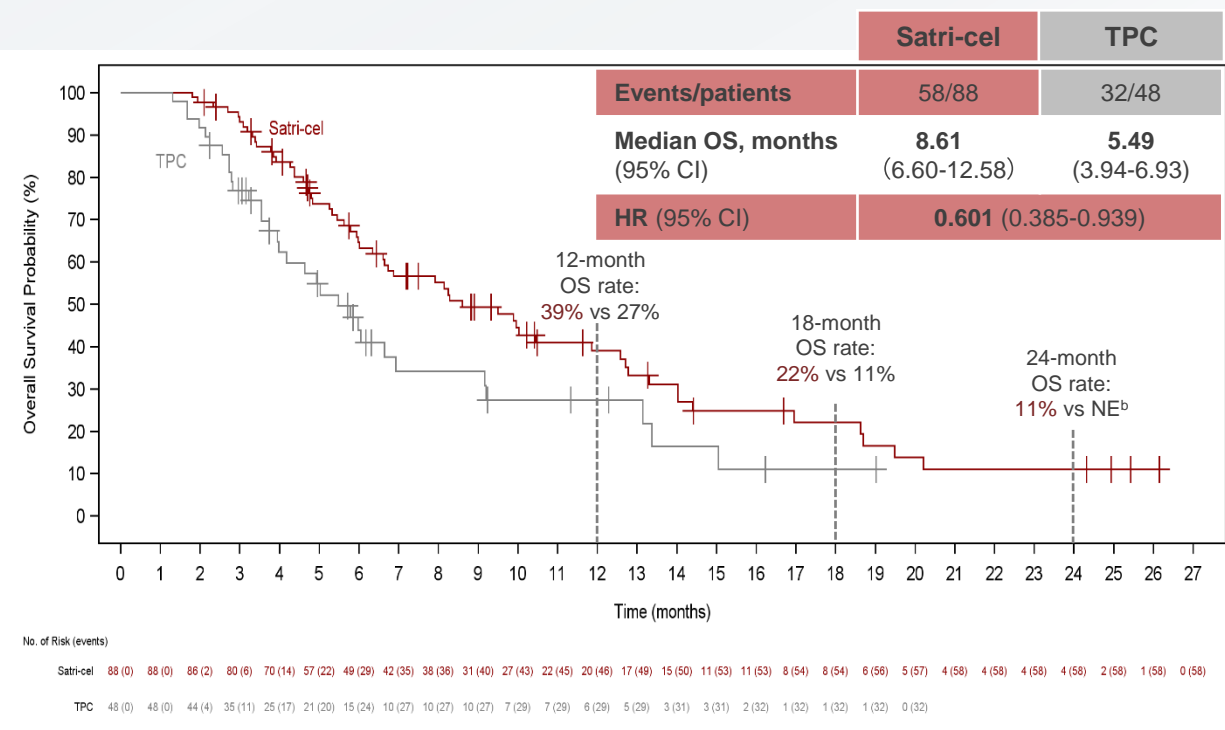


In treated population (mITT), PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

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



OS in mITT population



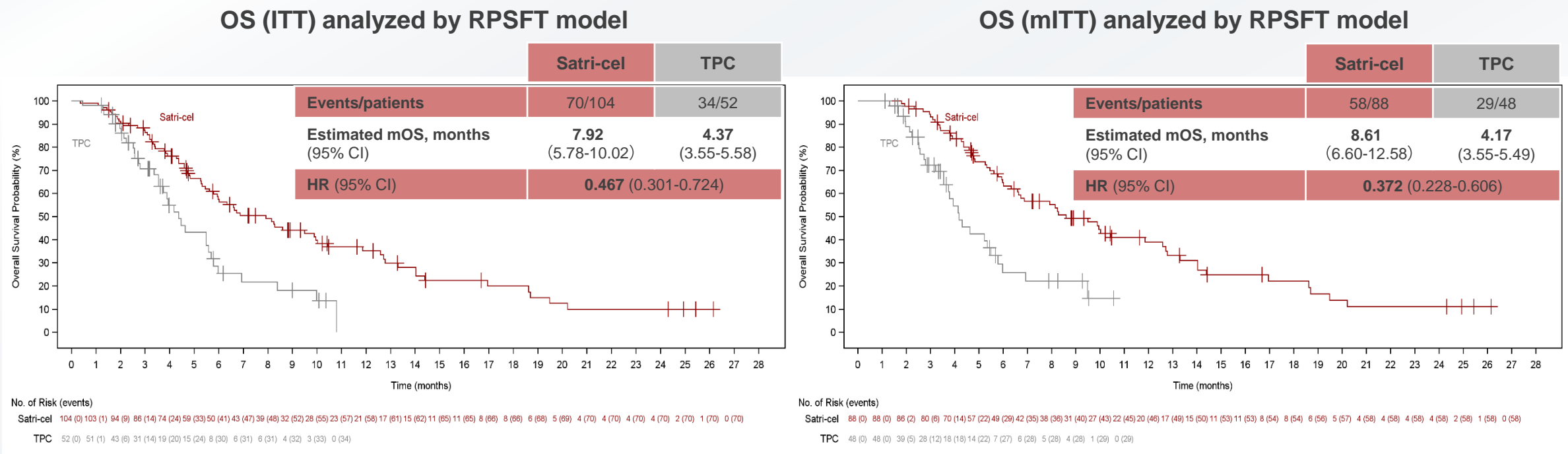
1. Qi C, et al. 2025 ASCO Abstract #4003

Date cutoff: October 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.



- 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).

Date cutoff: October 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. 2025 ASCO Abstract #4003



# 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.

1. Qi C, et al. 2025 ASCO Abstract #4003

# 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.

# 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>	
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. 2024 ASCO Abstract #2501

2. Qi C, et al. *Nat Med* (2024). <https://doi.org/10.1038/s41591-024-03037-z2>

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

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

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



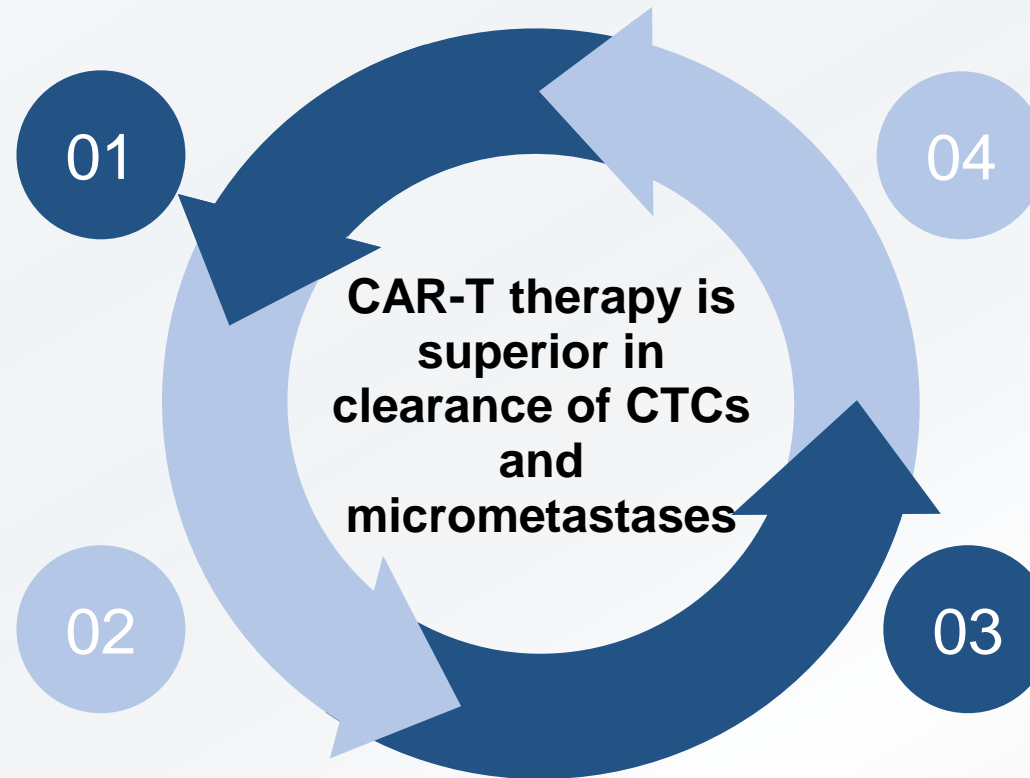
*Promising greater clinical value in earlier line / earlier disease stage and providing better chances of cure for a much broader patient population*

## 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 end-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 <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.**

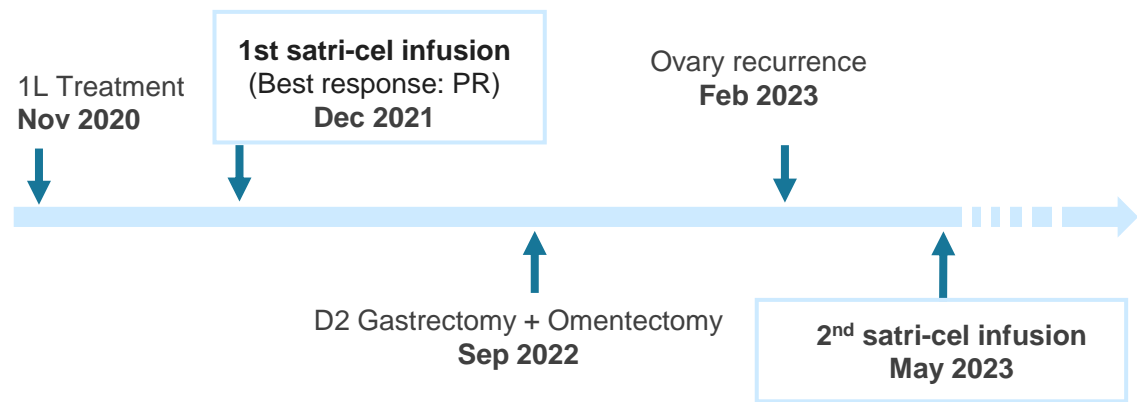
# Following Satri-cel Infusion, Two Patients Underwent Surgical Resection, and Remain in Long-term Survival at the Latest Follow-up



## Case 1

### 1L Treatment

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

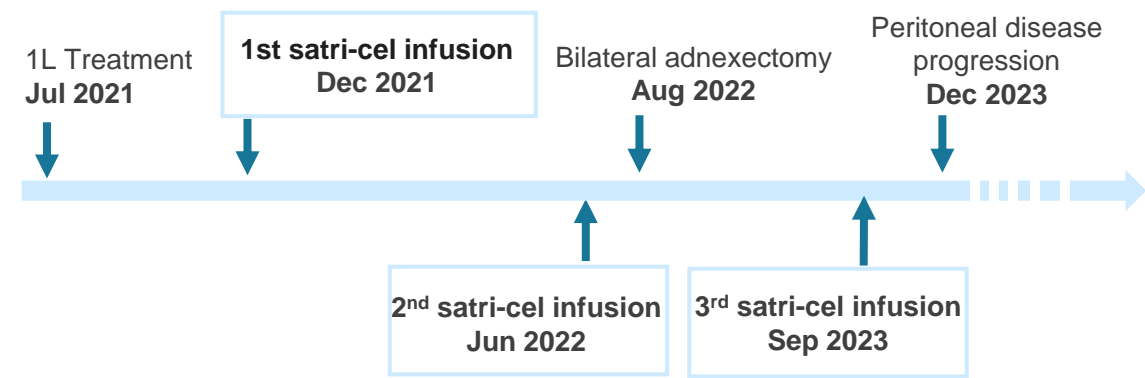


**OS: 36.0+ months (last FU: Dec2024)**

## Case 2

### 1L Treatment

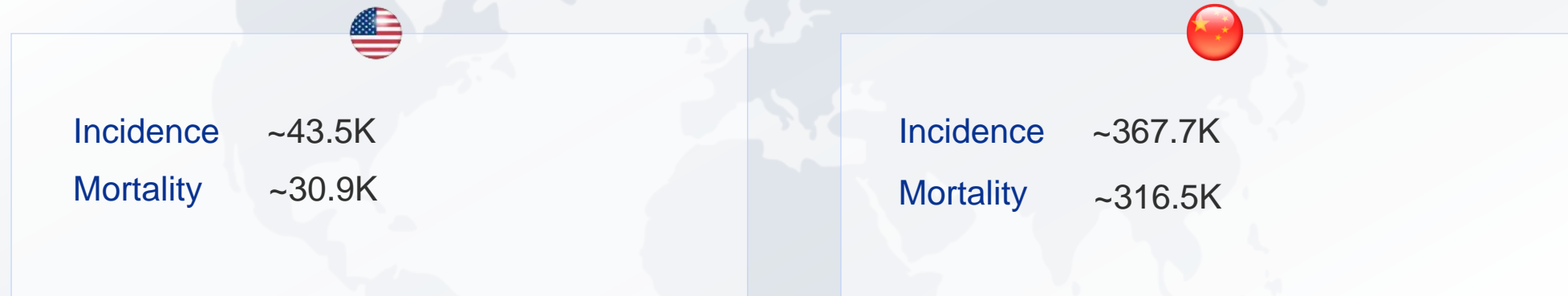
- **Regimen:** SOX regimen (4 cycles)
- **BOR :** PR



**OS: 39.0+ months (last FU: Mar2025)**

# 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



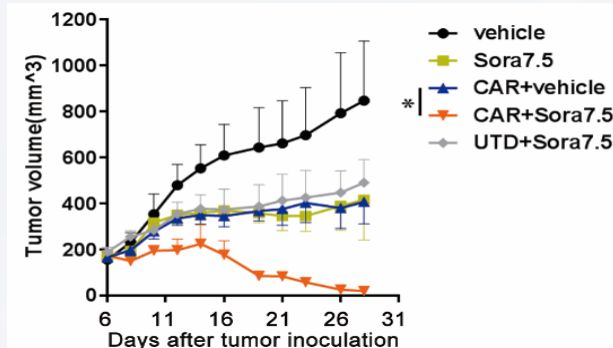
# GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*



> 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

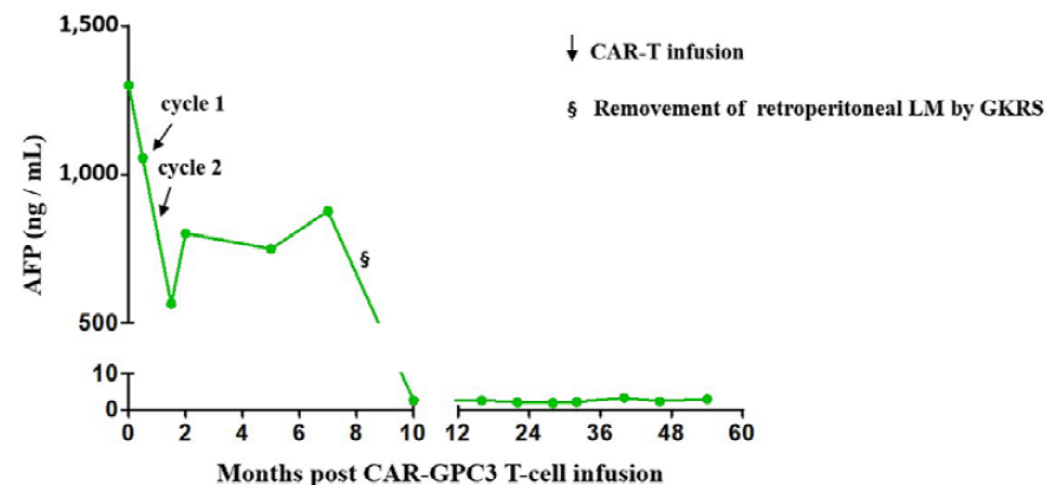
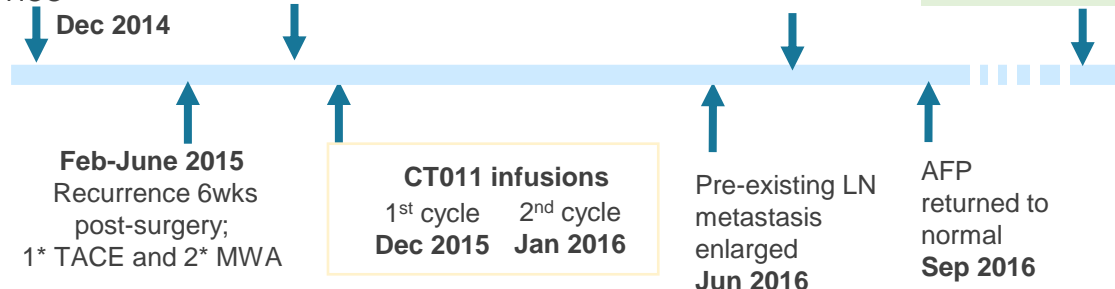
## • Case: a 54-year-old male

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

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

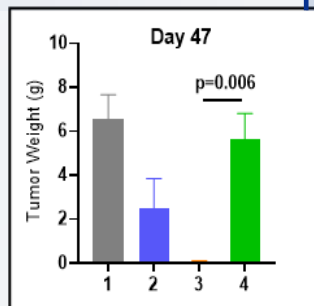
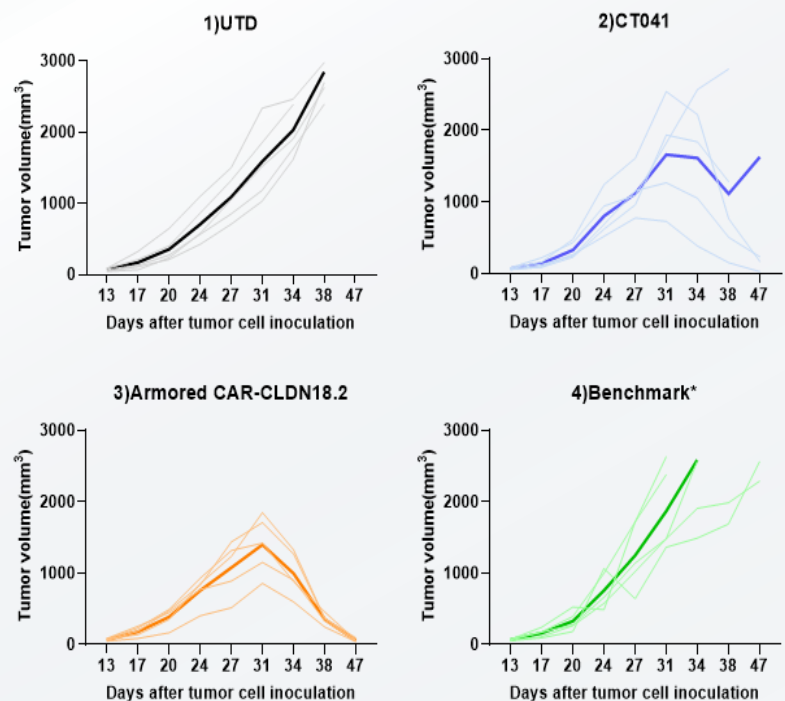
GKRS July 2016

tumor free survival (> 5 years) Nov 2021

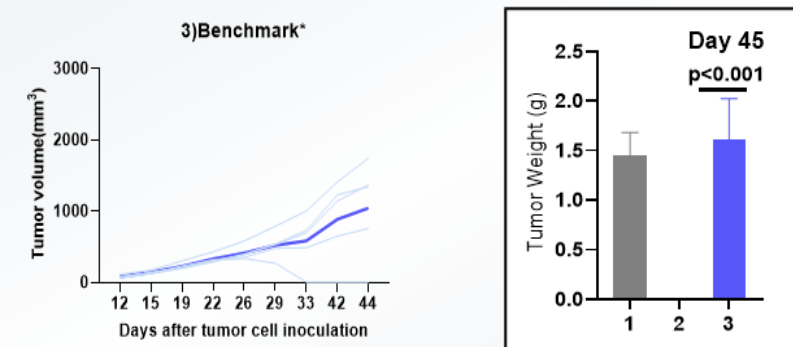
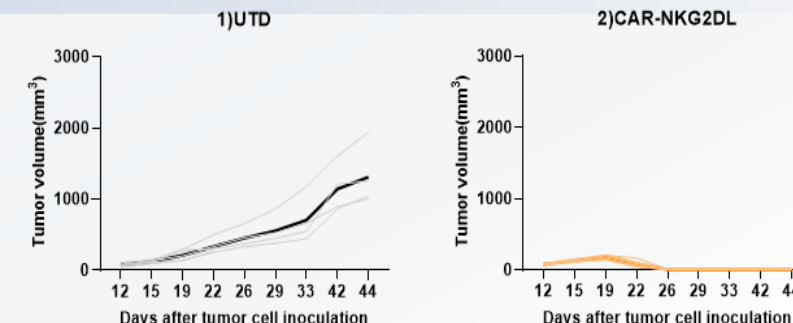


# Next-Gen CAR-T Development: Tackling Key Challenges in Solid Tumors

## 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)

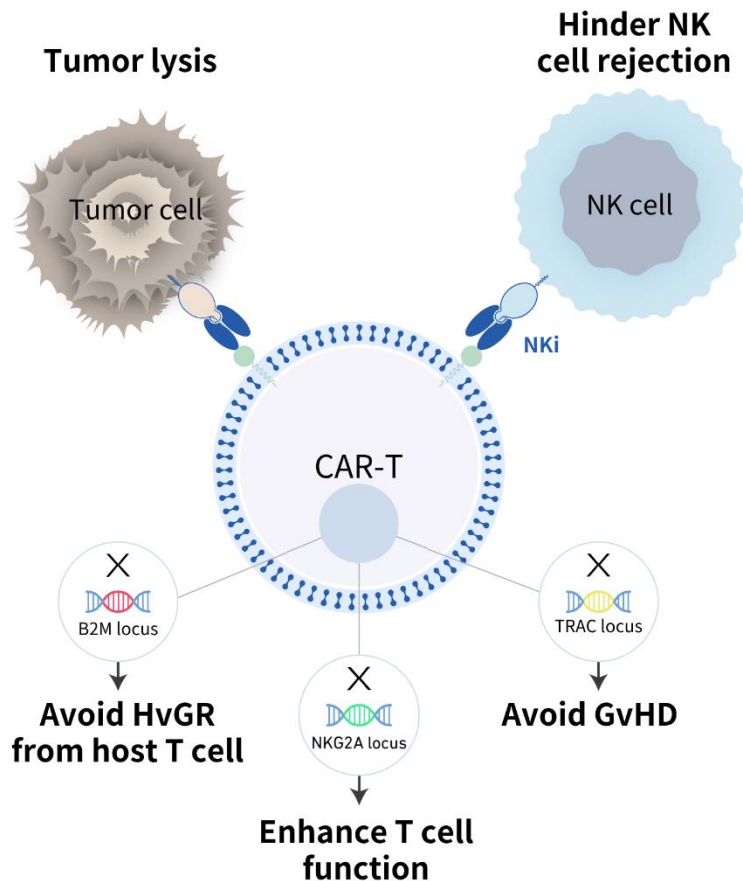
2. ciltacabtagene autoleucel [Prescribing Information]. Janssen Biotech

3. W Chen, et al. *EHA* 2024. 2024 May

# THANK-uCAR® : 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

- 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



- An open-label, single-arm, phase 1, first-in-human trial in China (NCT05066022).
- Lymphodepletion: F: Fludarabine (30mg/m<sup>2</sup>/day x 3days), C: Cyclophosphamide (500 mg/m<sup>2</sup>/day x 3 days).
- Doses: 50 × 10<sup>6</sup>, 150 × 10<sup>6</sup>, 300 × 10<sup>6</sup>, 450 × 10<sup>6</sup> 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

# 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.

Data cut-off : 22-Apr-2024

# 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/ $\mu$ 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/ $\mu$ g gDNA at Day 15.



# A Case of CT0590 to Treat R/R MM

## Baseline Characteristics

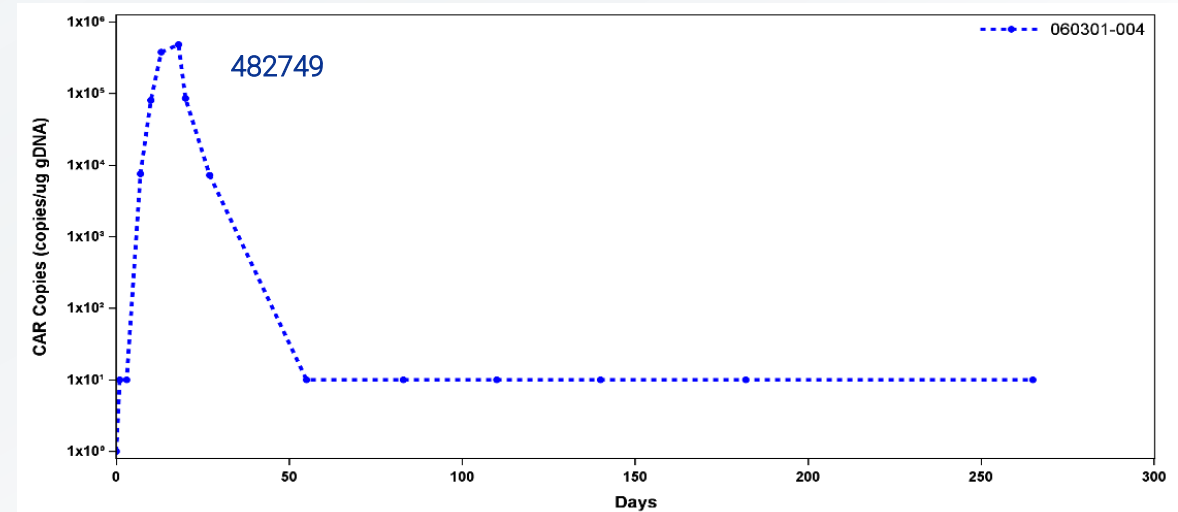
- A 71-year-old male diagnosed with MM,
- Double-refractory, with 94.5% plasma cells in bone marrow.
- 2 prior lines of therapies, including 3 regimens.
- Received  $3 \times 10^8$  CT0590 CAR-T cells infusion.

## 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  $\geq 23$  months (ongoing)



# A Case of CT0590 to Treat R/R pPCL



## Baseline Characteristics

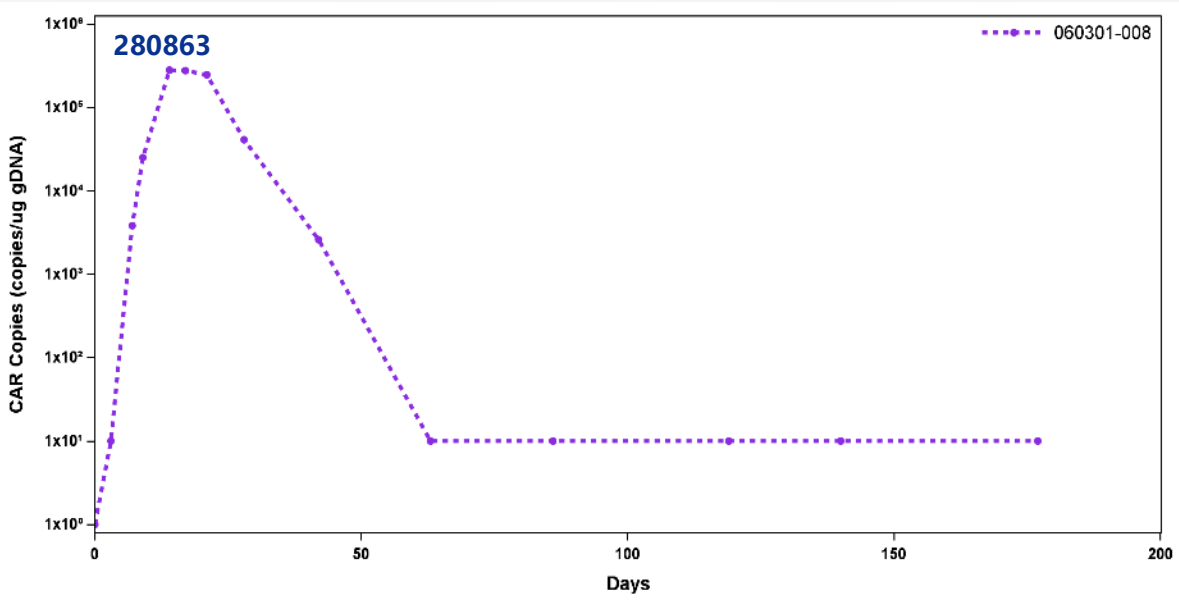
- A 52-year-old male diagnosed with pPCL
- Double-refractory
- 3 prior lines, including 3 regimens (ASCT, etc.)
- Received an infusion of  $3 \times 10^8$  CT0590 CAR-T cells.

## 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)	<a href="#">Deng J, et al. Front Oncol.</a> 2022; 12: 901266.

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

# 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 <sup>6</sup>	23	SD
PT 1-reinf (MM)	300 × 10 <sup>6</sup>		
<b>PT 2 (MM)</b>	300 × 10 <sup>6</sup>	<b>38</b>	<b>sCR</b>
PT 3 (MM)	300 × 10 <sup>6</sup>	12	SD
PT 4 (MM)	450 × 10 <sup>6</sup>	NA	PR
PT 4-reinf (MM)	450 × 10 <sup>6</sup>		PR
<b>PT 5 (pPCL)</b>	300 × 10 <sup>6</sup>	<b>46</b>	<b>sCR</b>

1. Fu C, et al. 2024 ASH. 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

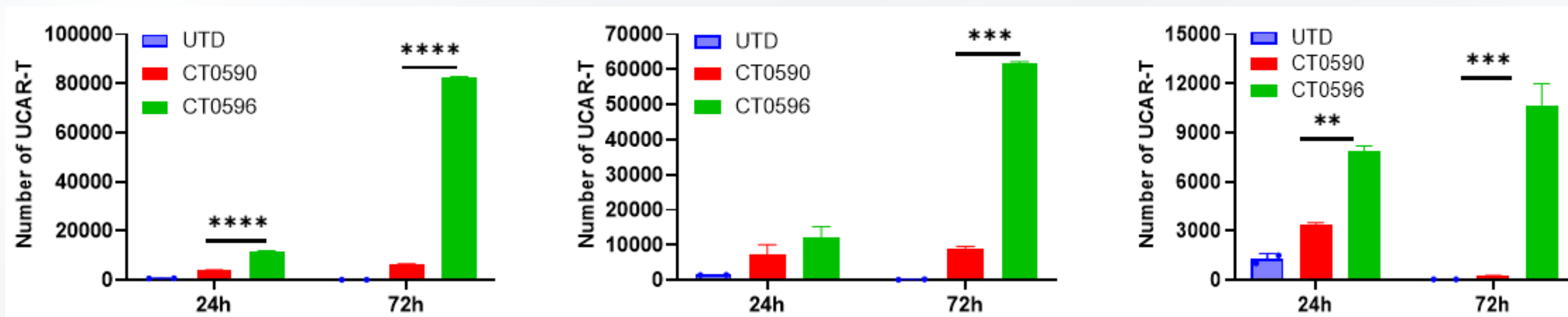
- CT0596 is under evaluation in an IIT for the treatment of R/R MM or R/R PCL:
  - ✓ As of May 6, 2025, 8 patients with R/R MM have been infused.
- Further exploration is planned in plasma cell malignancies and autoimmune diseases.
- IND submission is planned in the H2, 2025.

# 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



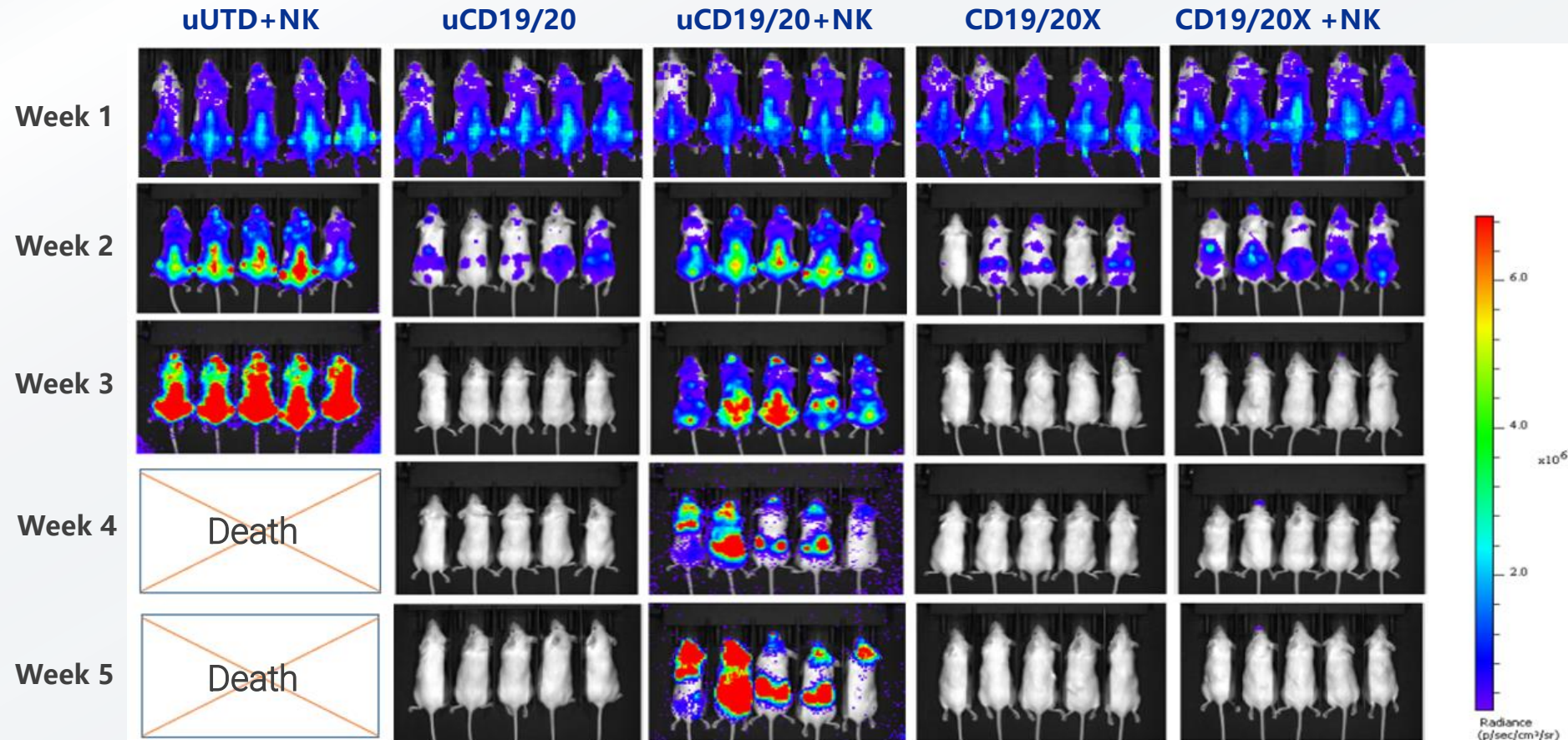
## Safety

- **CT0596 demonstrated favorable tolerability:**
  - ✓ **NO** ≥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/m<sup>2</sup> and cyclophosphamide 350-500 mg/m<sup>2</sup>**). 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 **≥92%** and **≥65%**, respectively.
  - ✓ 1 patient had not yet reached the protocol-specified efficacy assessment timepoint.
  - ✓ **CAR-T expansion was observed across all predefined dose levels.**

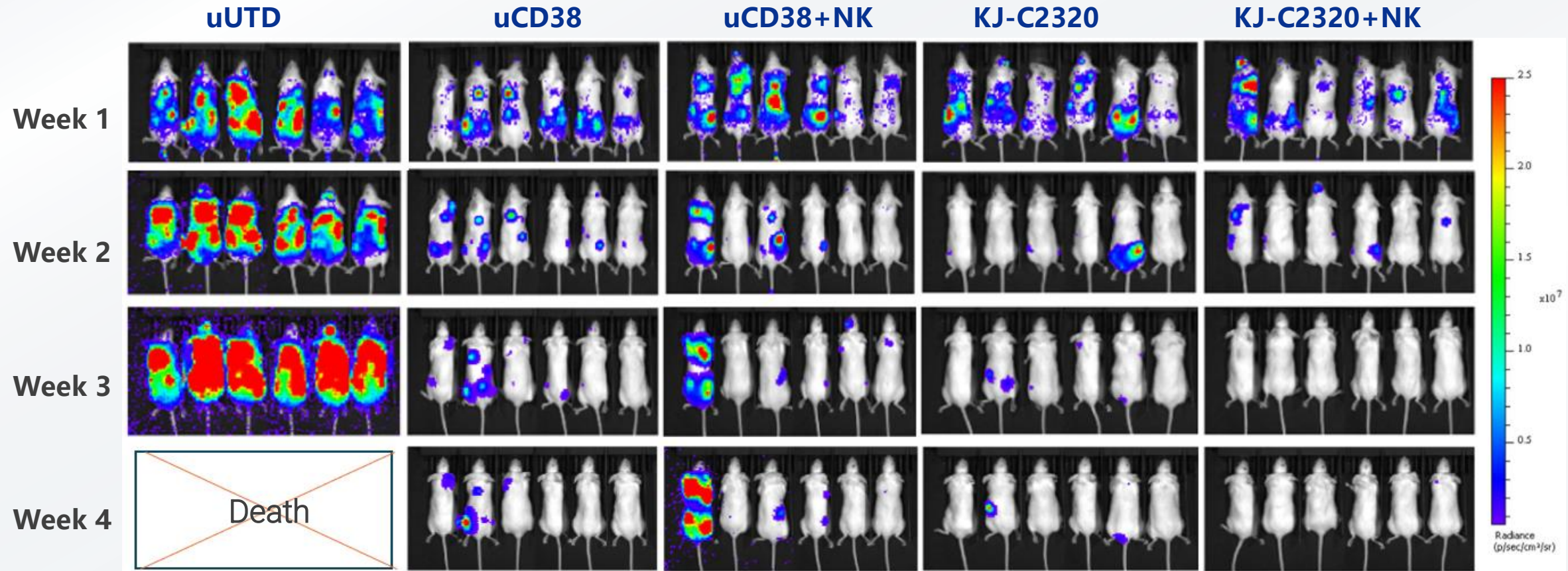
# Allogeneic CD19/20X CAR-T (THANK-u Plus™) Exhibits Robust Anti-lymphoma Activity in the Presence of NK Cells



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



- **H1 2025:** Planned NDA submission for satri-cel to the NMPA.
- **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



上海锐劲生物技术有限公司



**Hua Jiang, MD, PhD**  
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Business Development  
and Strategic Planning



Bristol Myers Squibb



# Making Cancer Curable