

# CARsgen Therapeutics (HKEX: 02171)

July 2025

Making Cancer Curable

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



# 1

Marketed product:

- zevorcabtagene autoleucel (zevor-cel, CT053)

# 1

CAR-T product at NDA stage:

- Satri-cel (targeting Claudin18.2)

# 2

CAR-T products at IND stage:

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

# 300+

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

# 4+

Core technology platforms:

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

# 10+ years

Focus on innovative CAR-T therapies since company initiation

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



CGMP Facility



Durham

Beijing Office



Beijing  
Shanghai

Headquarter (Xuhui)



GMP Facility (Jinshan)



## Shanghai

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



## Durham, North Carolina

CGMP manufacturing facility

## Partnerships



(SZ: 000963)

Exclusive commercialization of zevor-cel in mainland China



(NASDAQ: MRNA)

Evaluate satri-cel in combination with an mRNA Cancer Vaccine



(KOSDAQ: 195940)

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

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



## Allogeneic CAR-T

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

## Autologous CAR-T

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

## Enabling Technologies



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



**LADAR®**  
(precise targeting)



**Lymphodepletion**  
(FNC regimen)



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

# Competitive Product Pipeline with Global Rights



	Product Candidate <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				

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

<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 (Approved in China)



Data presented at: **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)

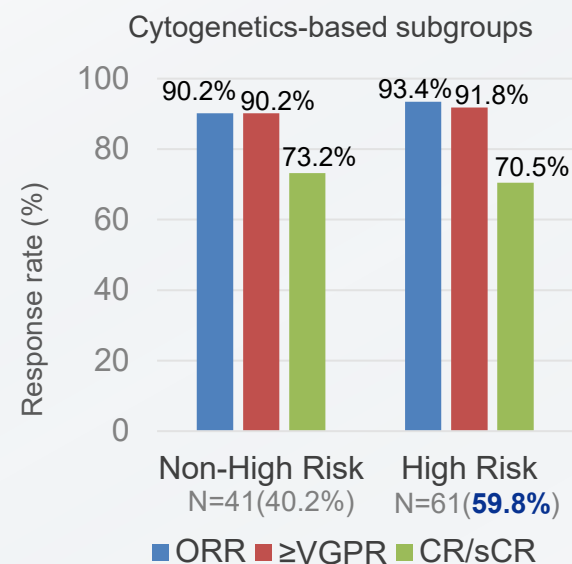
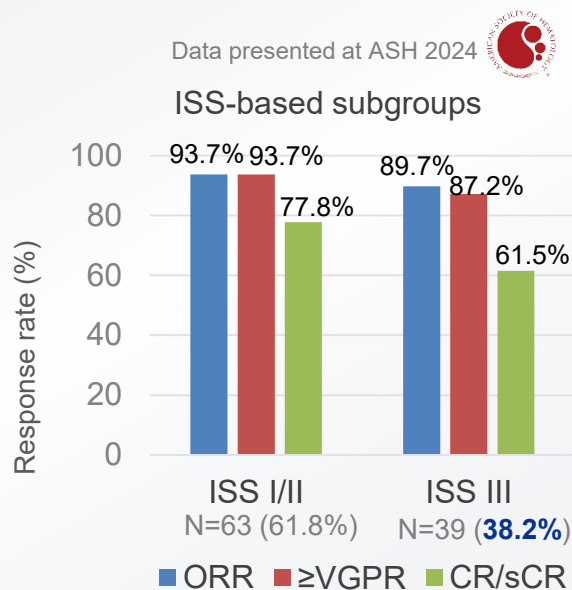
## China Pivotal Phase II (LUMMICAR-1) <sup>1</sup> N=102

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



## 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

# 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

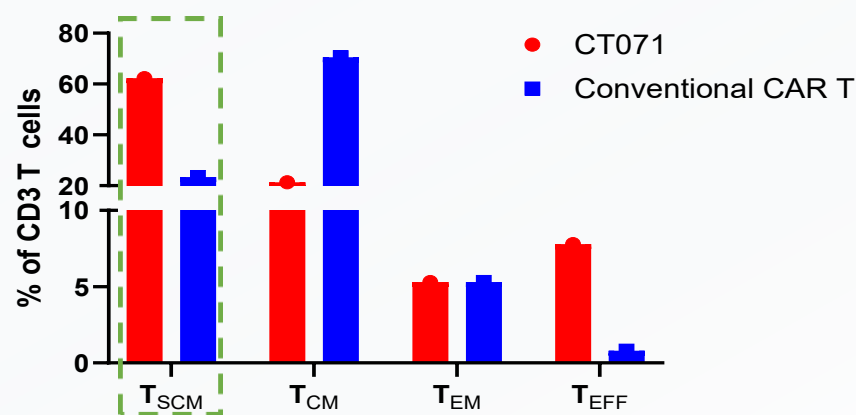
Manufacturing Time:

 **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: Baseline Characteristics in China IIT



Data presented at ASH 2024 

Patient Characteristics	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)
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.

R/R MM: Relapsed/Refractory Multiple Myeloma; IIT: Investigator-initiated Trial; R-ISS: Revised International Staging System; ECOG PS: Eastern Cooperative Oncology Group Performance Status; ASCT: Autologous Stem Cell Transplantation.

Cut-off date: Jun 21, 2024

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



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



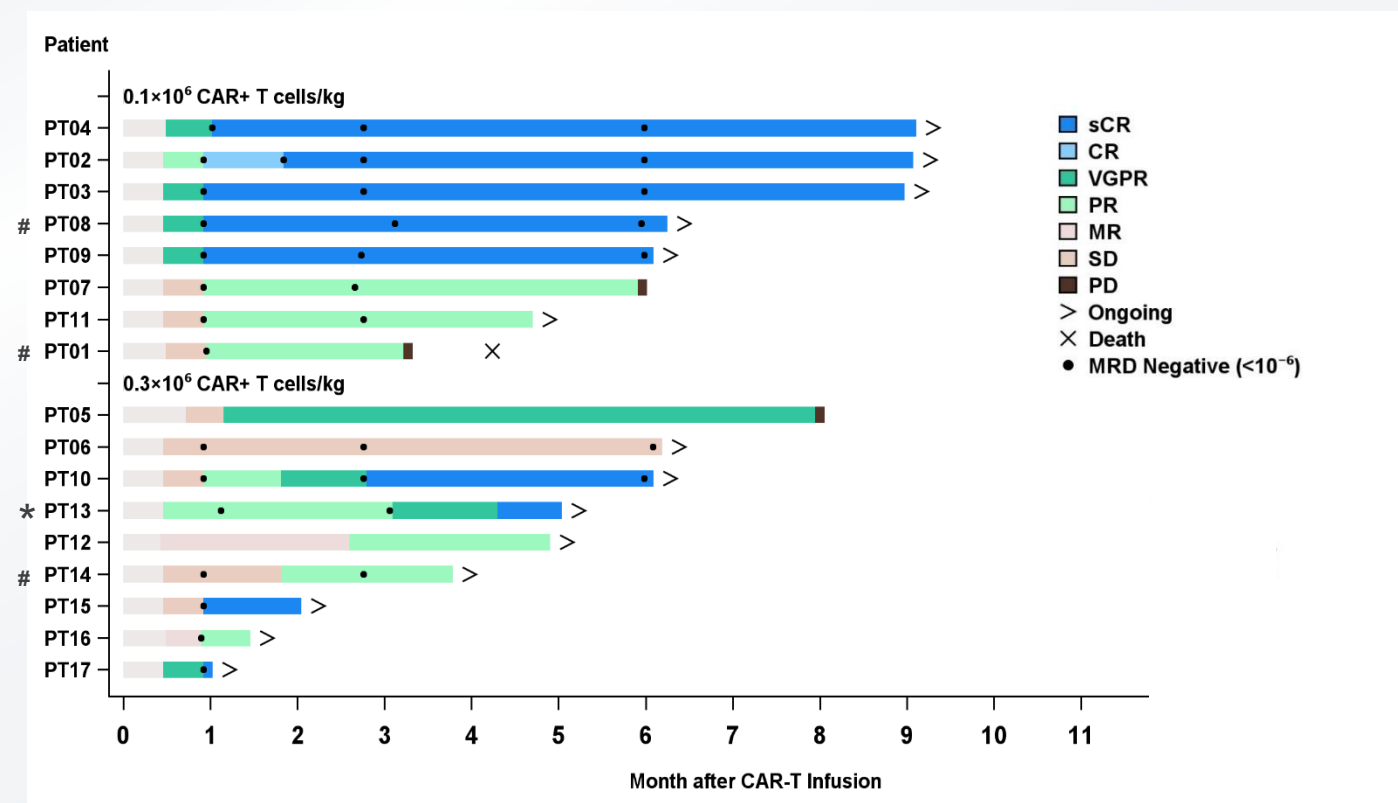
	0.1 × 10 <sup>6</sup> cells/kg (n=8)	0.3 × 10 <sup>6</sup> cells/kg (n=9)	All Patients (n=17)
ORR, No. (%)	8 (100)	8 (88.9)	16 (94.1)
CR/sCR rate, No. (%)	5 (62.5)	4 (44.4)	9 (52.9)
VGPR or better rate, No. (%)	5 (62.5)	5 (55.6)	10 (58.8)
Time to CR or better, Median (range), Month	1 (1.0, 1.1)	1.9 (1.0, 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

R/R MM: Relapsed/Refractory Multiple Myeloma; IIT: Investigator-initiated Trial; ORR: Objective Response Rate; CR: Complete Response; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; MRD: Minimal Residual Disease; BM: Bone Marrow; 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 R/R MM: Rapid and Durable Response in China IIT



Note:  
 \* Previous exposure to BCMA CAR-T.  
 # Previous exposure to BCMA/CD19 CAR-T.

- 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.

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



Data presented at: **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

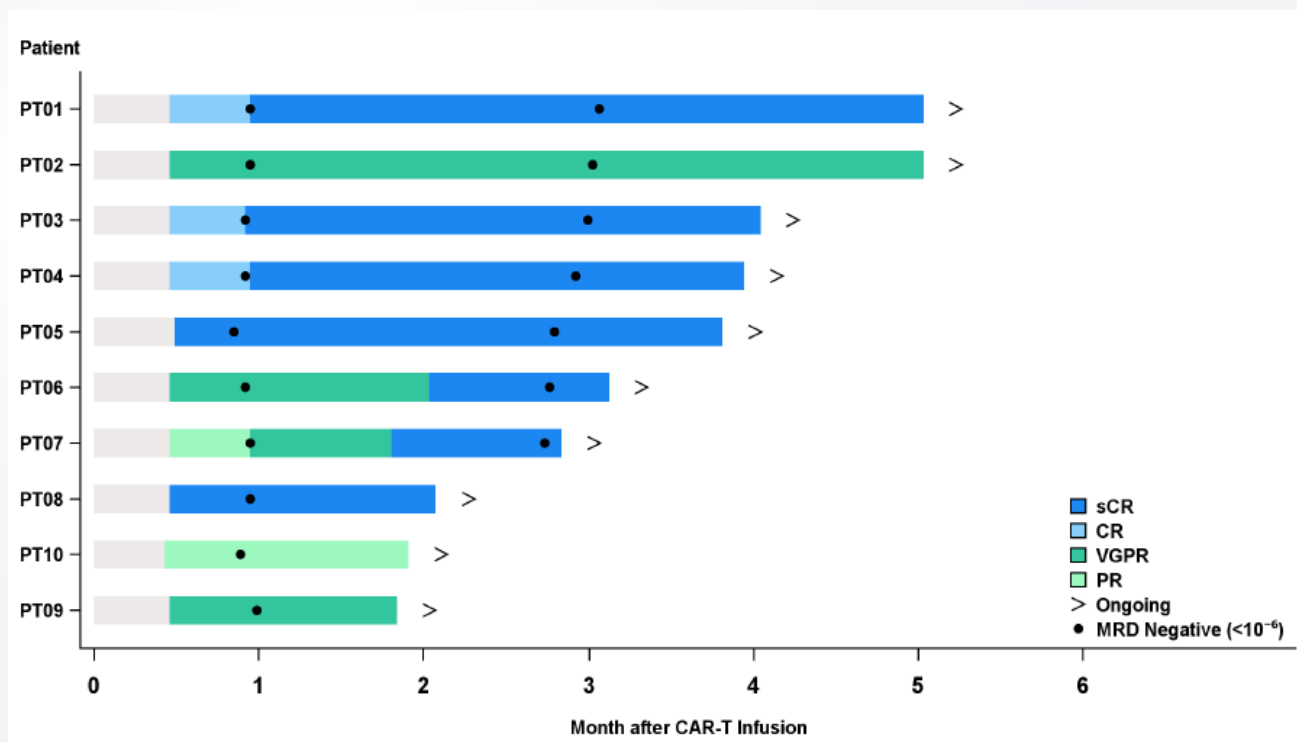
NDMM: Newly Diagnosed Multiple Myeloma; IIT: Investigator-initiated Trial; ECOG PS: Eastern Cooperative Oncology Group Performance Status; ORR: Objective Response Rate; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; PR: Partial Response; MRD: Minimal Residual Disease; CRS: Cytokine 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



# CT071 in High-risk NDMM: Deep Rapid Responses in China IIT



- As of Jan 02, 2025, the median follow-up time was 3.4 months (range 1.8 to 5.9).
- The ORR assessed by investigator was 100% (95%CI: 69.2, 100).
- Five patients achieved sCR by week 4.
- All 10 patients achieved MRD negativity at 10<sup>-6</sup> threshold.

NDMM: Newly Diagnosed Multiple Myeloma; IIT: Investigator-initiated Trial; sCR: Stringent Complete Response; CR: Complete Response; VGPR: Very Good Partial Response; PR: Partial Response; MRD: Minimal Residual Disease; ORR: Objective Response Rate

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>

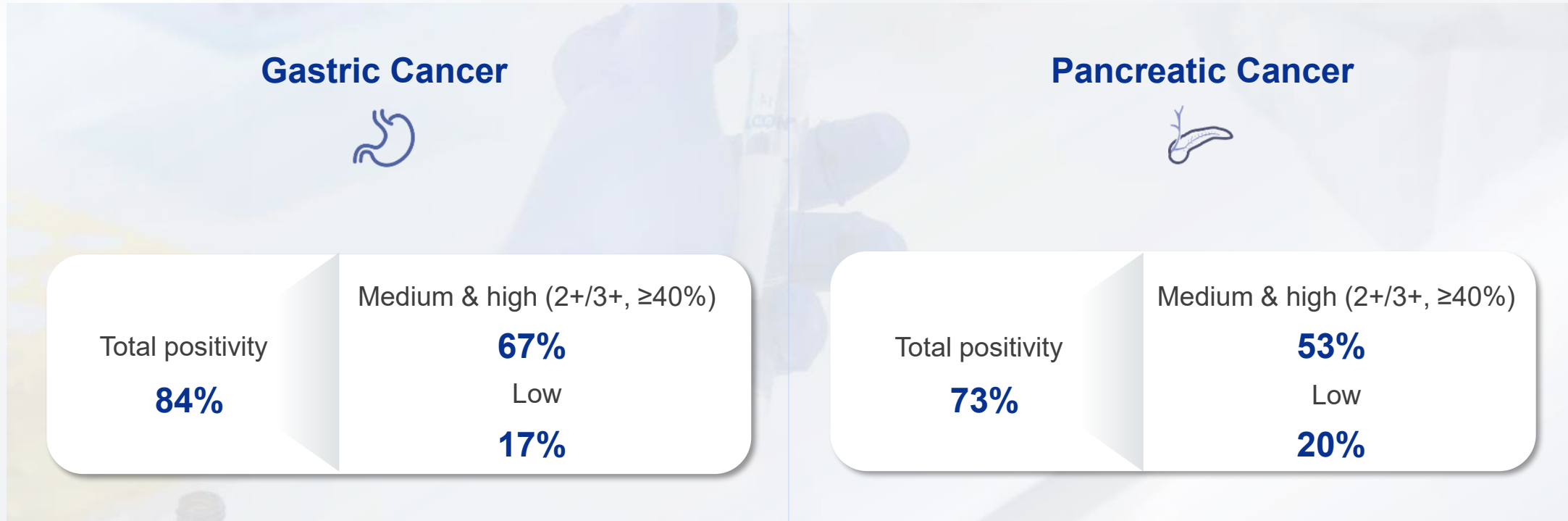
1. International Agency for Research on Cancer. Population factsheets. 2022

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

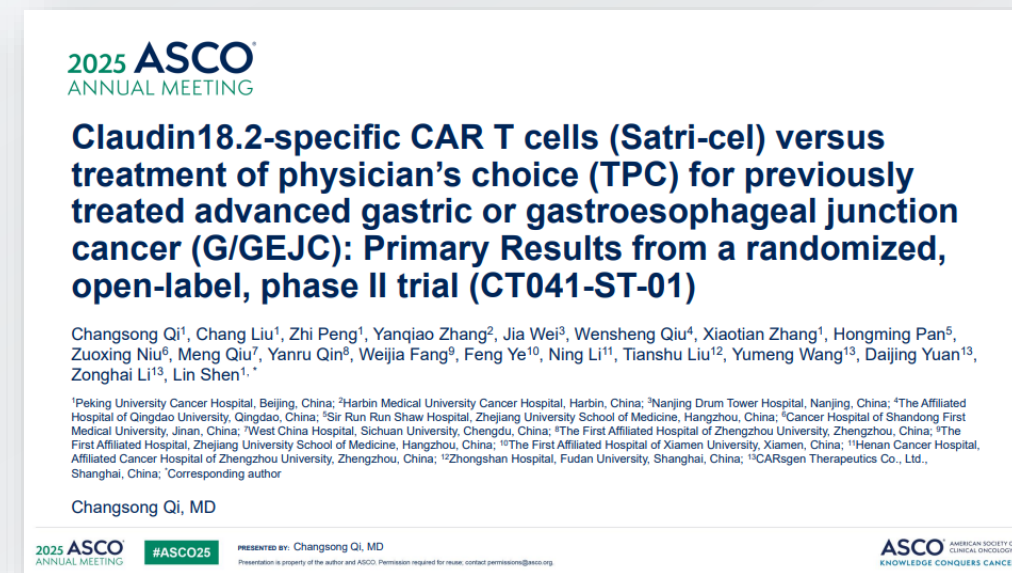
# Satri-cel (CT041): Global First-in-Class CAR-T for Claudin18.2-Positive Solid Tumors



Product 	Designations 	Clinical Development Plan 
<ul style="list-style-type: none"> <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



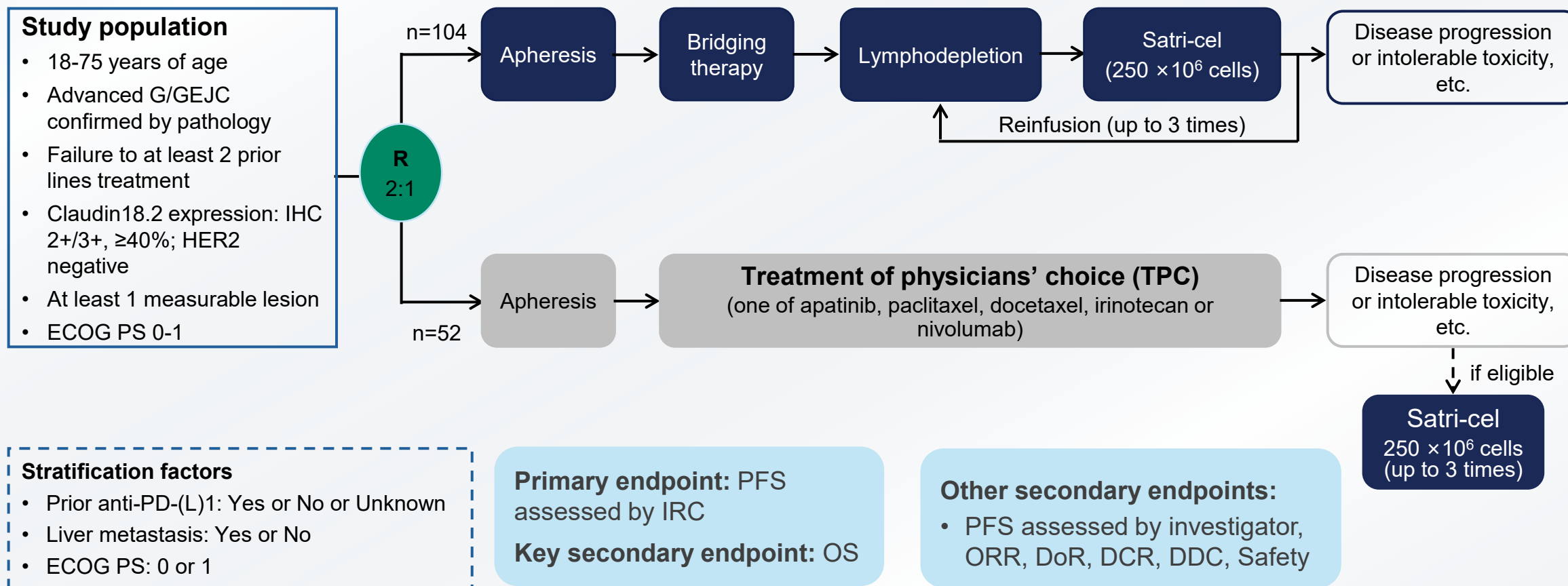
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8



# Satri-cel China Pivotal Phase II: Trial Design



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

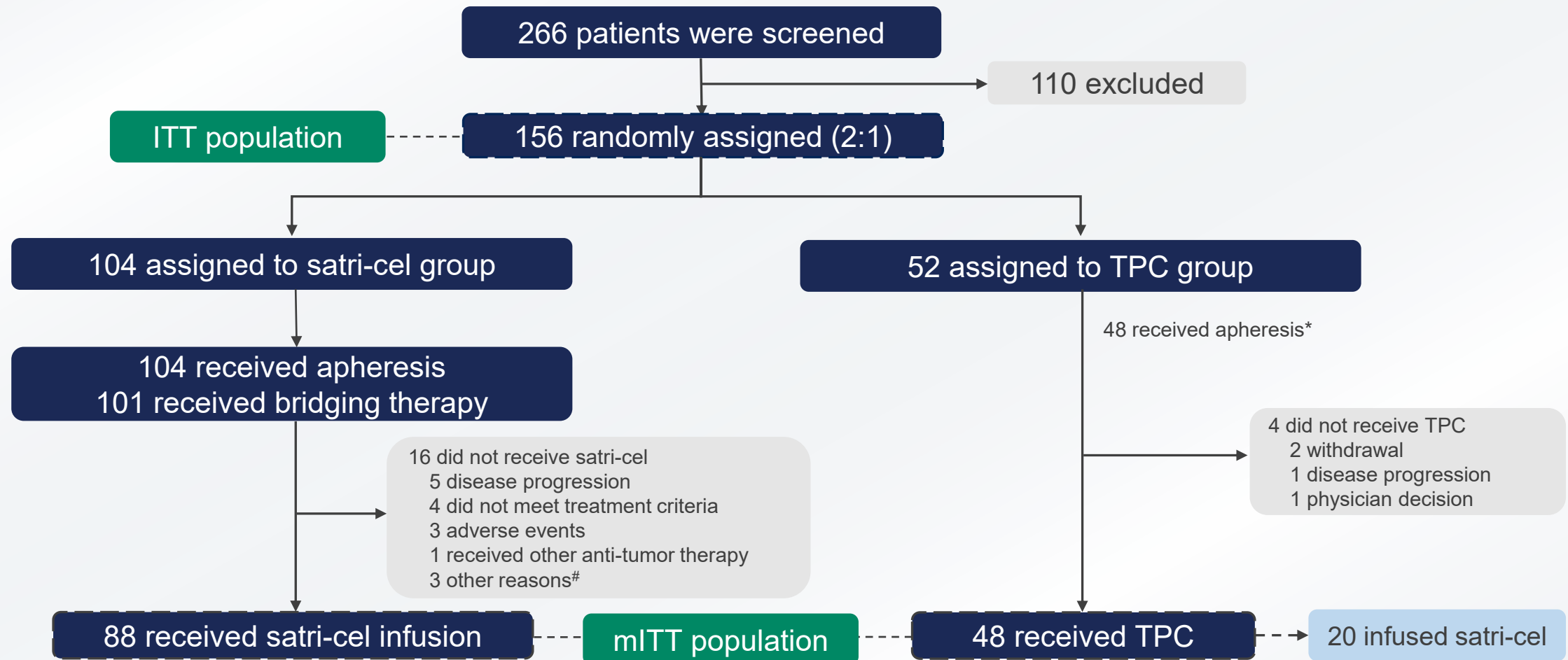


G/GEJC: Gastric or Gastroesophageal Junction Cancer; ECOG PS: Eastern Cooperative Oncology Group Performance Status; PFS: Progression-Free Survival; IRC: Independent Review Committee; OS: Overall Survival; ORR: Objective Response Rate; DoR: Duration of Response; DCR: Disease Control Rate; DDC: Duration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

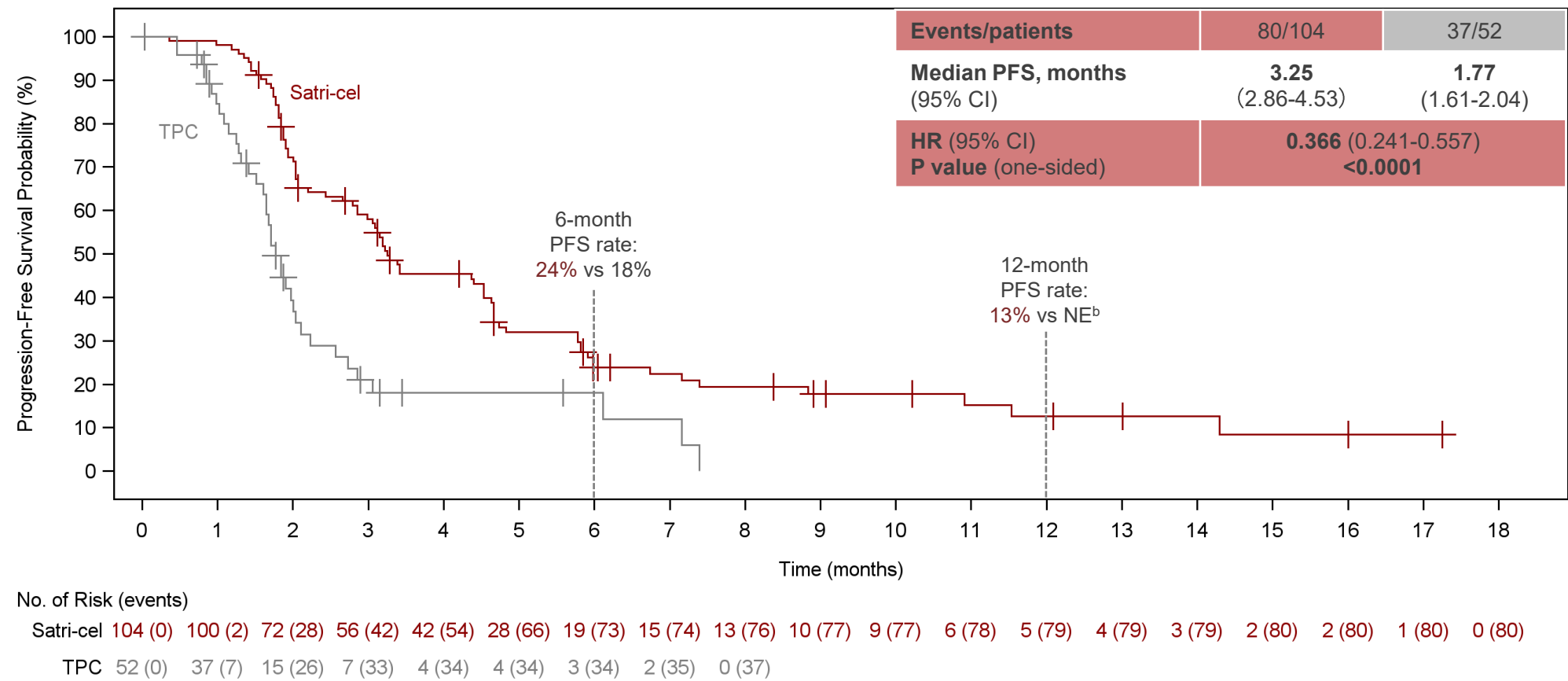
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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

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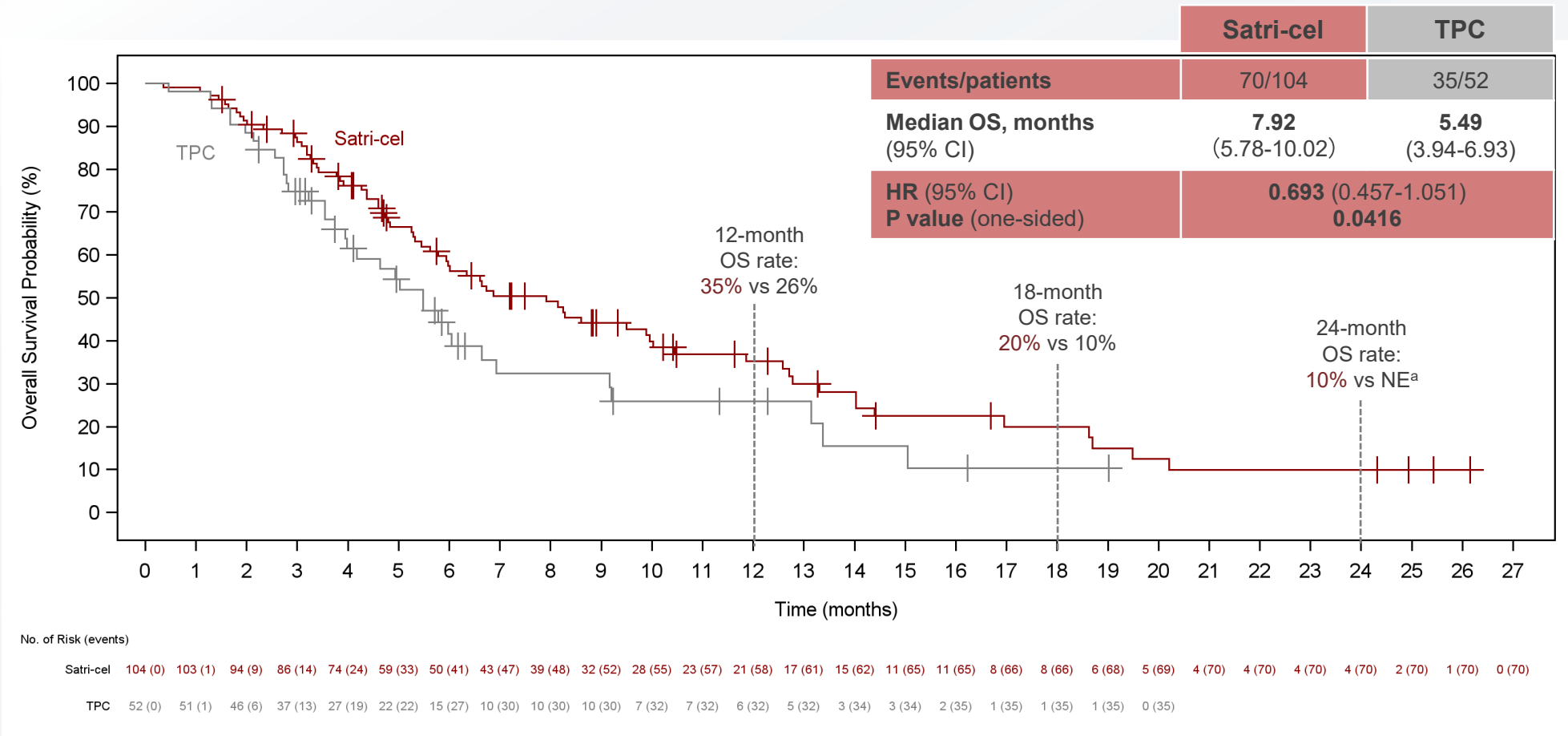
23



# 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).

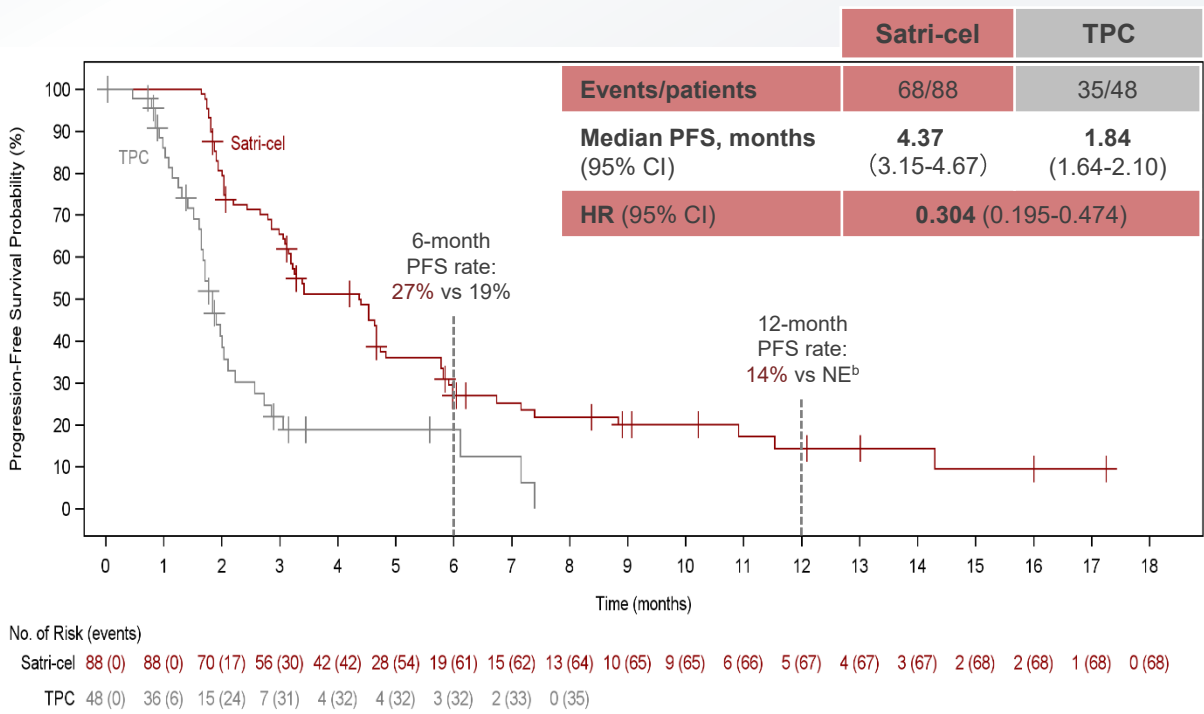
1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003  
2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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

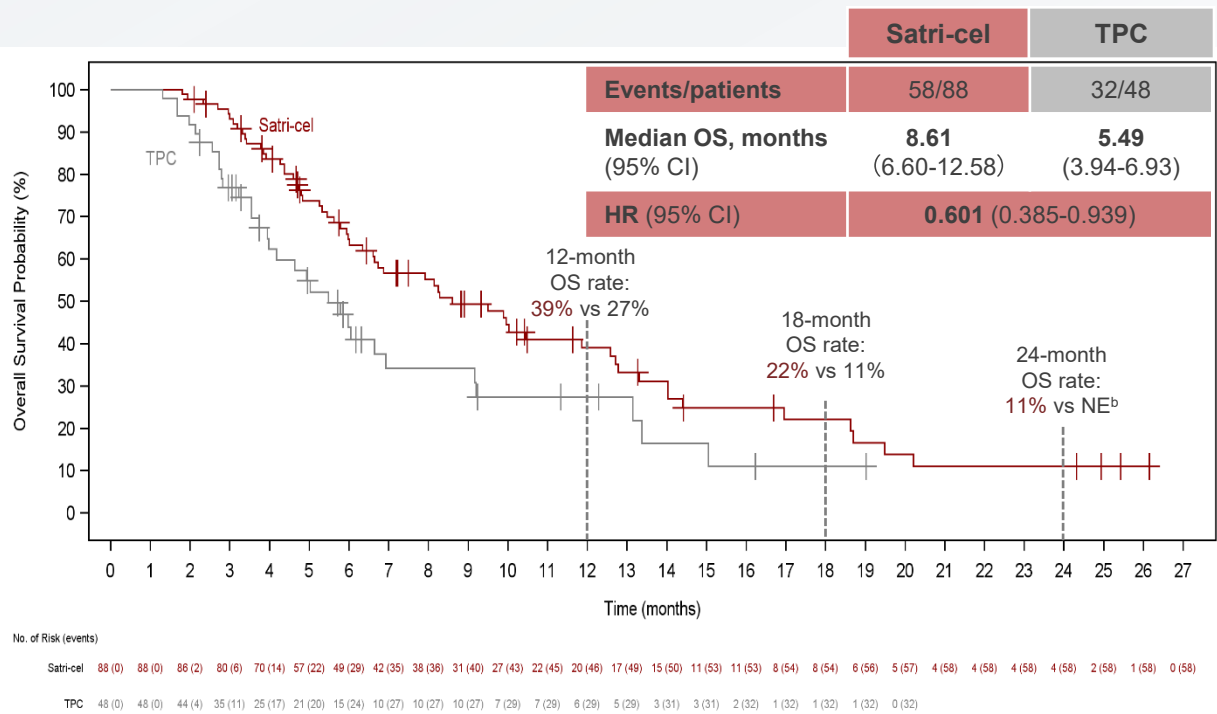


In treated population (mITT), PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

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.

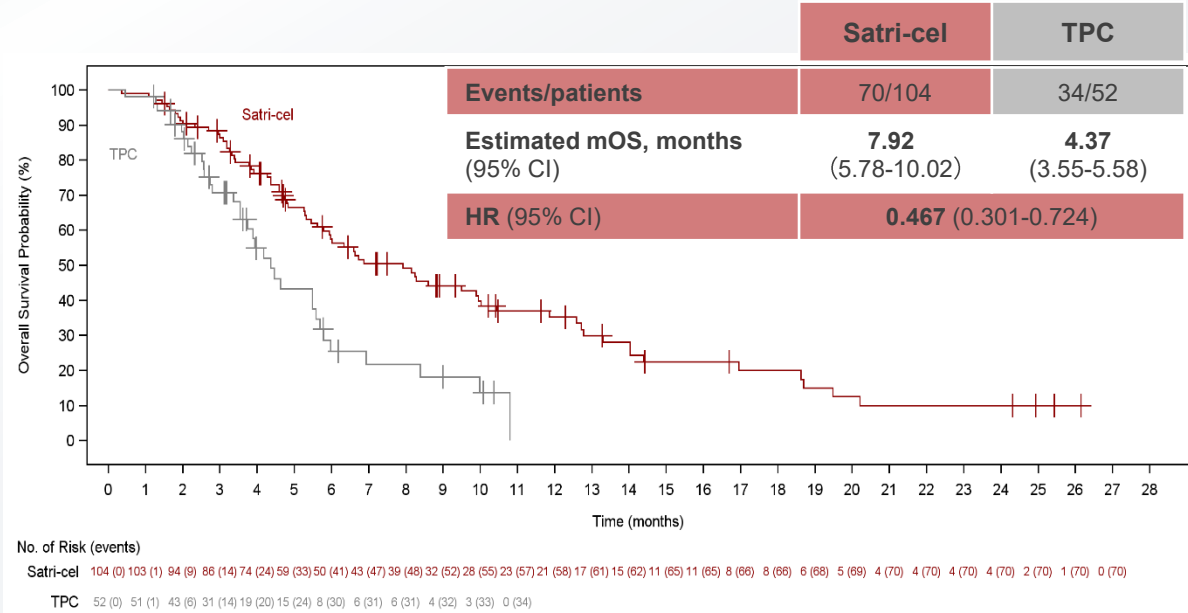
- 1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
- 2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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

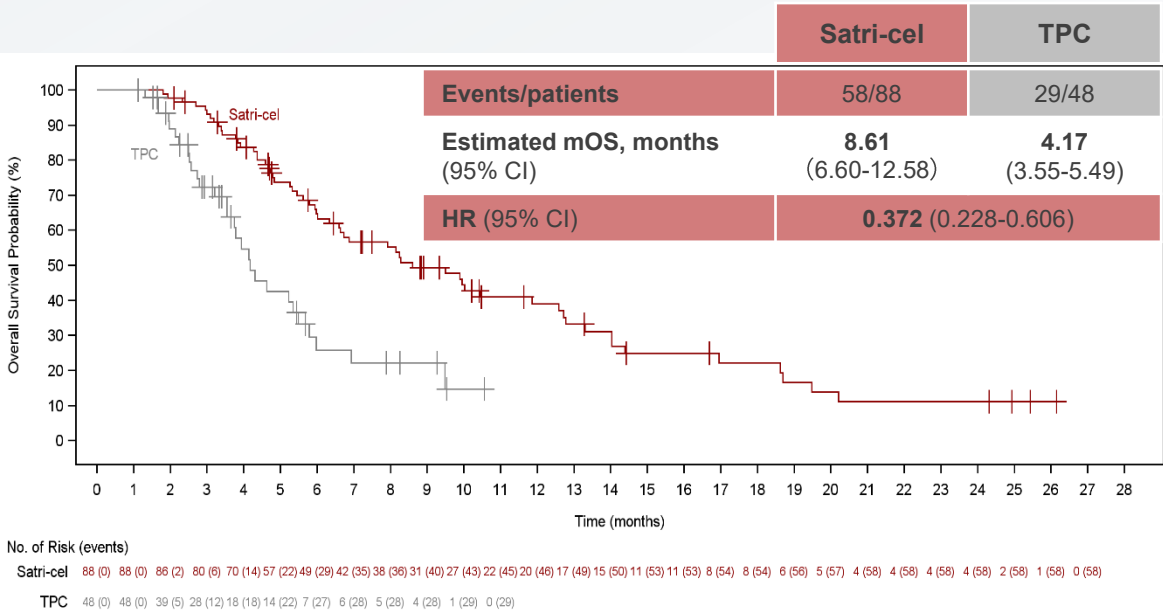


The estimated mOS was 1.81-2.06 fold longer with satri-cel vs TPC by RPSFT model, providing a 53% and 63% reduction in risk of mortality in the ITT and mITT populations, respectively.

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> Data presented at:  		Phase Ib in China (NCT04581473) <sup>3</sup> Data presented at: 	Phase 1b in the US (NCT04404595) <sup>4</sup> Data presented at: 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



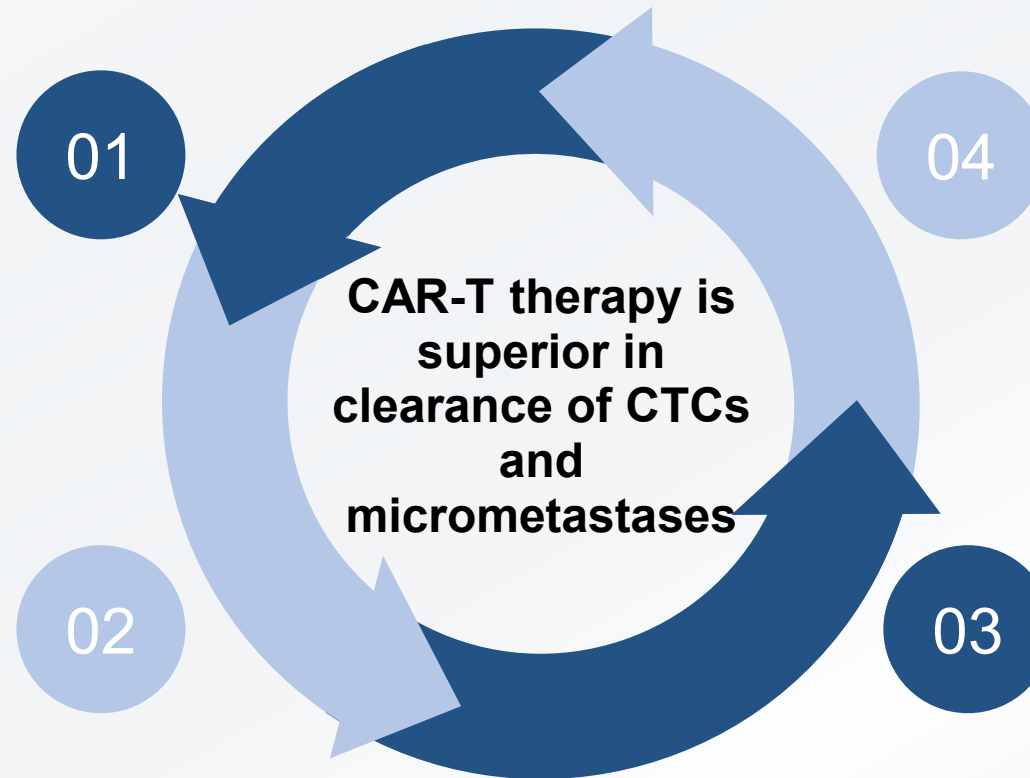
*Promising greater clinical value in earlier line / earlier disease stage and providing better chances of cure for a much broader patient population*

## 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 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



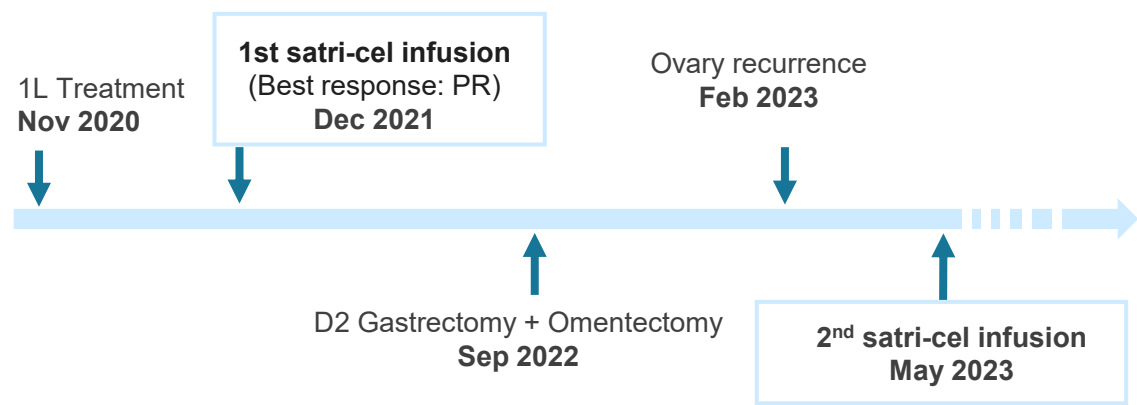
# Following Satri-cel Infusion, Two Patients Underwent Surgical Resection, and Remain in Long-term Survival at the Latest Follow-up



## Case 1

### 1L Treatment

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

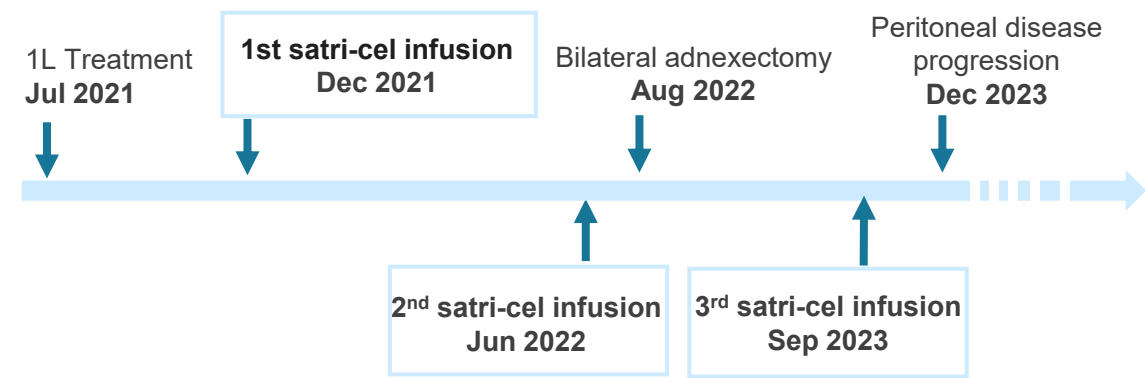


**OS: 36.0+ months (last FU: Dec 2024)**

## Case 2

### 1L Treatment

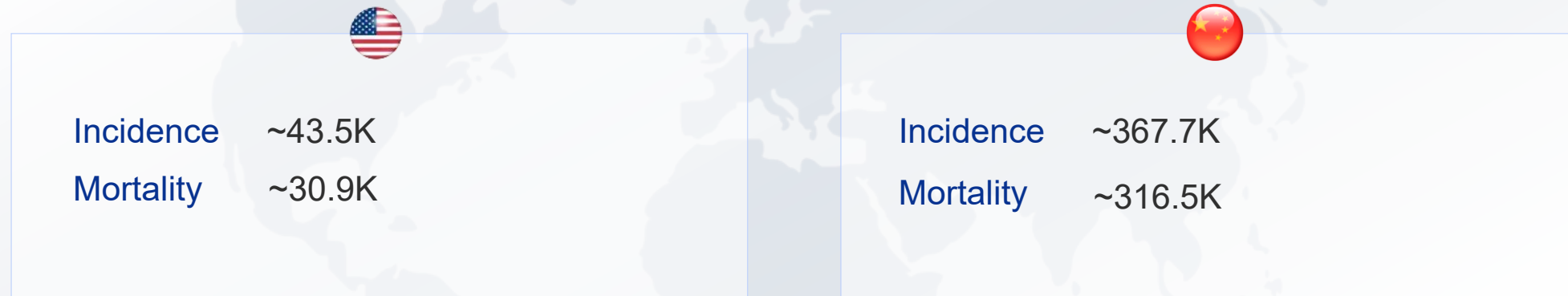
- **Regimen:** SOX regimen (4 cycles)
- **BOR :** PR



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

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

## 2022 Liver Cancer Epidemiology in the US and 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

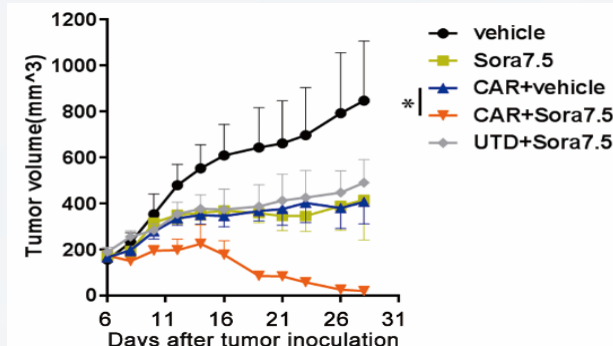
# GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*



> 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

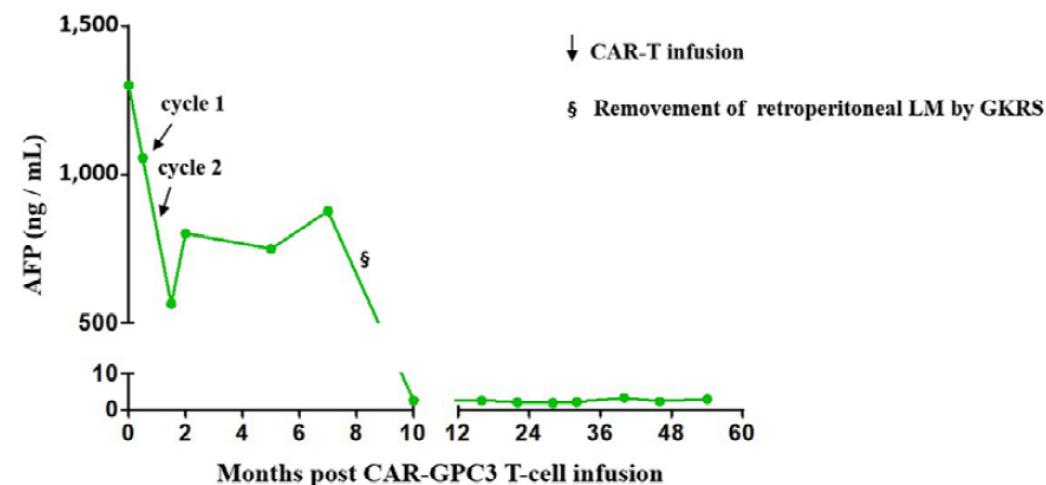
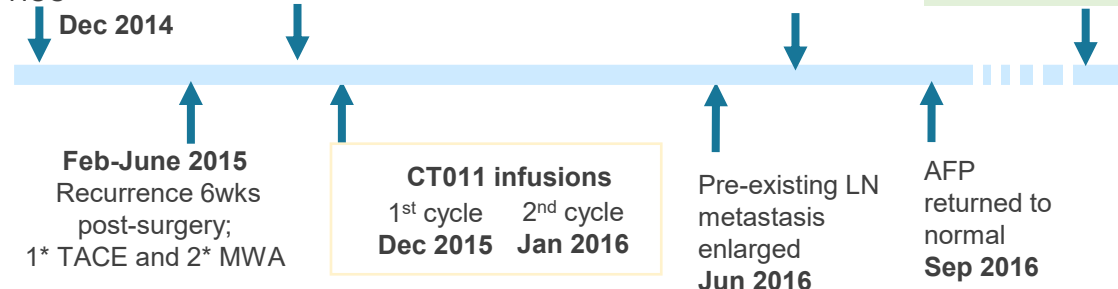
## • Case: a 54-year-old male

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

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

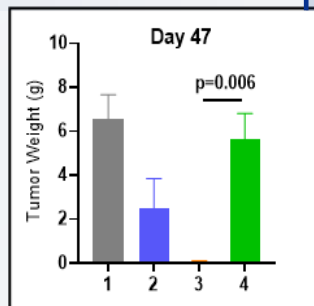
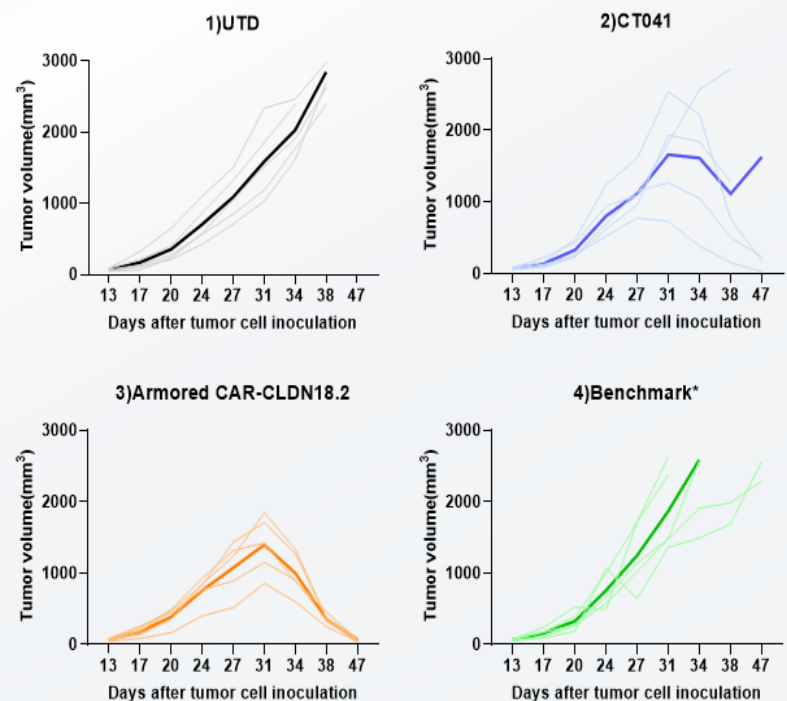
GKRS July 2016

tumor free survival (> 5 years) Nov 2021

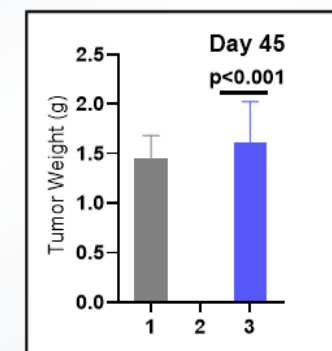
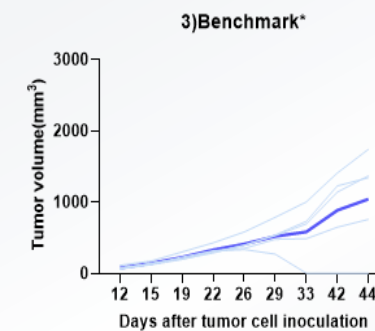
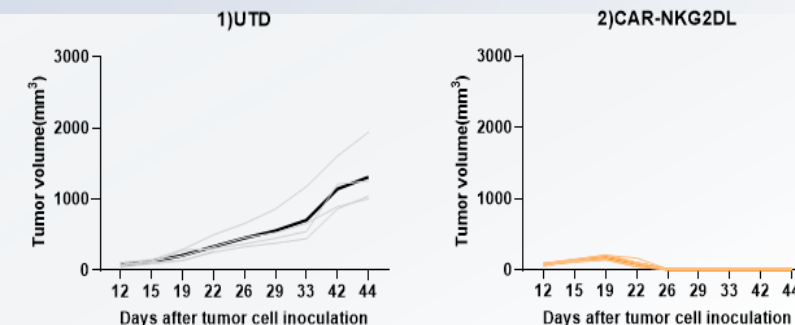


# Next-Gen CAR-T Development: Tackling Key Challenges in Solid Tumors

## 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.

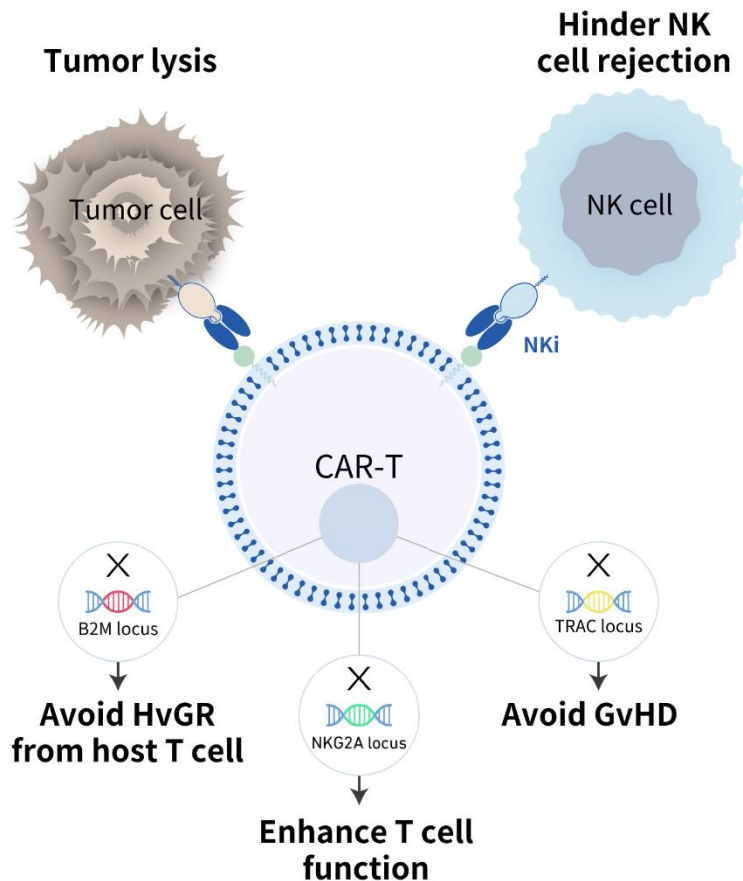
1. Mailankody S, et al. *Nat Med* 29, 422–429 (2023)  
2. cilta-cel autoleucl [Prescribing Information]. Janssen Biotech  
3. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209



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



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



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

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


## THANK-uCAR® to better address HvGR

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

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



- 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.

Data presented at ASH 2024 

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

Cut-off date: Apr 22, 2024

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

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

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

# CT0590: Manageable Safety Profile, Deep and Durable Responses



## Safety

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

## Efficacy

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

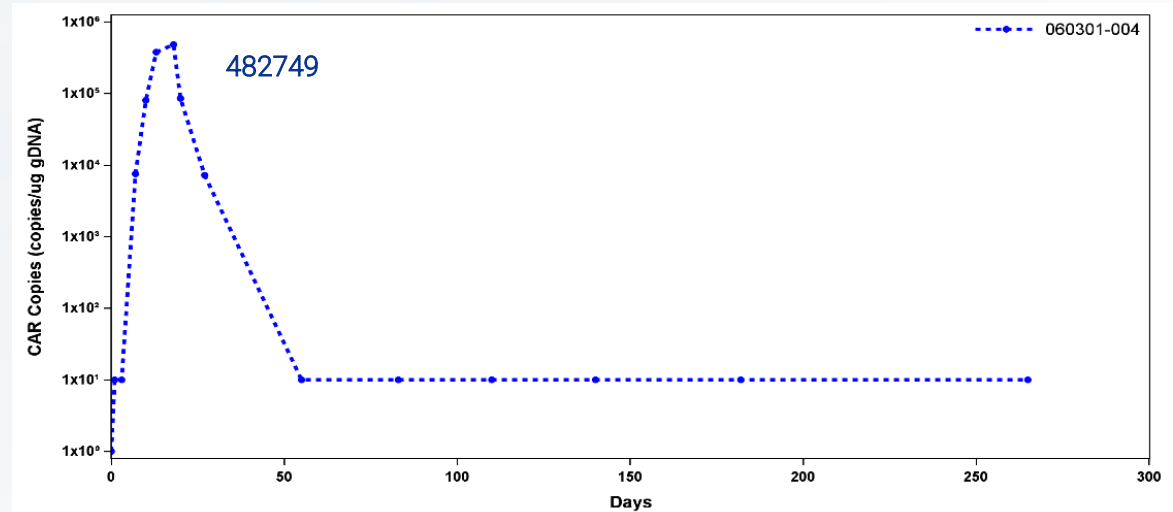
- A 71-year-old male diagnosed with MM,
- Double-refractory, with 94.5% plasma cells in bone marrow.
- 2 prior lines of therapies, including 3 regimens.
- Received  $3 \times 10^8$  CT0590 CAR-T cells infusion.

## 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)



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

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

# A Case of CT0590 to Treat R/R pPCL



## Baseline Characteristics

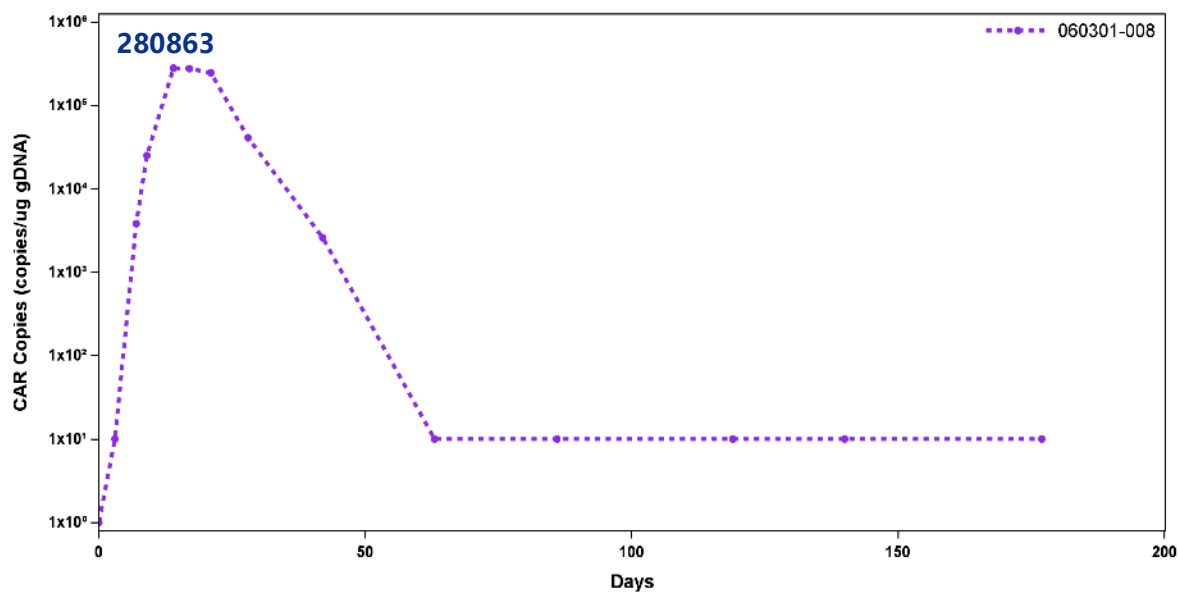
- A 52-year-old male diagnosed with pPCL
- Double-refractory
- 3 prior lines, including 3 regimens (ASCT, etc.)
- Received an infusion of  $3 \times 10^8$  CT0590 CAR-T cells.

## 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. 2022; 12: 901266.</a>

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

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



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



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

Patient (Diagnosis)	Dose (cells)	% Baseline NKG2A expression NK cells	Best overall response
PT 1 (MM)	50 × 10 <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>

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



## THANK-u Plus™ Platform

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

## CT0596

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

## Clinical Development

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

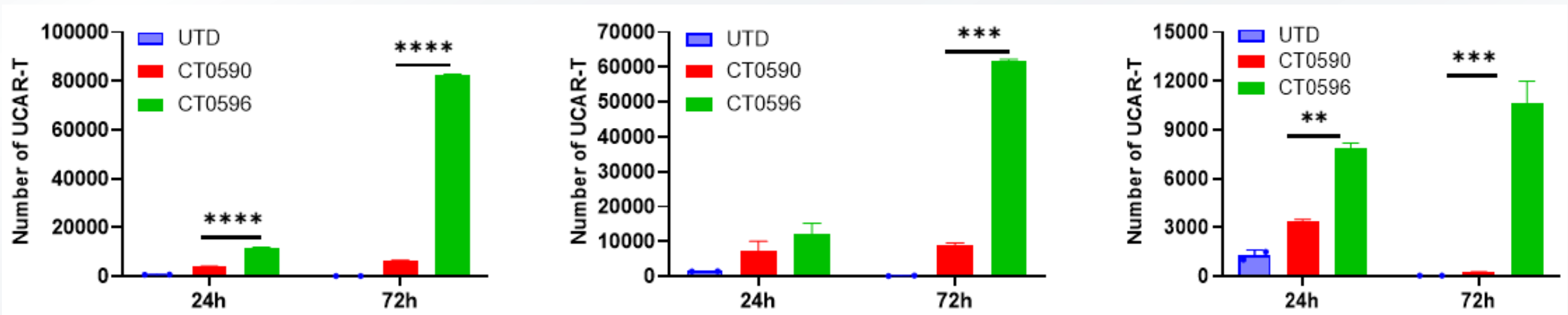
# CT0596: Enhanced and Sustained Allogeneic CAR-T Expansion Across Different NKG2A Expression Levels



NKG2A expression: High

Medium

Low



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

# CT0596 IIT Preliminary Data: Favorable Safety and Efficacy



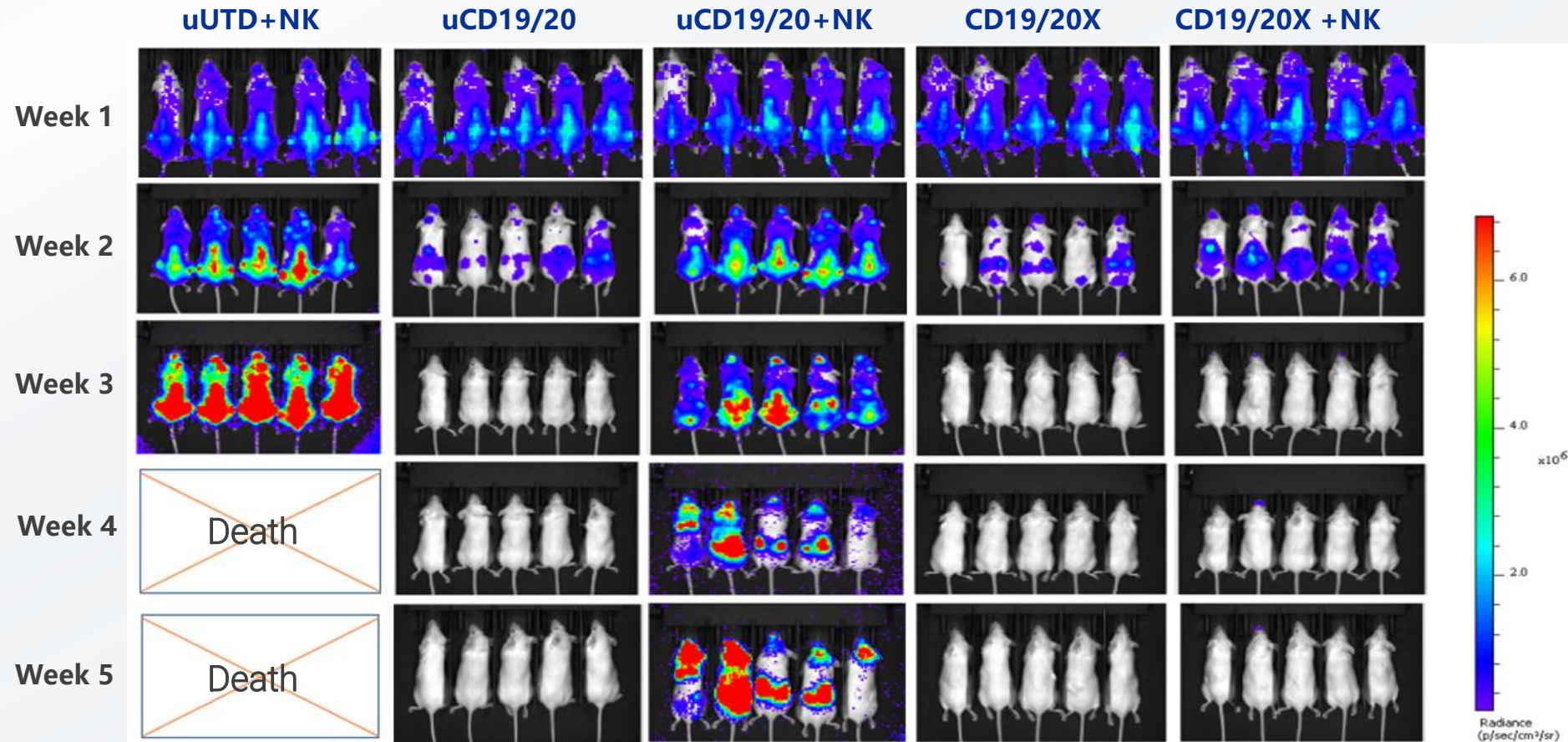
## Safety

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

## Efficacy

- As of May 6, 2025, 8 R/R MM patients (3L+) received infusion (Lymphodepletion: **fludarabine 22.5-30 mg/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  **$\geq 92\%$**  and  **$\geq 65\%$** , respectively.
  - ✓ 1 patient had not yet reached the protocol-specified efficacy assessment timepoint.
  - ✓ **CAR-T expansion was observed across all predefined dose levels.**

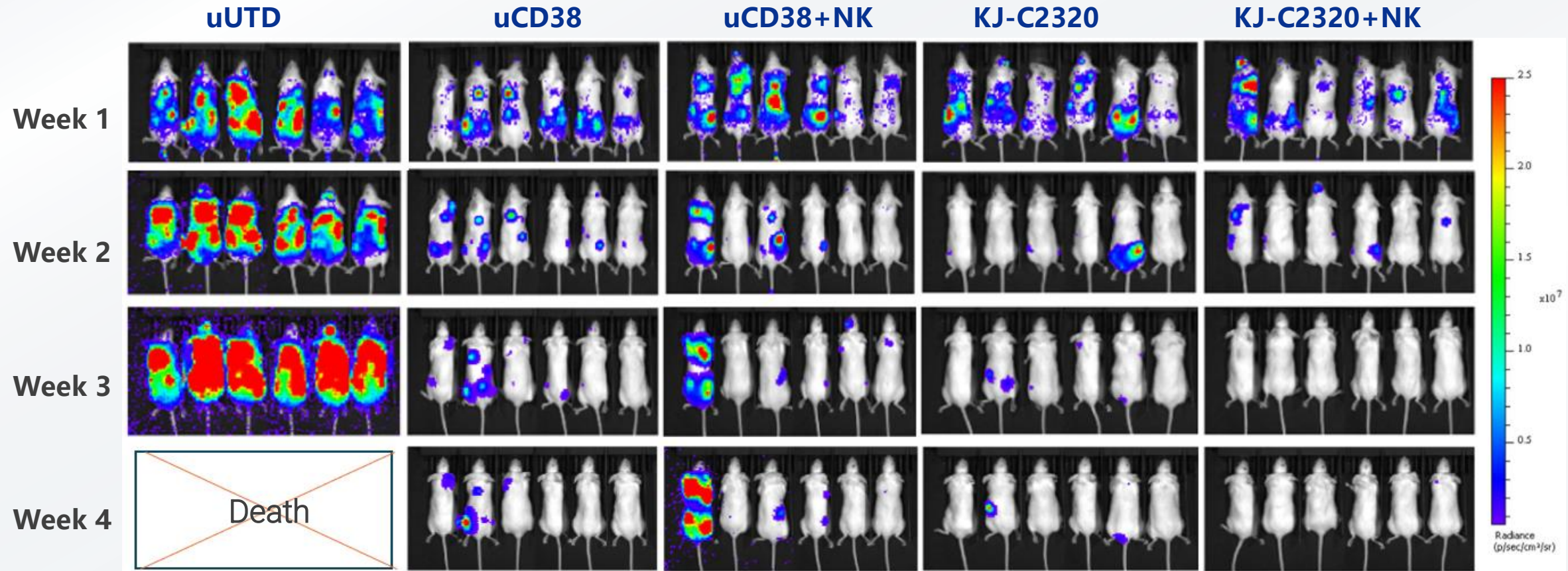
# Allogeneic CD19/20X CAR-T (THANK-u Plus™) Exhibits Robust Anti-lymphoma Activity in the Presence of NK Cells



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



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



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

# Summary of CARsgen's Allogeneic CAR-T Platform



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

# Multiple Value Inflection Milestones in the Near Future



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



# Experienced Senior Management Team



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



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



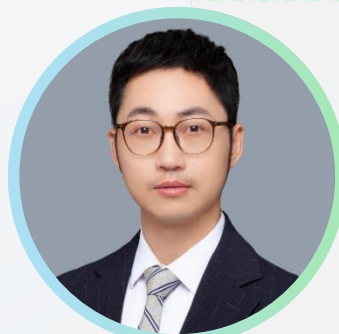
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Business Development  
and Strategic Planning



Bristol Myers Squibb



# Making Cancer Curable