

CARsgen Therapeutics (HKEX: 02171)

June 2025

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



Marketed product:

zevorcabtagene autoleucel (zevor-cel, CT053)

CAR-T product reaches NDA stage:

Satri-cel (targeting Claudin18.2)

CAR-T products at IND stage:

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

300

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



Core technology platforms:

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



Focus on innovative CAR-T therapies since company initiation

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





Partnerships





(SZ: 000963)

Exclusive commercialization of zevor-cel in mainland China



moderna

(NASDAQ: MRNA)

Evaluate satri-cel in combination with an mRNA Cancer Vaccine



inno.N

(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



LADAR® (precise targeting)

Lymphodepletion (FNC regimen)

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

Competitive Product Pipeline with Global Rights



	Product Candidate ¹	Target	Indication	Pre-clinical	Phase I	Phase II/III ²	BLA/ NDA
	Zevor-cel (CT053) ³	ВСМА	R/R MM R/R MM	LUMMICAR 1 (China) LUMMICAR 2 (US, Canada)			launched
Autologous CAR-T	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) IIT (China)			
Au	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	ВСМА	R/R MM, R/R PCL	IIT (China)			
0	СТ0596	ВСМА	R/R MM, R/R PCL	IIT (China)			
eneic R-T	KJ-C2219	CD19/CD20	B-cell malignancies SLE, SSc	IIT (China) IIT (China)			
Allogeneic CAR-T	KJ-C2320	CD38	AML	IIT (China)			
	KJ-C2114	Undisclosed	Solid tumors				
	KJ-C2526	NKG2DL	AML, other malignancies, senescence				

¹ All product candidates are self-developed with global rights

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

for solid tumors for autoimmune diseases

for hematologic malignancies

² Phase II trials of some indications are pivotal studies

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



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) ¹ N=102		
Follow-up, median (range), Month	20.3 (0.4-27)	
ISS stage III, No. (%)	39 (38.2%)	
High risk Cytogenetic, No. (%)	61 (59.8%)	
EMD+ , No. (%)	11 (10.8%)	
Prior lines of therapies, median (range)	4 (3-15)	
Double-class refractory*, No. (%)	91 (89.2%)	
Triple-class refractory**, No. (%)	23 (22.5%)	
ORR, No. (%)	94 (92.2%)	
CR/sCR, No. (%)	73 (71.6%)	
≥VGPR, No. (%)	93 (91.2%)	
mDoR, Month	Not mature	
mPFS, Month	Not mature	
MRD Negativity***, No. (%)	73 (100%)	
≥Grade 3 CRS, No. (%)	7 (6.9%)	
≥Grade 3 NT, No. (%)	0	
Treatment related death, No.	1	

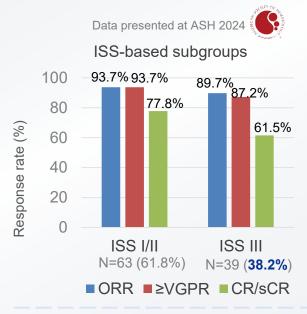
^{*}Double-class refractory: Refractory to a proteasome inhibitor and immunomodulatory drug; **Triple-class refractory: Refractory to a proteasome inhibitor, immunomodulatory drug and anti-CD38 antibody; ***In the patients achieved CR/sCR

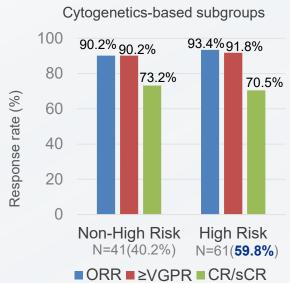
1. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209

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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

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

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

Higher safety, lower incidence of SAE

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

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

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CT071: Differentiated GPRC5D CAR-T with CARcelerate® Platform



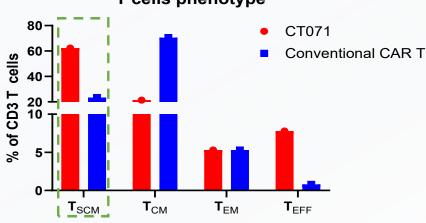
Product



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

Manufacturing Time:





Younger, healthier, possibly more potent CAR-T

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

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CT071 in R/R MM: Baseline Characteristics in China IIT





Patient Characteristics	0.1×10 ⁶ cells/kg (n=8)	0.3×10 ⁶ cells/kg (n=9)	All Patients (n=17)
R-ISS Stage, No. (%)			
II	4 (50.0)	8 (88.9)	12 (70.6)
III	4 (50.0)	0	4 (23.5)
ECOG PS, No. (%)			
1	4 (50.0)	5 (55.6)	9 (52.9)
2	1 (12.5)	0	1 (5.9)
Extramedullary Disease a, 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 b, No. (%)	7 (87.5)	9 (100)	16 (94.1)
Triple-class Refractory ^c , 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

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



	0.1×10 ⁶ cells/kg (n=8)	0.3×10 ⁶ 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 ⁻⁶) in BM, No. (%)	8 (100)	7 (77.8)	15 (88.2)
MRD Negativity (<10 ⁻⁶) with CR/sCR subjects*, No. (%)	5 (100)	4 (100)	9 (100)
CRS, No. (%)	6 (75.0)	5 (55.6)	11 (64.7)
Grade 1, No. (%)	5 (62.5)	3 (33.3)	8 (47.1)
Grade 2, No. (%)	1 (12.5)	2 (22.2)	3 (17.6)
ICANS, No. (%)	0	0	0
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

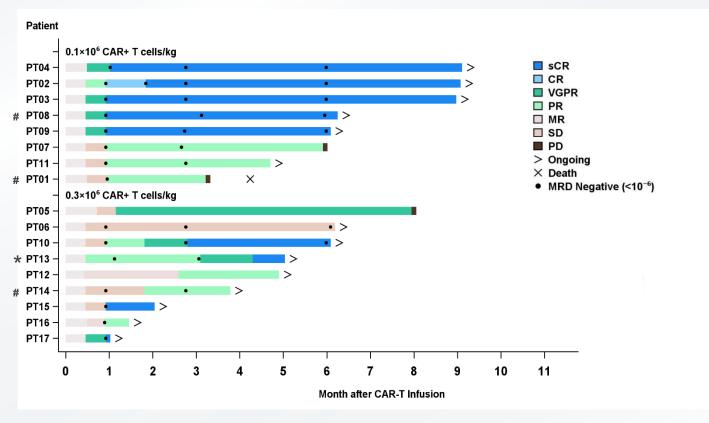
R/R MM: Relapsed/Refractory Multiple Myeloma; IIT: Investigator-initiated Trial; ORR: Objective Response Rate; CR: Complete Response; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; MRD: Minimal Residual Disease; BM: Bone Marrow; CRS: Cytokine Release Syndrome; ICANS: Immune Effector 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





- 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.

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





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

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

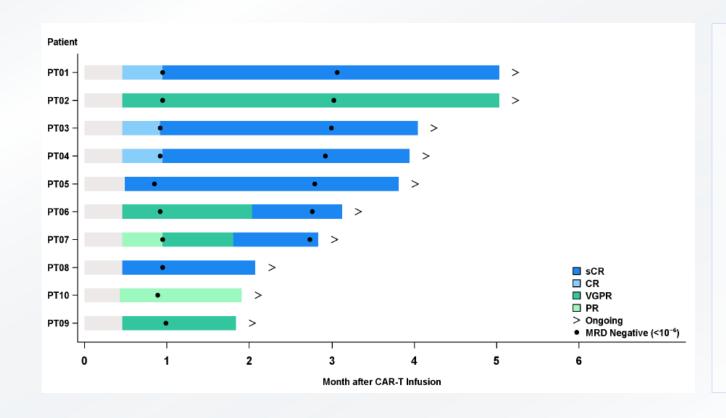
NDMM: Newly Diagnosed Multiple Myeloma; IIT: Investigator-initiated Trial; ECOG PS: Eastern Cooperative Oncology Group Performance Status; ORR: Objective Response Rate; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; PR: Partial Response; MRD: Minimal Residual Disease; CRS: Cytokine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

Cut-off date: Jan 2, 2025

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

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 10⁻⁶ threshold



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



Gastric Cancer	Incidence ~25.6K¹ • Resectable ~10.0K Mortality ~11.0K¹ 5-year survival rate of advanced GC is \$1.000000000000000000000000000000000000	Incidence ~358.7K ¹ • Resectable ~300.0K Mortality ~260.4K ¹
Pancreatic Cancer	Incidence ~60.1K ¹ Mortality ~49.5K ¹	mPFS < 2 months, mOS < 6 months (TAGS study) ² Incidence ~118.7K ¹ Mortality ~106.3K ¹
	5-year survival rate of PC is about 10%; No effective SOC for PC (2L+)	

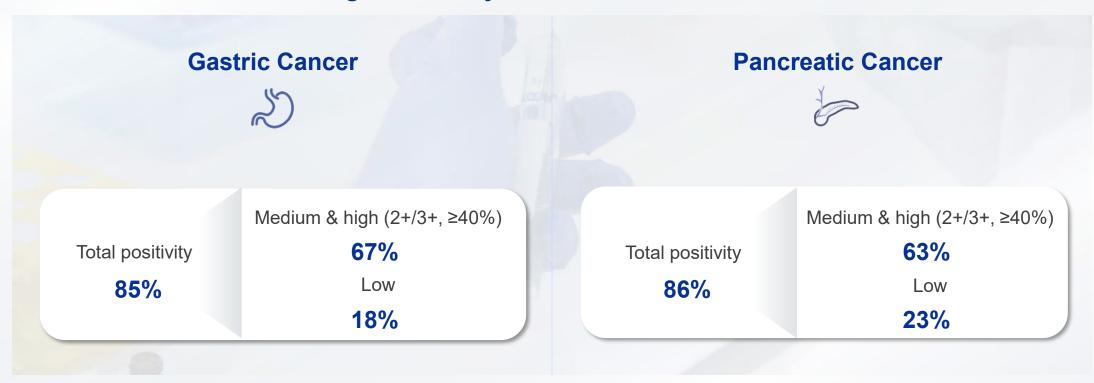
^{1.} International Agency for Research on Cancer. Population factsheets. 2022

^{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, 25% 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



- Optimized scFv¹
- High binding affinity
- High stability

 Innovative FNC (FC + low-dose Nab-Paclitaxel) preconditioning regimen to enhance penetration and anti-tumor effect of CAR-T cells



- RMAT (FDA)
- Orphan Drug (FDA)

Collaboration



Collaboration with Moderna, Inc. (Nasdaq: MRNA) to investigate satri-cel in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine



- GC (3L+) confirmatory Phase II trial in China achieved positive results; Priority Review granted; NDA submitted
- PC adjuvant therapy Phase I trial in China: **Ongoing**
- GC adjuvant therapy IIT in China: Ongoing

Expansion of clinical development in

- earlier lines of therapy
- additional Claudin18.2 positive cancers

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







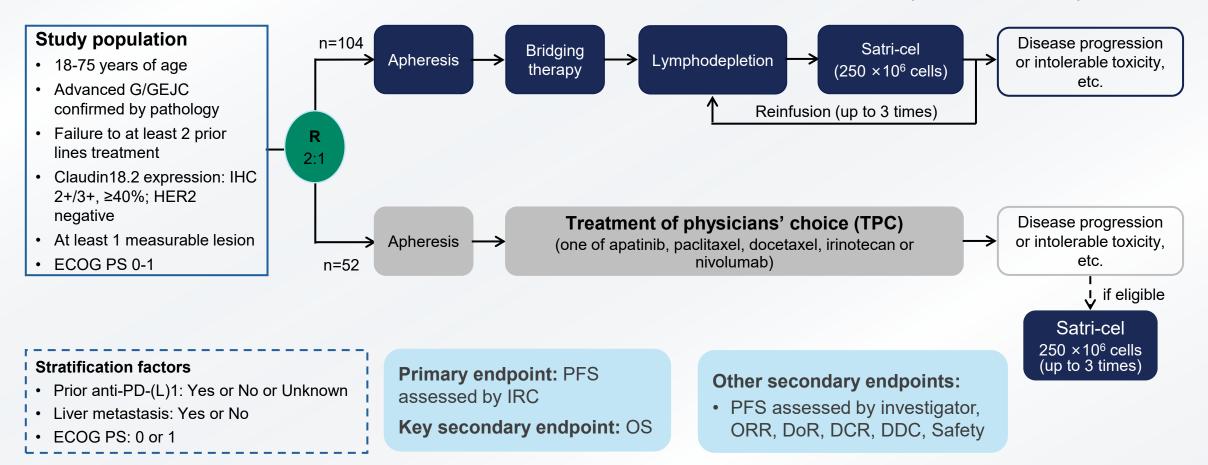
- 1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
- 2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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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

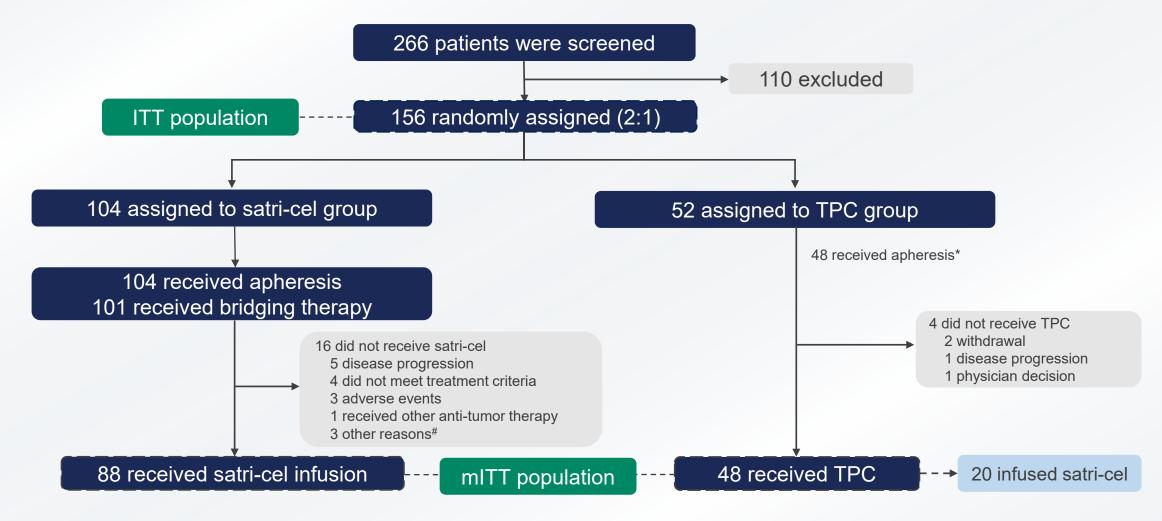
Cut-off date: Oct 18, 2024

^{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





Cut-off date: Oct 18, 2024

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

[#]Three patients requested to withdraw from study treatment.

^{1.} Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

^{2.} Qi C, et al. The Lancet (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Baseline Characteristics



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

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

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

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[†] 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.

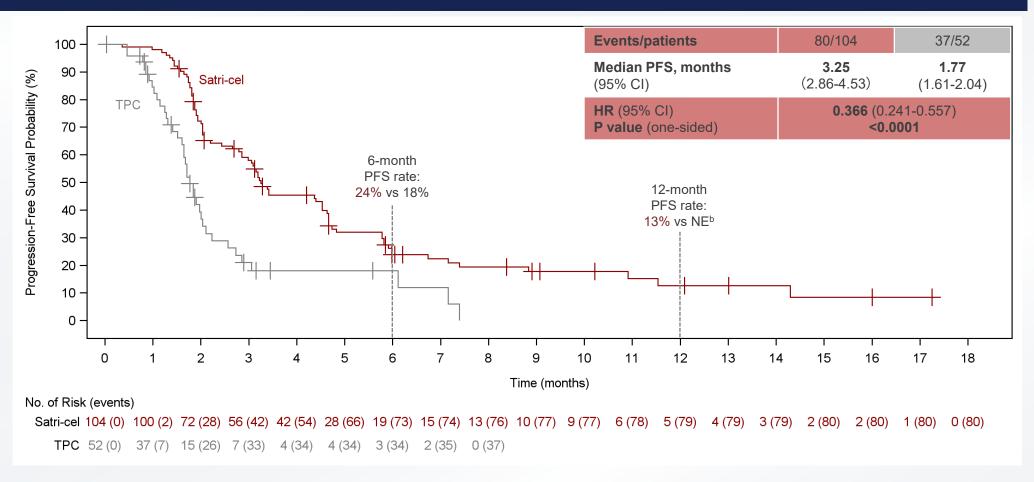
^{1.} Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

^{2.} Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Primary Endpoint—PFS by IRCa



Satri-cel demonstrated statistically significant PFS improvement



a: Per RECIST v1.1.

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

b: 12-month PFS rate could not be estimated in the TPC group.

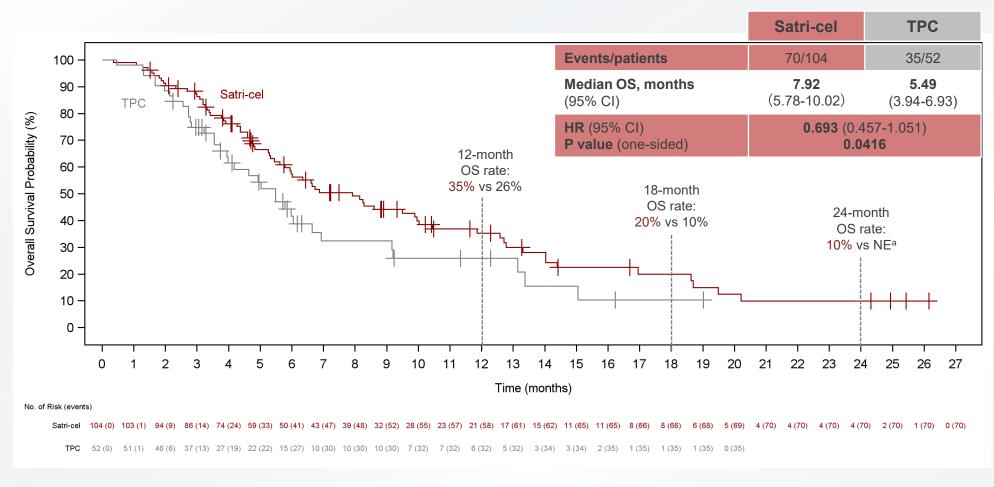
^{1.} Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

^{2.} Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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



Satri-cel demonstrated clinically meaningful OS benefit



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

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

2. Qi C, et al. The Lancet (2025). DOI: 10.1016/S0140-6736(25)00860-8

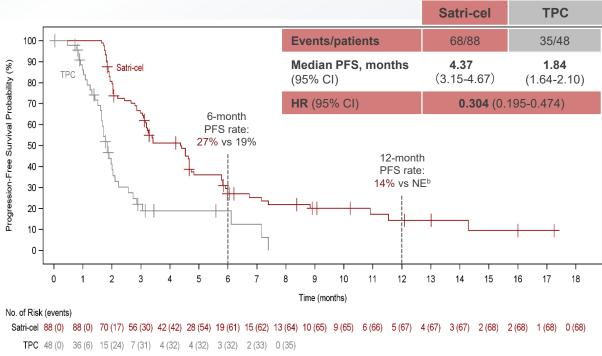
Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

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

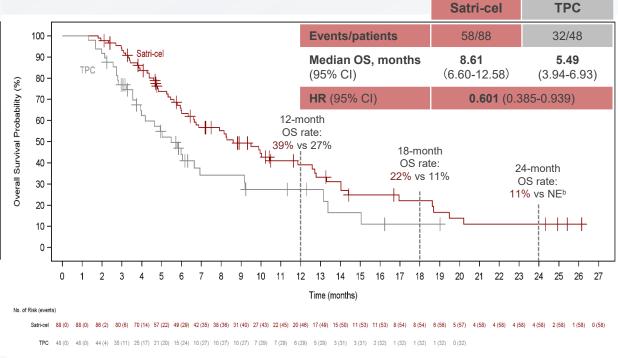


In treated population (mITT), PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

PFS assessed by IRC^a



OS in mITT population



Cut-off date: Oct 18, 2024

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

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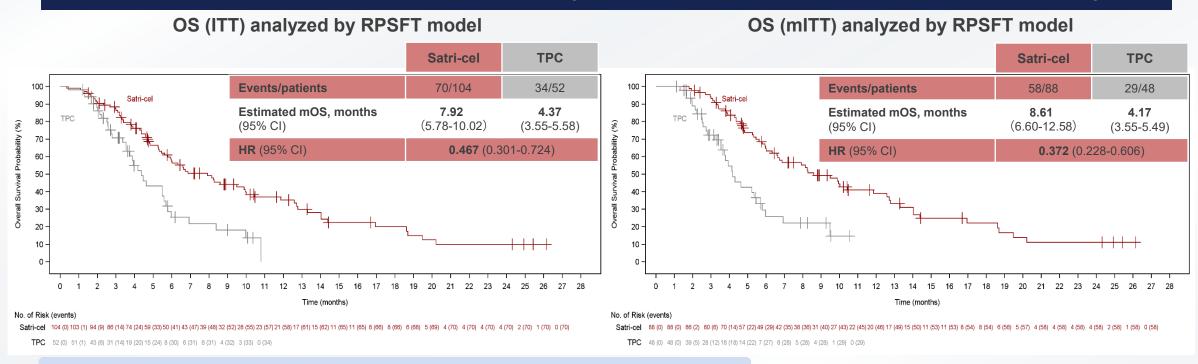
l. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

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



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



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

^{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)	
Salety, II (70)	All grade	Grade ≥3	All grade	Grade ≥3
All treatment-emergent adverse events (TEAEs)	88 (100%)	87 (98.9%)	44 (91.7%)	30 (62.5%)
TEAEs related to treatment (TRAEs)	88 (100%)	87 (98.9%)	44 (91.7%)	27 (56.3%)
TRAEs leading to discontinuation	0	0	2 (4.2%)	1 (2.1%)
TRAEs leading to death	1 (1.1%) ^[1]	1 (1.1%)	1 (2.1%)[2]	1 (2.1%)
Cytokine release syndrome (CRS)	84 (95.5%)	4 (4.5%) [3]	0	0
Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	0	0	0	0

Treatment was defined as bridging therapy, lymphodepletion and Satri-cel infusion in Satri-cel group and treatment of physician's choice in TPC group. [1] disseminated intravascular coagulation; [2] coagulopathy; [3] all grade 3.

Cut-off date: Oct 18, 2024

^{1.} Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

^{2.} Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

Satri-cel China Pivotal Phase II: Conclusions



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

[.] Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

^{2.} Qi C, et al. The Lancet (2025). DOI: 10.1016/S0140-6736(25)00860-8

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



	China investigator-initiated trial (NCT03874897) ^{1,2} Data presented at: 2024 ASCO nature medicine	Phase Ib in China (NCT04581473) ³ Data presented at: 2022 ASCO ANNUAL MEETING	Phase 1b (NCT044) 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	8.8	9
ORR	54.9%*	57.1%	42.9%	16.7%
mPFS, Month	5.8**	5.6	5.7	2.7
mDoR, Month	6.4*	Not reported	6.9	3.4
mOS, Month	9.0**	10.8	8.9	8.9
≥Grade 3 CRS, No.	0	1***	0	2
≥Grade 3 ICANS, No.	0	0	0	
Treatment related death, No.	0	0	0	

^{*51} G/GEJA patients with target lesions at baseline received satri-cel monotherapy.

^{**59} G/GEJA patients received satri-cel monotherapy.

^{***}One patient was related to the investigational disease (lung metastasis of GC) and fully recovered after corticosteroids treatment.

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

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

^{2.} Qi C, et al. Nat Med (2024). DOI: 10.1038/s41591-024-03037-z2 4.

^{4.} Botta G, et. al. ASCO GI 2024. 2024 Jan; Poster #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

CAR-T therapy is superior in clearance of CTCs and micrometastases 02 03

Better Tolerability

- Mild CRS
- Good hematopoietic and organ function

Preserved Immune System

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

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 1st 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

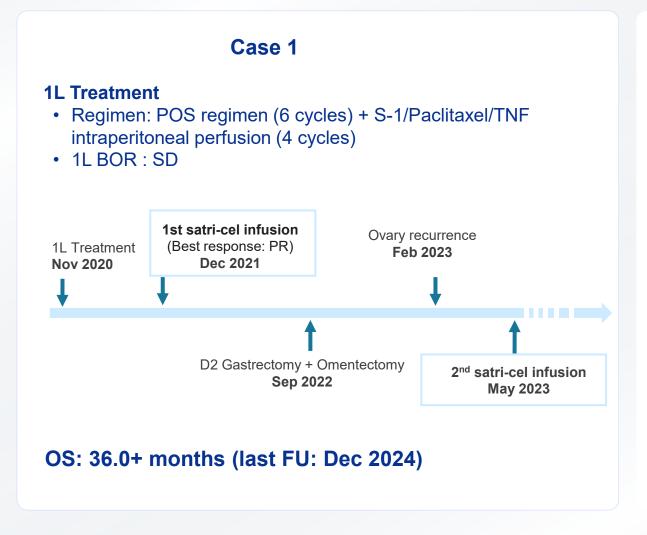
Satri-cel Efficacy Highlights

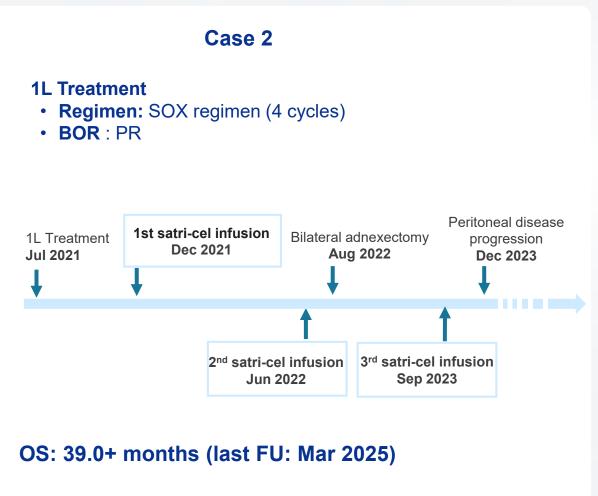
- ORR 100% in 4 patients with target lesions,
 TTR (Time to Response) Week 4
- 1 NN patient remained stable beyond 15 months
- 2 pts subsequently underwent surgical resection after satri-cel infusion, and remain alive until now.

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







Liver Cancer: The Third Leading Cause of Cancer Mortality Worldwide



2022 Liver Cancer Epidemiology in the US and China¹

Incidence	~43.5K	Incidence	~367.7K
Mortality	~30.9K	Mortality	~316.5K

Liver Cancer 5-year survival rate

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

^{1.} International Agency for Research on Cancer. Population factsheets. 2022

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

^{3. 2022} American Cancer Society medical information

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

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



34

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**

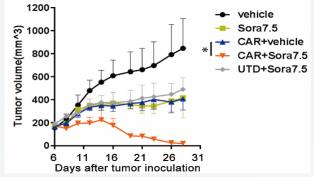
GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*

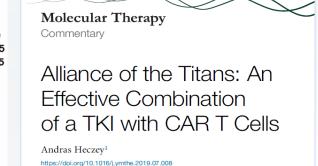


> Mol Ther. 2019 Aug 7;27(8):1483-1494. doi: 10.1016/j.ymthe.2019.04.020. Epub 2019 Apr 29.

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

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







Frontiers in Immunology

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)

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

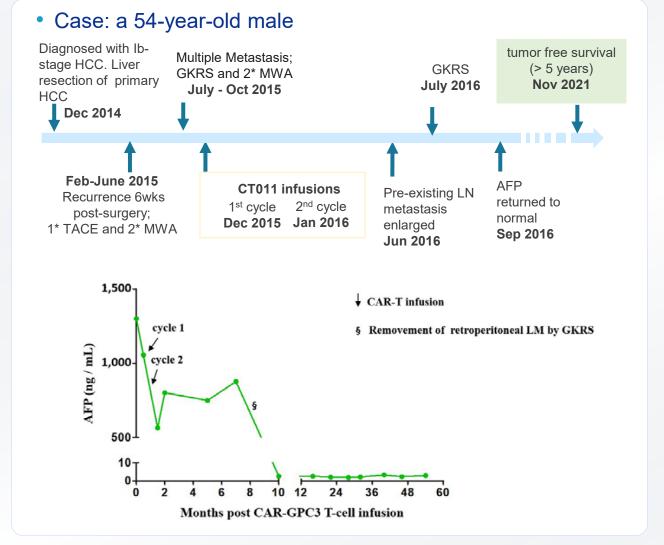








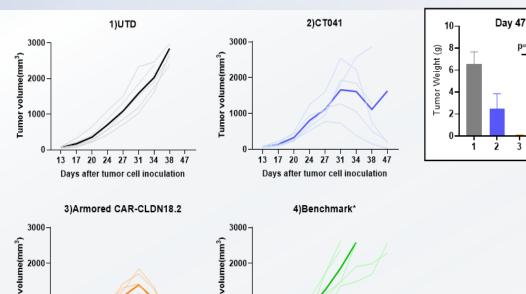
Patients stayed tumor free till latest follow-up on Apr 11, 2025



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



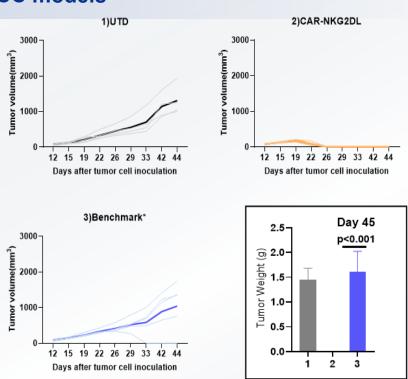
Next-gen Claudin18.2 CAR-T shows enhanced antitumor activity in GC models



13 17 20 24 27 31 34 38 47

Days after tumor cell inoculation



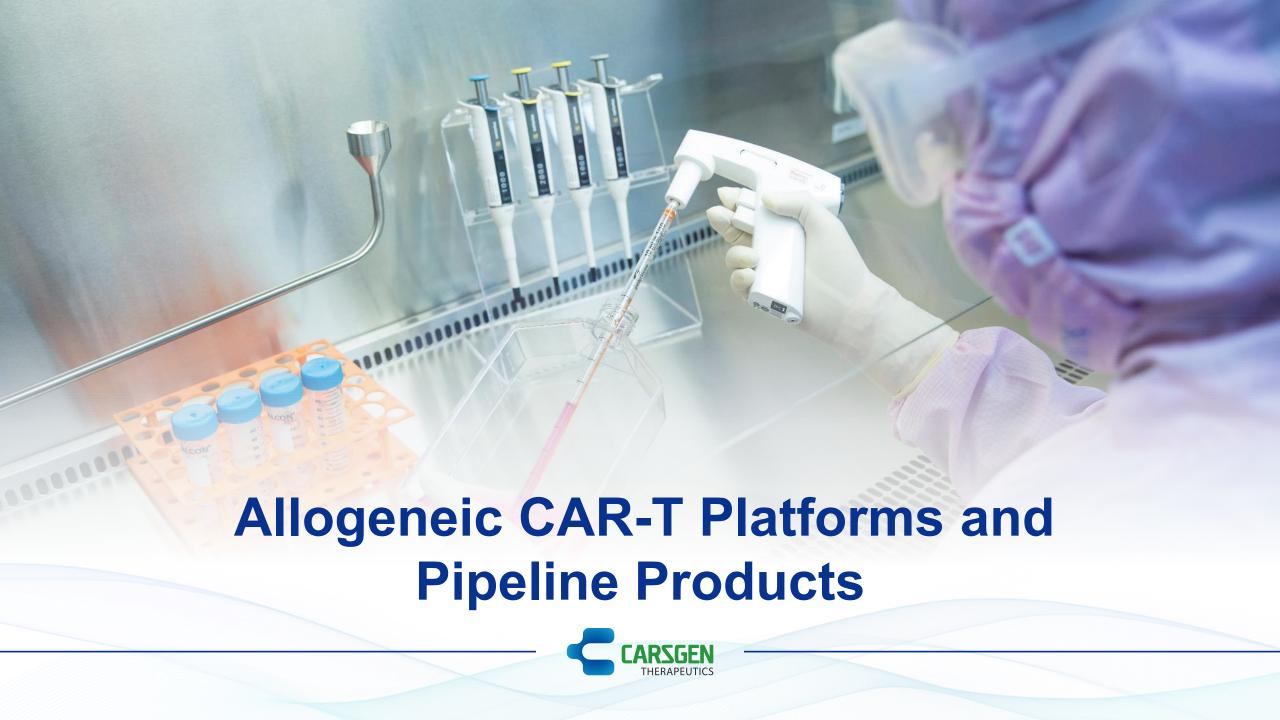


Satri-cel-derived Armored CAR-T demonstrates enhanced therapeutic efficacy

13 17 20 24 27 31 34 38 47

Days after tumor cell inoculation

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



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



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

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

^{**}Four arms in total, Arm C (cy 750 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10⁶ and Arm B (cy 1000 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10⁶ , Arm S (cy 300 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10⁶ .

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

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

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

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

^{3.} ciltacabtagene autoleucel [Prescribing Information]. Janssen Biotech

Relatively Limited Expansion of Allogeneic CAR-T in Patients



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

Autologous and Allogeneic BCMA CAR-T in Multiple Myeloma						
	Allogeneic CAR-T	Autologous CAR-T				
	ALLO-715	cilta-cel	zevor-cel			
	UNIVERSAL Phase I1*	CARTITUDE-1 ²	LUMMICAR-1 Phase 1 ³			
Median C _{max} (copies/ug gDNA)	6,419*	47,806	202,543			
Lymphodepletion Regimen	 Fludarabine: 30 mg m²*3 days; Cyclophosphamide: 300 mg m²*3days; ALLO-647 mAb**: 13mg/20mg/30mg*3days 	 Fludarabine: 30 mg m²*3 days; Cyclophosphamide: 300 mg m²*3 days; 	Fludarabine: 25 mg m ² *3 days; Cyclophosphamide: 300 mg m ² *3 days			

^{*}Data from all patients (N=24) receiving the FCA regimen with 3.2 x108 cells.

^{**}ALLO-647: A humanized anti-CD52 monoclonal antibody for the depletion of CD52-positive host lymphocytes.

^{1.} Mailankody S, et al. *Nat Med* 29, 422–429 (2023)

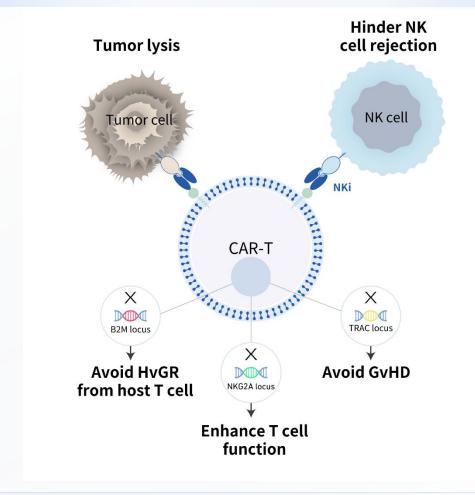
^{2.} ciltacabtagene autoleucel [Prescribing Information]. Janssen Biotech

^{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 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.

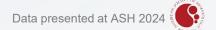
THANK-uCAR® to better address HvGR

- 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/m²/day x 3days), C: Cyclophosphamide (500 mg/m²/day x 3 days).
- Doses: 50×10⁶, 150×10⁶, 300×10⁶, 450×10⁶ CT0590 cells.

Patient (Diagnosis)	High risk cytogenetics Y/N	ISS stage	# of prior lines	Refractorine ss 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) PT 1-reinf (MM)	Υ	I	2	1	23	SD	NA	NA	BLQ 5,102	
PT 2 (MM)	Υ	I	2	2	38	sCR	23	1.1	482,749	
PT 3 (MM)	Υ	III	3	2	12	SD	NA	NA	BLQ	
PT 4 (MM)			0	0	NA	PR	4	2.3	DI O	
PT 4-reinf (MM)	Υ	III	3	2		NA	NA	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

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

[#] 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.

^{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 ≥ Grade 3 CRS;
 - ✓ Time to onset was 8-10 days postinfusion;
 - ✓ 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/µg 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/µg gDNA at Day 15.

A Case of CT0590 to Treat R/R MM

CARSGEN

Baseline Characteristics

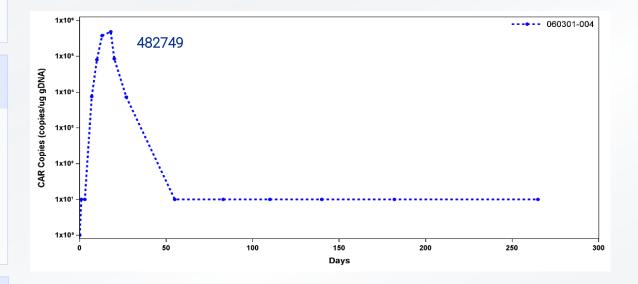
- A 71-year-old male diagnosed with MM,
- Double-refractory, with 94.5% plasma cells in bone marrow.
- 2 prior lines of therapies, including 3 regimens.
- Received 3×10⁸ CT0590 CAR-T cells infusion.

Safety

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

Efficacy

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



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

A Case of CT0590 to Treat R/R pPCL



Baseline Characteristics

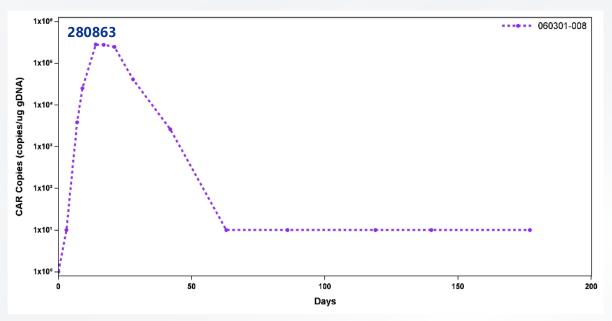
- A 52-year-old male diagnosed with pPCL
- Double-refractory
- 3 prior lines, including 3 regimens (ASCT, etc.)
- Received an infusion of 3×10⁸ CT0590 CAR-T cells.

Safety

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

Efficacy

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



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

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

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

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



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

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

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

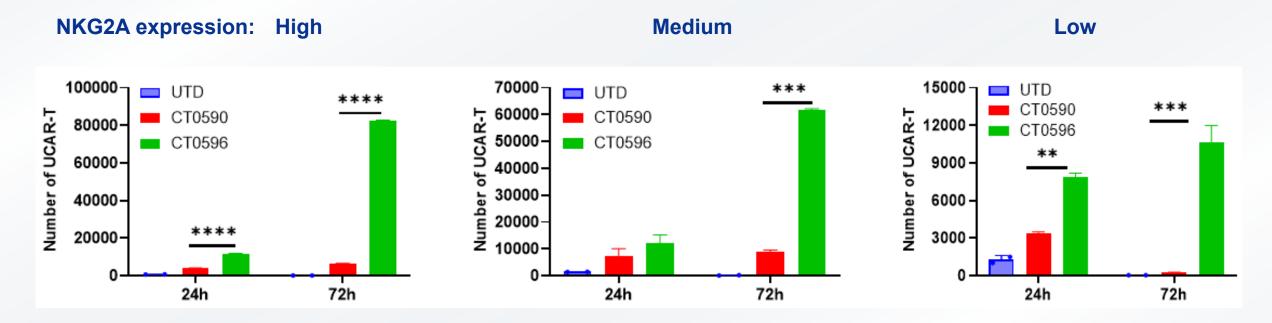
 Based on THANK-u Plus[™], CT0596—an allogeneic BCMA-targeted CAR-T therapy was developed for the treatment of R/R MM or R/R PCL.

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





- 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:

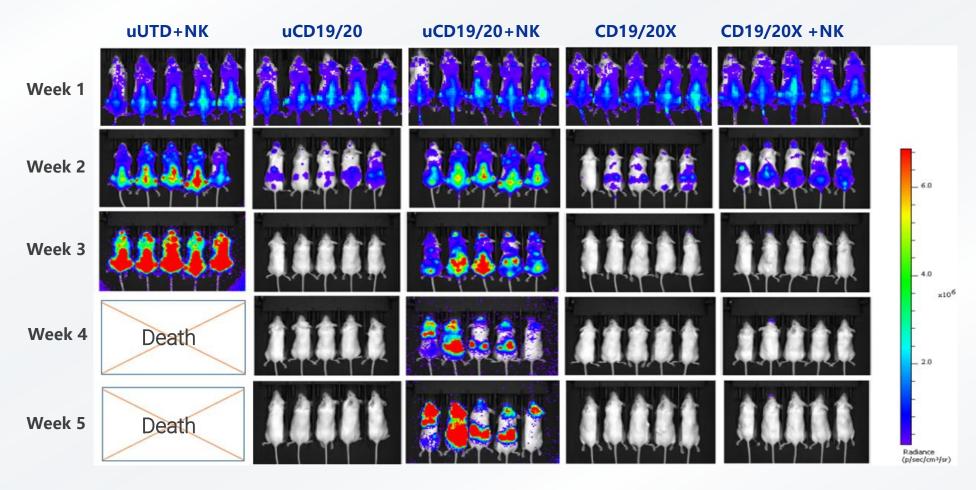
- ✓ NO ≥Grade 3 CRS
- ✓ NO ICANS or GvHD
- ✓ NO DLTs, no patients discontinuing treatment due to AE

Efficacy

- As of May 6, 2025, 8 R/R MM patients (3L+) received infusion (Lymphodepletion: **fludarabine 22.5-30 mg/m² and cyclophosphamide 350-500 mg/m²**). Key findings from up to four months of follow-up include:
 - ✓ 5 patients completed the first efficacy assessment at Week 4:
 - 3 patients (60%) achieved sCR/CR; all are in ongoing response.
 - 4 patients (80%) attained MRD-negativity in the bone marrow.
 - ✓ 2 patients at Day 14 showed reductions in measurable lesions by ≥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

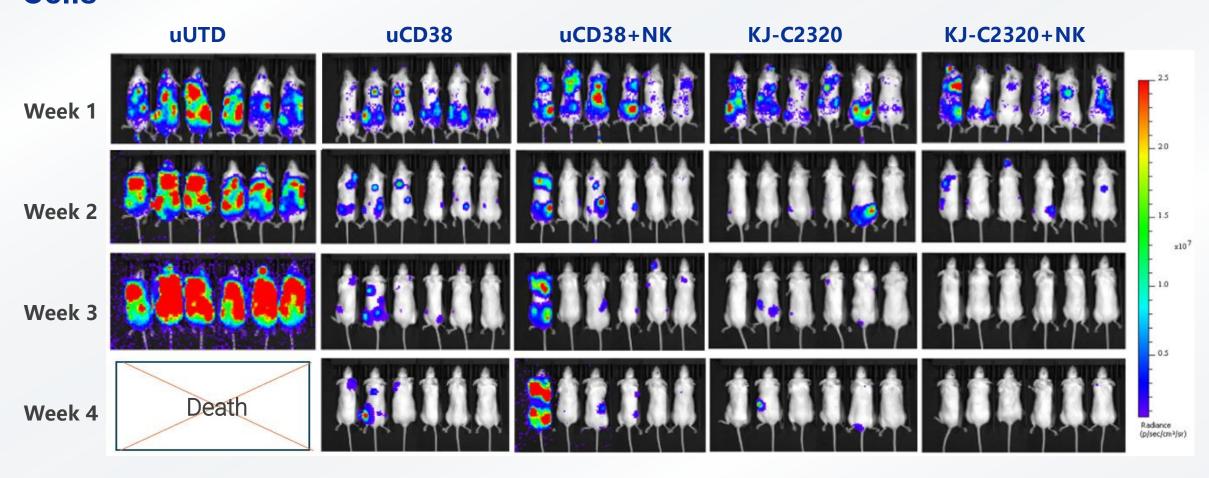




In the presence of NK cells, allogeneic CD19/20X CAR-T (THANK-u Plus[™] platform) demonstrates much better anti-tumor efficacy than conventional allogeneic CD19/20 CAR-T.

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



- 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 Vice President, Early Discovery





Yi Luo, MD, PhD Vice President, Clinical Sciences



Innovent







Nishan Rajakumaraswamy, MD Vice President, US Clinical Sciences Head







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



GSK

Bristol Myers Squibb

