CARSGEN THERAPEUTICS

CARsgen Therapeutics (HKEX: 02171)

May 2025

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

1

Marketed product:
- zevorcabtagene autoleucel (zevor-cel, CT053)

3

CAR-T Products at IND stage:
- Satri-cel (Claudin18.2)
- CT011 (GPC3)
- CT071 (GPRC5D)

4+

Core technology platforms:
- CycloCAR®, THANK-uCAR®, THANK-u Plus™, LADAR®, CARcelerate®

300+

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

2

Manufacturing sites:
- Shanghai, China
- Durham, US

10+ years

Focus on innovative CAR-T therapies since company initiation

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

Shanghai

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

Durham, North Carolina

CGMP manufacturing facility

Partnerships

华东医药股份有限公司 HUADONG MEDICINE CO.,LTD.

(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

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

LADAR®
(precise targeting)

Lymphodepletion
(FNC regimen)

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

Competitive Product Pipeline with Global Rights

	Product Candidate[1]	Target	Indication	Pre-clinical / Phase I / Phase II/III[2] / BLA NDA
Autologous CAR-T	**Zevor-cel (CT053)[3]**	BCMA	R/R MM	LUMMICAR 1 (China) — launched
			R/R MM	LUMMICAR 2 (US, Canada)
	Satri-cel (CT041)	Claudin18.2	GC/GEJ	ST-01 (China)
			GC/PC	ST-02 (US, Canada)
			PC (adjuvant)	ST-05 (China)
			GC/GEJ, PC, etc.	IIT (China)
			GC/GEJ (adjuvant)	IIT (China)
	CT071	GPRC5D	R/R MM, R/R pPCL	(US)
			R/R MM, R/R PCL	IIT (China)
			NDMM	IIT (China)
	CT011	GPC3	HCC (adjuvant)	(China)
Allogeneic CAR-T	**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	IIT (China)
			SLE, SSc	IIT (China)
	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
[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)

for hematologic malignancies; for solid tumors; for autoimmune diseases

R/R MM: relapsed / refractory multiple myeloma; GC: gastric cancer; GEJ: gastroesophageal junction 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

Autologous CAR-T Against Hematologic Malignancies

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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)

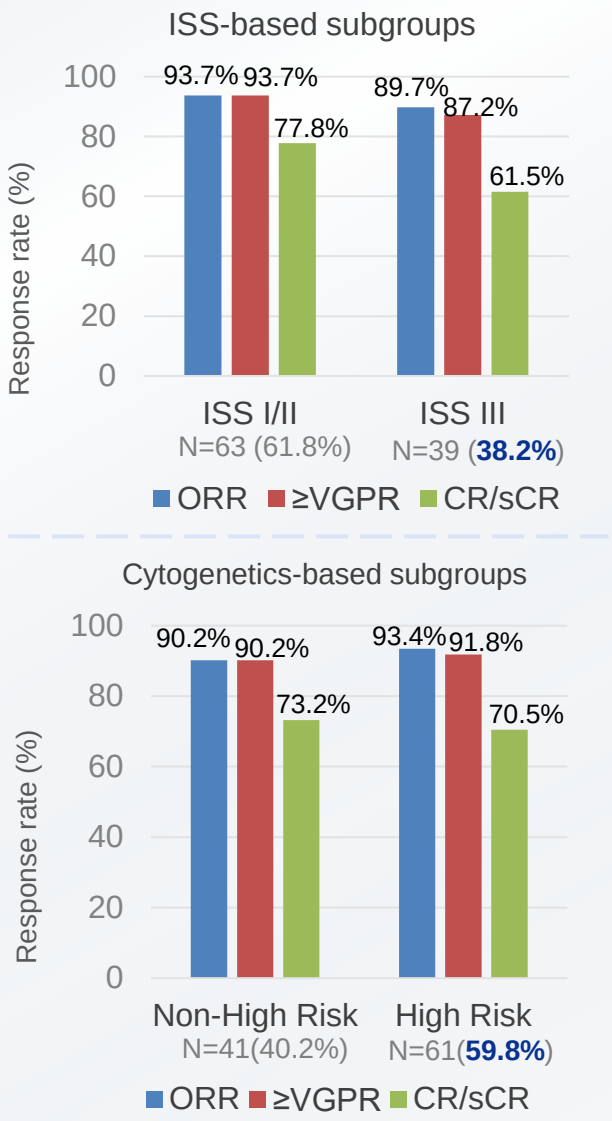
China Pivotal Phase II (LUMMICAR-1) [1]
N=102

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 negative***, No. (%)	73 (100%)
≥Grade 3 CRS, No. (%)	7 (6.9%)
≥Grade 3 NT, No. (%)	0
Treatment related death, No.	1

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

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

Zevor-cel: Outstanding Efficacy and Manageable Safety



Long-term survival with deep response

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

◆ Overall Superior efficacy

- IIT[1]: ORR of 87.5%, sCR/CR rate of 79.2%.
- Phase I[2]: **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) .

Higher safety, lower incidence of SAE

◆ In IIT, Phase I, and Phase II studies

- ≥Grade 3 CRS incidence: 0%, 0%, 6.9%, respectively.
- ≥Grade 3 neurotoxicity incidence: 4.2%, 0%, 0%, respectively.
- Treatment-related death: 0%, 0%, 1%, respectively.

◆ Low incidence of ≥Grade 3 infections or prolonged hematologic toxicity

- Low incidence of ≥Grade 3 infections.
- Significantly low incidence of ≥Grade 3 prolonged (>30 days) cytopenia.

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

CT071: Differentiated GPRC5D CAR-T with CARcelerate® Platform

Product

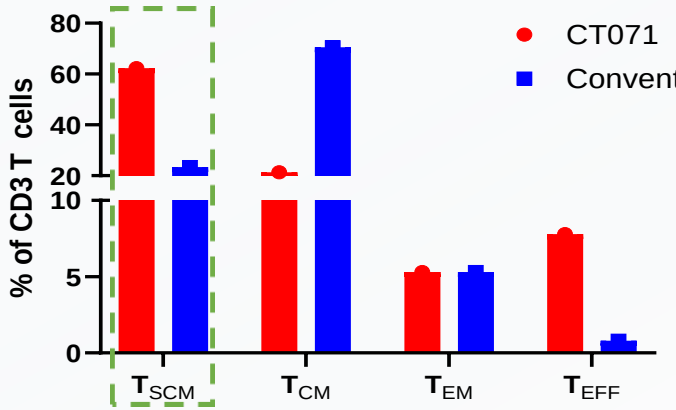
- Fully-human scFV generated by CARsgen
- For relapsed R/R Multiple Myeloma or R/R Primary Plasma Cell Leukemia
- Proprietary **CARcelerate®** platform

Manufacturing Time:

CARcelerate®: **~30 hours**

Conventional: **> 7 days**

Younger, healthier, possibly more potent CAR-T



Clinical Development Status

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

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

CT071: Baseline Characteristics

Patient Characteristics	0.1×10^6 cells/kg (n=8)	0.3×10^6 cells/kg (n=9)	All Patients (n=17)
R-ISS disease stage, No. (%)			
II	4 (50.0)	8 (88.9)	12 (70.6)
III	4 (50.0)	0	4 (23.5)
ECOG PS, No. (%)			
1	4 (50.0)	5 (55.6)	9 (52.9)
2	1 (12.5)	0	1 (5.9)
Extramedullary Disease [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.

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

*Cut-off date: June 21, 2024

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

CT071: Early and Deep Responses with Promising Safety Profile

	0.1×10⁶ cells/kg (n=8)	0.3×10⁶ 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

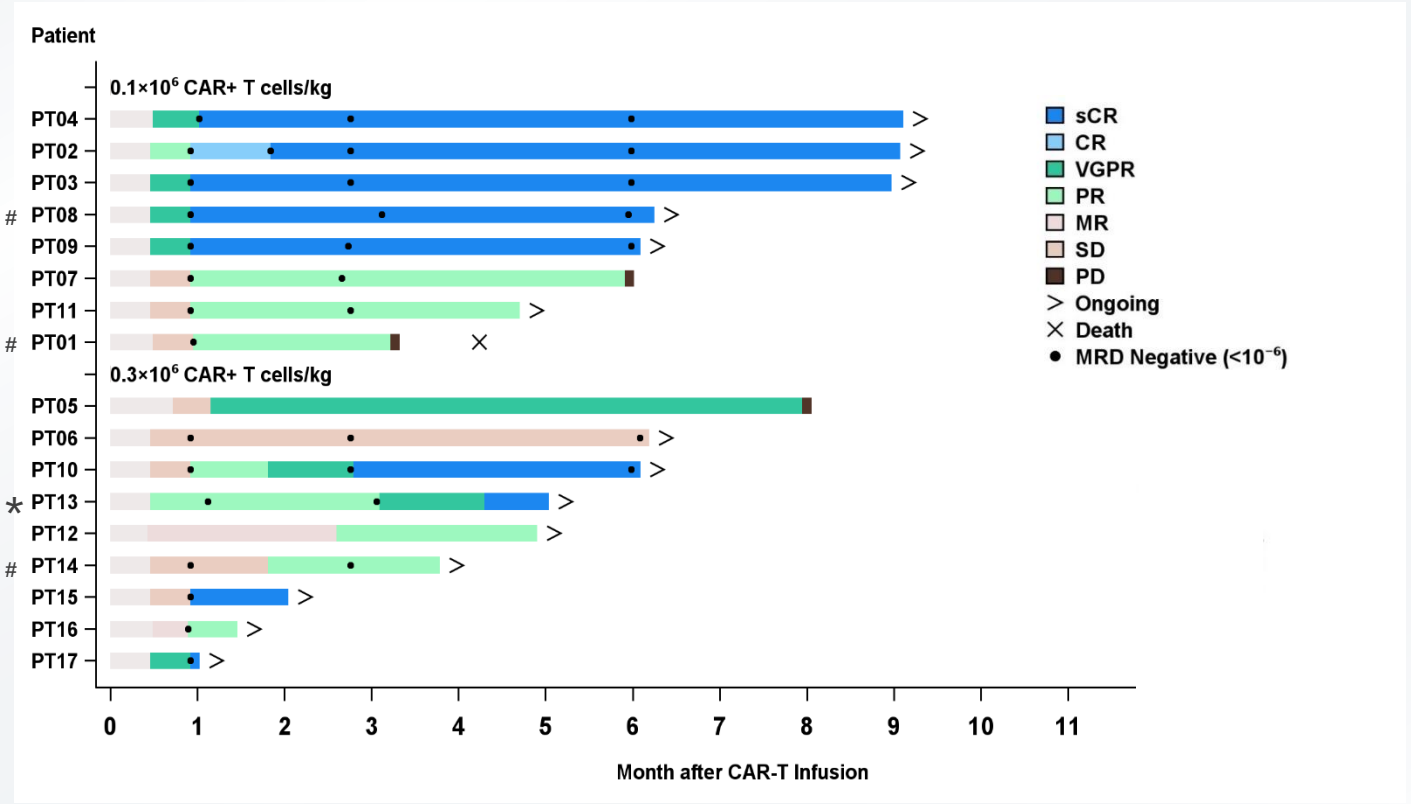
Abbreviations: CI, Confidence Interval; CR, Complete Response; DOR, Duration of Response; MRD, Minimal Residual Disease; NA, Not Applicable; ORR, Objective Response Rate; PR, Partial Response; sCR, Stringent Complete Response; SD, Stable Disease; VGPR, Very Good Partial Response; TRAE, Treatment-related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

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

*Cut-off date: June 21, 2024

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

CT071: Rapid and Durable Responses



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

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

*Cut-off date: June 21, 2024

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

Autologous CAR-T Against Solid Tumors

CARSGEN THERAPEUTICS

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

Gastric Cancer 	Incidence ~25.6K[1] • Resectable ~10.0K Mortality ~11.0K[1]	Incidence ~358.7K[1] • Resectable ~300.0K Mortality ~260.4K[1]
	5-year survival rate of advanced GC is 5-20%; For advanced GC (3L+), ORR is 4.5%, mPFS < 2months, mOS < 6 months (TAGS study)[2]	
Pancreatic Cancer 	Incidence ~60.1K[1] Mortality ~49.5K[1]	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

Gastric Cancer

Medium & high positivity rate

(≥2+, ≥40%)

68%

Pancreatic Cancer

Medium & high positivity rate

(≥2+, ≥40%)

55%

Bile Duct Cancer

Medium & high positivity rate

(≥2+, ≥40%)

25%

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

Product

- **Optimized scFv[1]**
  - ✓ 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

Designations

- **RMAT** (FDA)
- **Orphan Drug** (FDA)
- **Breakthrough Therapy** (NMPA)

Collaboration

CARsgen and Moderna, Inc. (Nasdaq: MRNA) have initiated a collaboration agreement to investigate satri-cel in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine

Clinical Development Plan

- GC (3L+) confirmatory Phase II trial in China: **Enrollment completed**; **positive topline results**; **plan to submit the NDA in H1, 2025**
- PC adjuvant therapy Phase I trial in China: **Ongoing**
- GC adjuvant therapy IIT in China: **Ongoing**

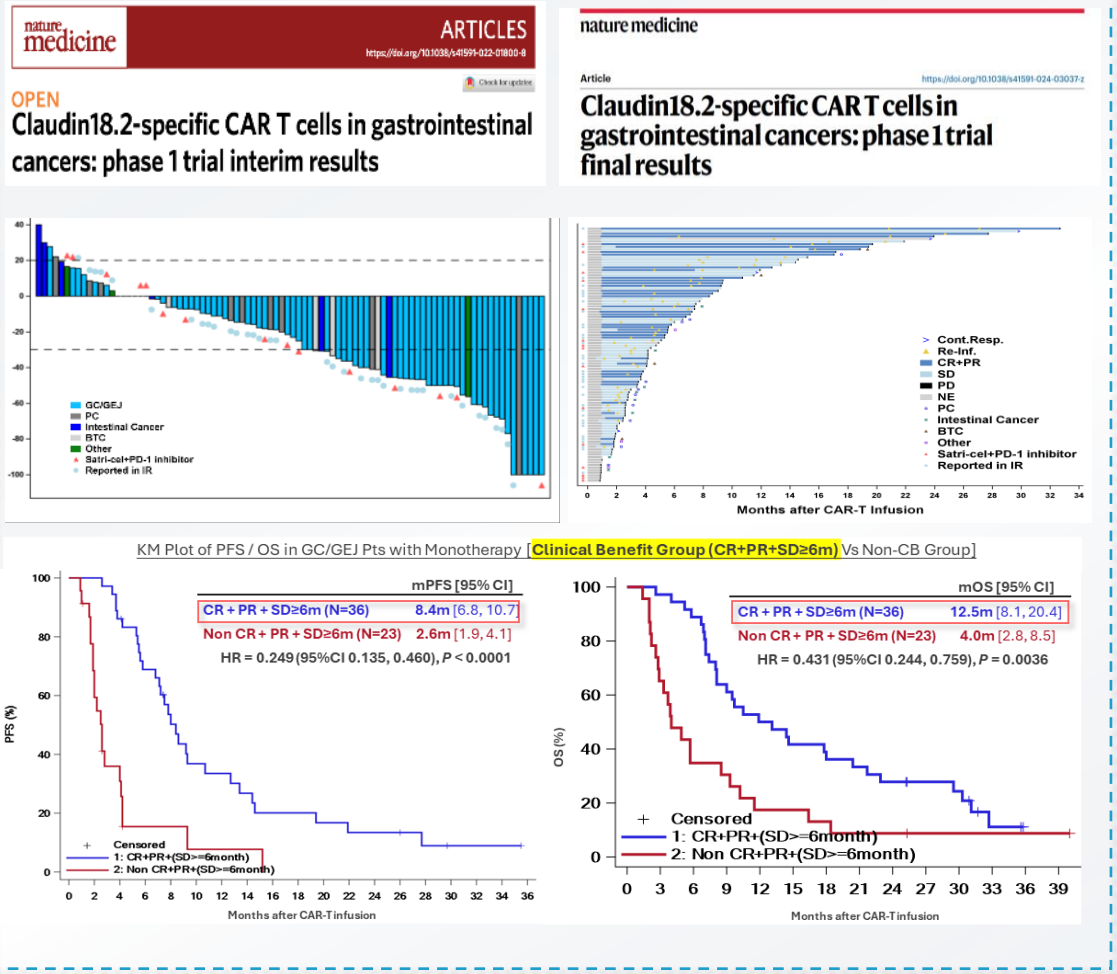
Expansion of clinical development in
- earlier lines of therapy
- additional Claudin18.2 positive cancers

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

Satri-cel: Breakthrough Efficacy in Later-Line Therapy for GC/GEJ

	ORR	mPFS | mOS (month)
CT041	55%	5.8 | 9.0
Immunotherapy	11%	1.6 | 5.2
Chemotherapy, Targeted Therapy	<5%	<2 | <6

Presentations at international conferences and publications in top-tier journals



1. Qi C, et. al. *Nat Med*. 2022 Jun;28(6):1189-1198.
2. Qi C, et. al. *Nat Med*. 2024 Aug;30(8):2224-2234.

Satri-cel: Clinical Data from China and the United States

	China investigator-initiated trial (NCT03874897)[1,2]	Phase Ib/II in China (NCT04581473)[3]	Phase 1b in the US (NCT04404595)[4]	
Sample size, No.	51 GC/GEJ*	14 GC/GEJ	7 GC/GEJ	12 PC
Median follow-up, Month	32.4*	8.8	8.9	
ORR	54.9%*	57.1%	42.9%	16.7%
mPFS, Month	5.8**	5.6	5.7	2.7
mDoR, Month	6.4*	Not reported	6.9	3.4
mOS, Month	9.0**	10.8	8.9	8.9
≥Grade 3 CRS, No.	0	1***	0	2
≥Grade 3 ICANS, No.	0	0	0	
Treatment related death, No.	0	0	0	

*51 GC/GEJ patients with target lesions at baseline received satri-cel monotherapy.
**59 GC/GEJ patients received satri-cel monotherapy.
***One patient was related to the investigational disease (lung metastasis of GC) and fully recovered after corticosteroids treatment.

1. Qi C, et al. 2024 ASCO Abstract #2501
2. Qi C, et al. *Nat Med* (2024). https://doi.org/10.1038/s41591-024-03037-z2
3. Qi C, et. al. ASCO 2022. 2022 Jun; Abstract #4017
4. Botta G, et. al. ASCO GI 2024. 2024 Jan; Abstract #356

Satri-cel: Extension to GC/PC Earlier Line Treatment

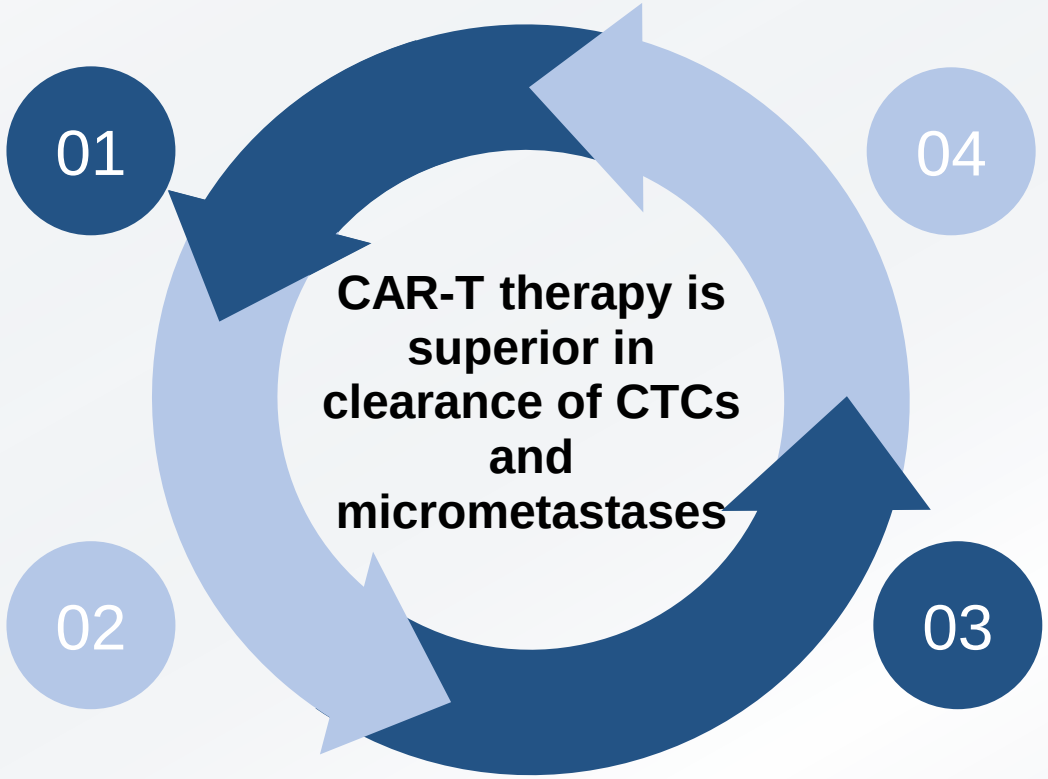
Promising great clinical value in earlier line / earlier disease stage and providing better chances of cure for a much broader patient population

More Accessible Tumor

- Low disease burden & aggressiveness
- Easier tissue penetration

Preserved Immune System

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



Better Tolerability

- Mild CRS
- Good hematopoietic and end-organ function

Favorable TME

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

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

No.	Age/Gender	BOR of 1st line	BOR of CT041	TTR
1	**50/F**	**SD**	**PR**	**W4**
2	**55/F**	**PR**	**PR**	**W4**
3	30/F	SD	**PR**	W4
4	48/M	SD	**NN**	No target lesion
5	53/F	NE (intolerable to chemo, myelosuppression)	**PR**	W4

Satri-cel Efficacy Highlights

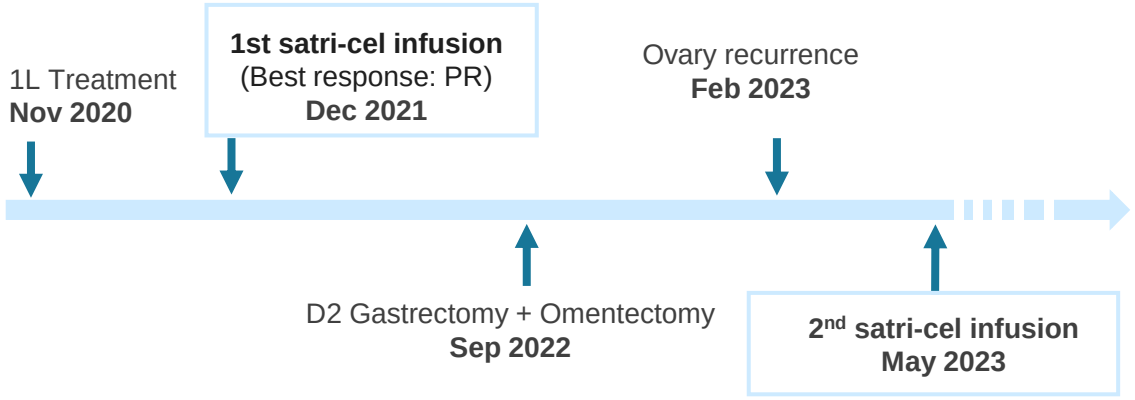
- **ORR 100%** in 4 patients with target lesions, TTR (Time-To-Response) Week 4
- 1 NN patient remained stable **beyond 15 months**
- 2 pts subsequently underwent **surgical resection** after satri-cel infusion**, and remain alive until now.**

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

Case 1

1L Treatment

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

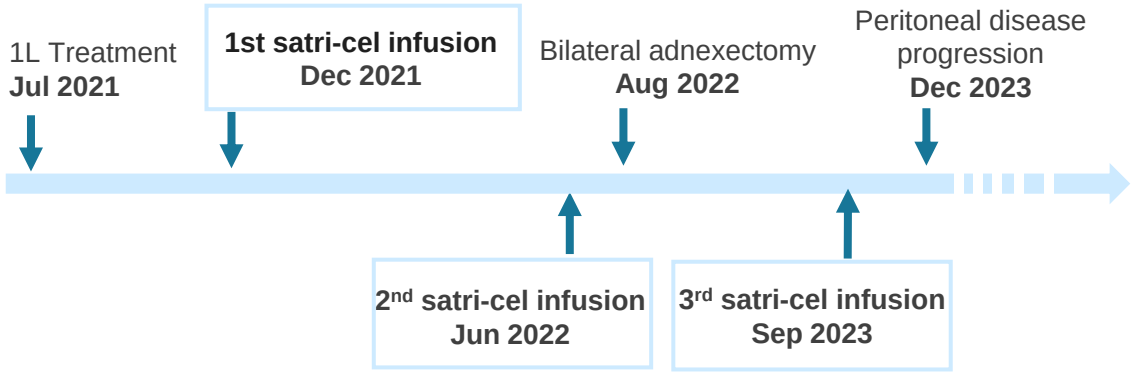


OS: 36.0+ months (last FU: Dec2024)

Case 2

1L Treatment

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



OS: 39.0+ months (last FU: Mar2025)

Liver Cancer: The Third Leading Cause of Cancer Mortality Worldwide

2022 Liver Cancer Epidemiology in the US and China[1]

Incidence	~43.5K
Mortality	~30.9K

Incidence	~367.7K
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

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**

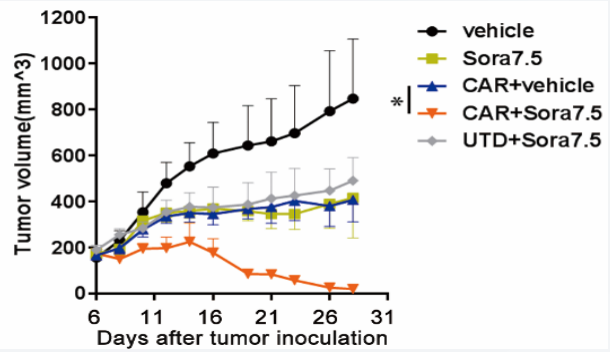
*CARsgen internal data

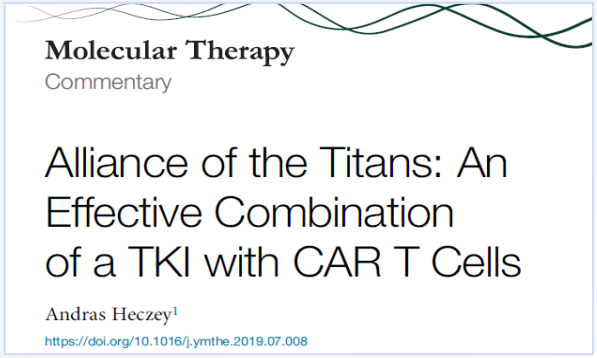
GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*

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 [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 | Frontiers in Immunology

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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
Dec 2014

Feb-June 2015
Recurrence 6wks post-surgery;
1* TACE and 2* MWA

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

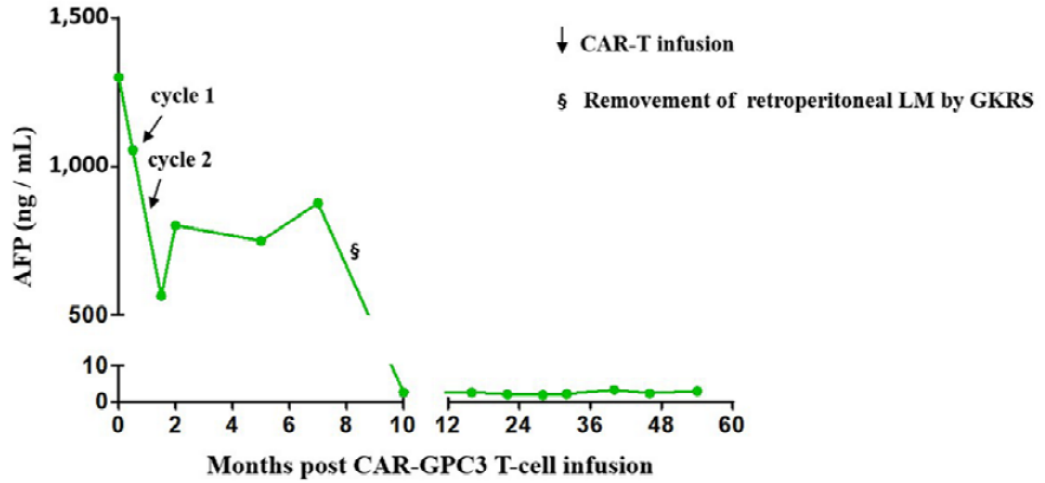
CT011 infusions
1st cycle **Dec 2015**
2nd cycle **Jan 2016**

GKRS
July 2016

Pre-existing LN metastasis enlarged
Jun 2016

tumor free survival (> 5 years)
Nov 2021

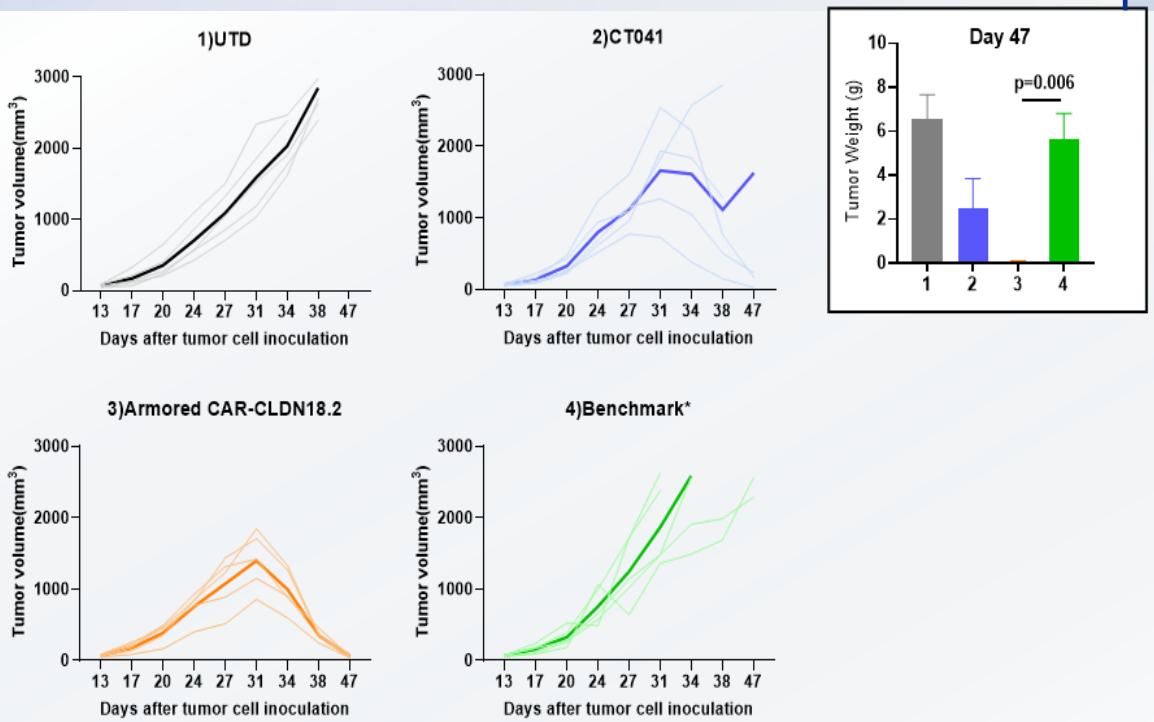
AFP returned to normal
Sep 2016



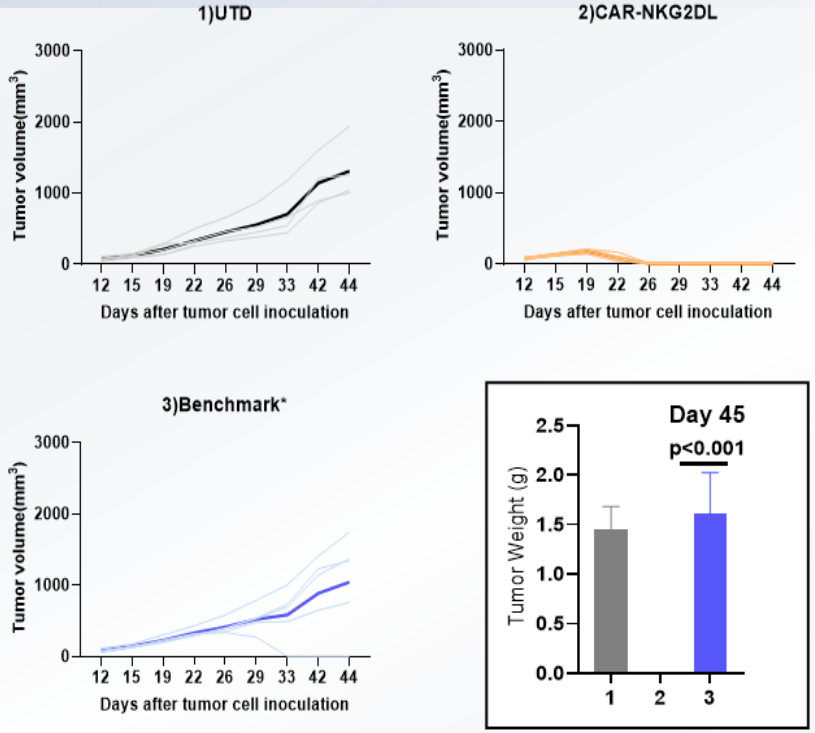
1. Shi Y, et al. *Cancer Commun* (Lond). 2023 Jul 21

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



CT041-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

CARSGEN THERAPEUTICS

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

Treatment and outcomes	Allogeneic BCMA CAR-T			Autologous BCMA CAR-T
	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/m^2/day +Flu 30 mg/m^2/day) P-BCMA-ALLO1 Dose 2 × 10^6 and Arm B (cy 1000 mg/m^2/day +Flu 30 mg/m^2/day) P-BCMA-ALLO1 Dose 2 × 10^6 , Arm S (cy 300 mg/m^2/day +Flu 30 mg/m^2/day) P-BCMA-ALLO1 Dose Range of 0.25-6×10^6, and Arm A (cy 500 mg/m^2/day +Flu 30 mg/m^2/day) P-BCMA-ALLO1 Dose 2 × 10^6 .
***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

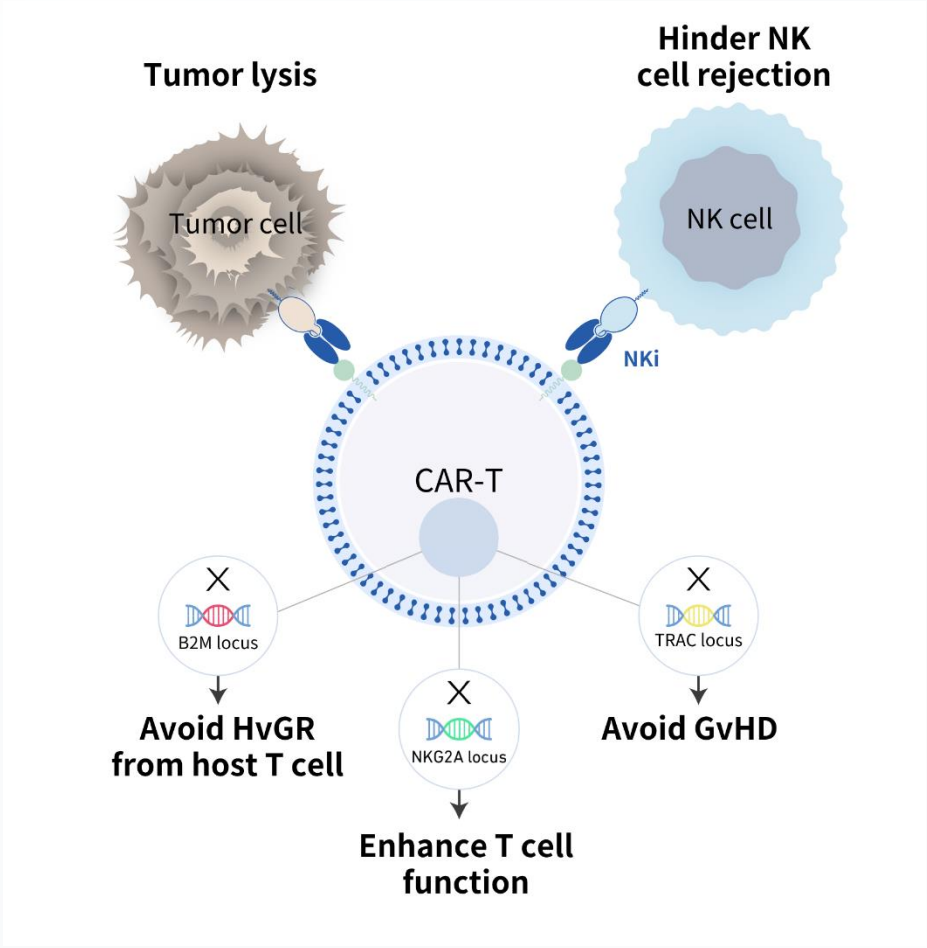
	Allogeneic CAR-T	Autologous CAR-T	
	ALLO-715	cilta-cel	zevor-cel
	UNIVERSAL Phase I[1]*	CARTITUDE-1[2]	LUMMICAR-1 Phase 1[3]
Median C_{max} (copies/ug gDNA)	**6,419***	**47,806**	**202,543**
Lymphodepletion Regimen	• Fludarabine: 30 mg m^2*3 days; • Cyclophosphamide: 300 mg m^2*3days; • ALLO-647 mAb**: 13mg/20mg/30mg*3days	• Fludarabine: 30 mg m^2*3 days; • Cyclophosphamide: 300 mg m^2*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 x10^8 cells.
**ALLO-647: A humanized anti-CD52 monoclonal antibody for the depletion of CD52-positive host lymphocytes.

1. Mailankody, S et al. *Nat Med* 29, 422–429 (2023)
2. ciltacabtagene autoleucel [Prescribing Information]. Janssen Biotech
3. W Chen, et al. *EHA 2024*. 2024 May

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

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



HvGR is the major challenge faced by Allogeneic CAR-T

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

THANK-uCAR® to better address HvGR

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

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

- An open-label, single-arm, phase 1, first-in-human trial in China (NCT05066022).
- Lymphodepletion: F: Fludarabine (30mg/m^2/day x 3days), C: Cyclophosphamide (500 mg/m^2/day x 3 days).
- Doses: 50×10^6, 150×10^6, 300×10^6, 450×10^6 CT0590 cells.

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

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

Data cut-off : 22-Apr-2024

1. Fu C, et al. 2024 ASH. 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 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/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.

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

A Case of CT0590 to Treat R/R MM

Baseline Characteristics

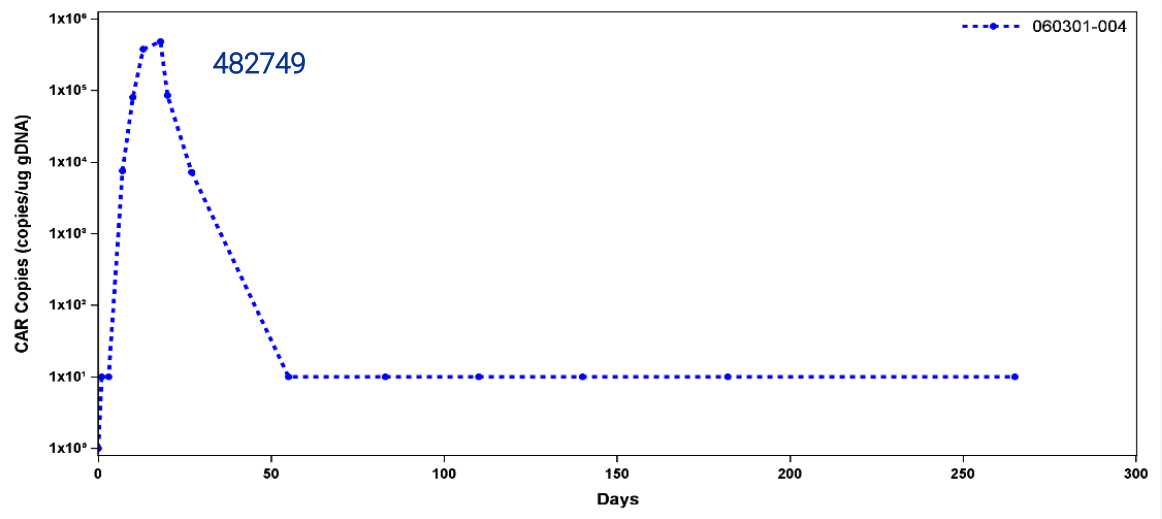
- A 71-year-old male diagnosed with MM,
- Double-refractory, with 94.5% plasma cells in bone marrow.
- 2 prior lines of therapies, including 3 regimens.
- Received 3×10^8 CT0590 CAR-T cells infusion.

Safety

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

Efficacy

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



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

A Case of CT0590 to Treat R/R pPCL

Baseline Characteristics

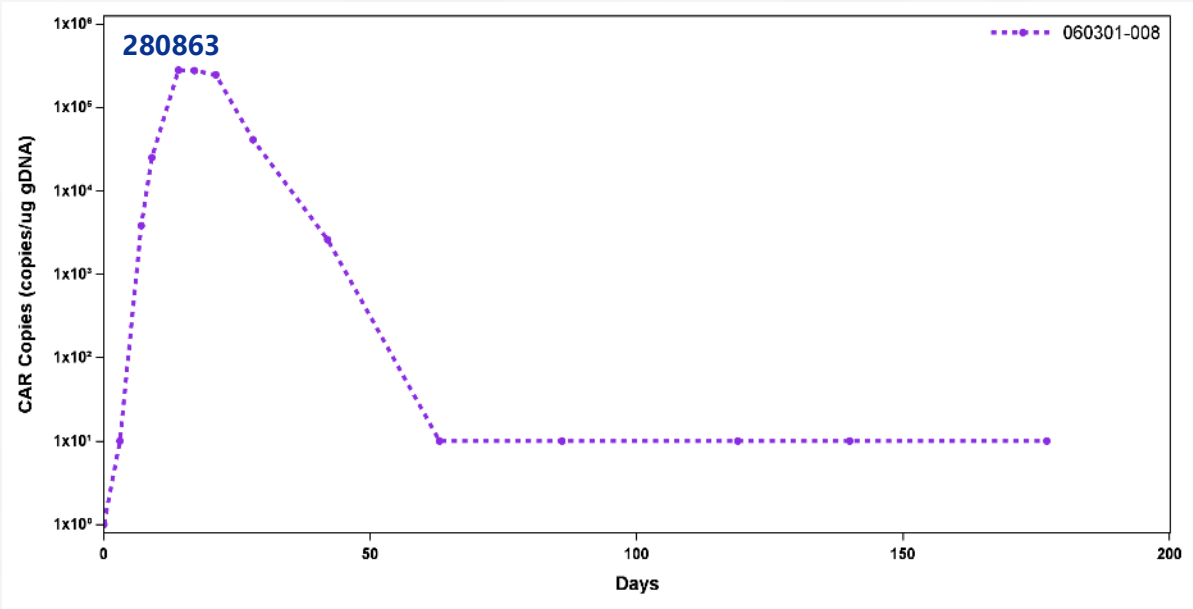
- A 52-year-old male diagnosed with pPCL
- Double-refractory
- 3 prior lines, including 3 regimens (ASCT, etc.)
- Received an infusion of 3×10^8 CT0590 CAR-T cells.

Safety

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

Efficacy

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



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

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

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

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

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

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

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

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

THANK-u Plus™ Platform

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

CT0596

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

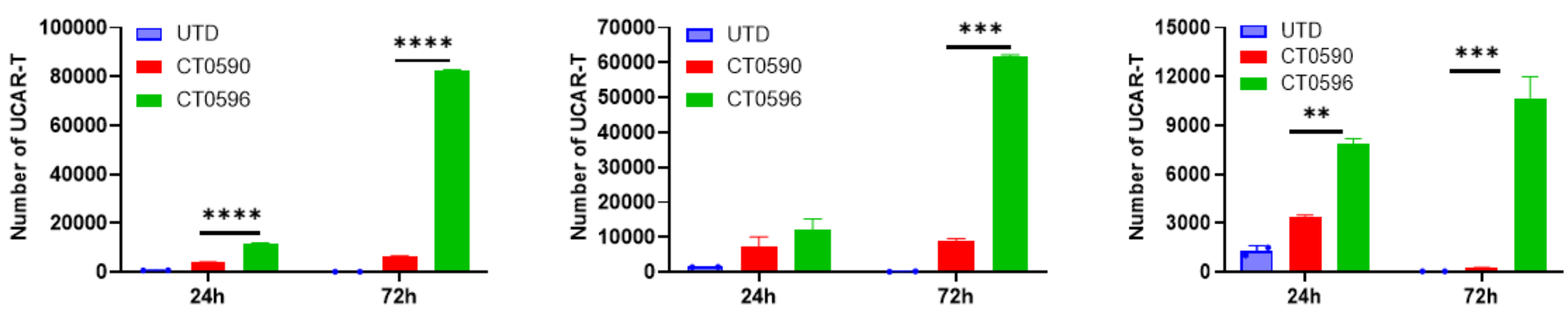
Clinical Development

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

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

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

NKG2A expression: **High** **Medium** **Low**



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

CT0596 IIT Preliminary Data: Favorable Safety and Efficacy

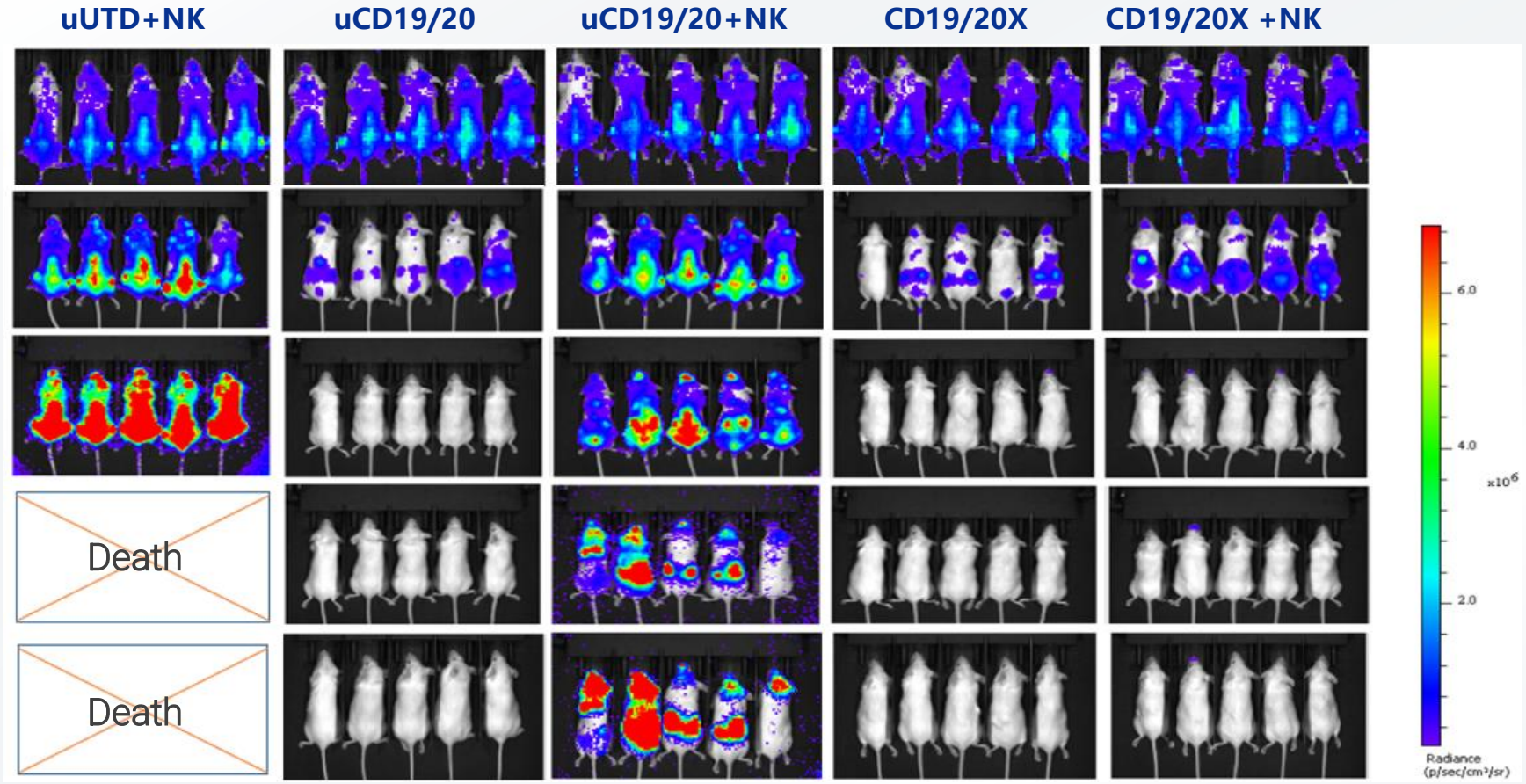
Safety

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

Efficacy

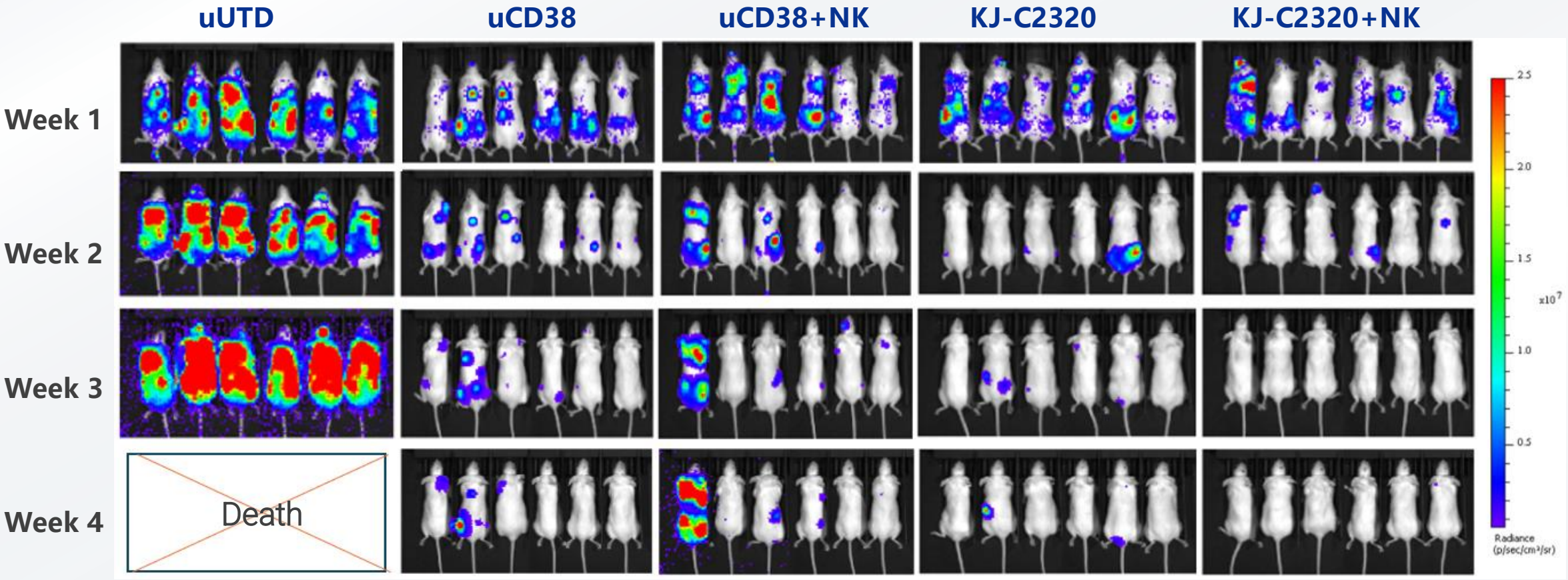
- As of May 6, 2025, 8 R/R MM patients (3L+) received infusion (Lymphodepletion: **fludarabine 22.5-30 mg/m² and cyclophosphamide 350-500 mg/m²**). Key findings from up to four months of follow-up include:
  - ✓ 5 patients completed the first efficacy assessment at Week 4:
    - **3 patients (60%) achieved 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

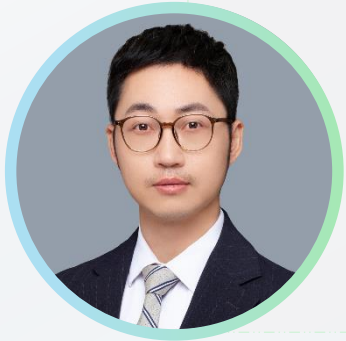
- **H1 2025**: Planned NDA submission for satri-cel (CT041) to the NMPA.
- **2025 ASCO**: Expected disclosure of satri-cel China Phase II pivotal trial data in 3L gastric cancer.
- **H2 2025**: Anticipated data release for satri-cel in pancreatic cancer adjuvant therapy.
- **H2 2025**: Anticipated IND 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

Hua Jiang, MD, PhD
Vice President, Early Discovery



Yi Luo, MD, PhD
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Vice President, US Clinical Sciences Head

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

Making Cancer Curable

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