

# **CARsgen Therapeutics** (HKEX: 02171)

Nov 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)

1

CAR-T product at NDA stage:

Satri-cel (targeting Claudin18.2)

2

CAR-T products at IND stage:

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

300+

Patents (including 140 issued, as of June 30, 2025)

4+

Core technology platforms:

 CycloCAR®, THANK-uCAR®, THANK-u Plus™, LADAR®, CARcelerate® 10+years

Focus on innovative CAR-T therapies since company initiation

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









with an mRNA Cancer Vaccine



#### inno.N

(KOSDAQ: 195940)

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





(SZ: 000963)

Exclusive commercialization of zevor-cel in mainland China



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



#### **Allogeneic CAR-T**

• THANK-uCAR<sup>®</sup>, THANK-u Plus<sup>™</sup> 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)

#### **Advancing a Competitive Pipeline with Global Rights**



	Product Candidate <sup>1</sup>	Target	Indication	Pre-clinic	al Phase	e I Phase I	I/III <sup>2</sup> BLA/ NDA
	Zevor-cel (CT053) <sup>3</sup>	ВСМА	R/R MM (4L+) R/R MM	LUMMICAR 1 (Chin LUMMICAR 2 (US, 0			On Market
Autologous CAR-T	Satri-cel (CT041)	Claudin18.2	G/GEJA (3L+) GC/PC PC (adjuvant) G/GEJA, PC, etc. G/GEJA (adjuvant) G/GEJA (1L sequential)	ST-01 (China) ST-02 (US, Canada) ST-05 (China) IIT (China) IIT (China) IIT (China)			
₹	СТ071	GPRC5D	R/R MM, PCL R/R MM, PCL NDMM	(US) IIT (China) IIT (China)			
	CT011	GPC3	HCC (adjuvant)	(China)			
	CT0590	ВСМА	R/R MM, PCL	IIT (China)			
O	СТ0596	ВСМА	R/R MM, 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				
				fo	or hematologic malignancies	for solid tumors	for autoimmune diseases

<sup>&</sup>lt;sup>1</sup> 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; PCL: Plasma Cell Leukemia; NDMM: Newly Diagnosed Multiple Myeloma; SLE: Systemic Lupus Erythematosus; SSc: Systemic Sclerosis; AML: Acute Myeloid Leukemia

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

<sup>&</sup>lt;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)



#### Zevor-cel: Differentiated Fully-human BCMA CAR-T for R/R MM



#### EHA2024

#### **Zevor-cel Highlights**



- Optimized scFv
- Enhanced binding affinity
- High stability
- Enhanced anti-tumor activity
- Excellent safety profile
- Co-stimulatory domain: 4-1BB
- Low immunogenicity
- Designations: RMAT (FDA), Orphan Drug(FDA)
- ✓ NDA approved by China NMPA (February 23, 2024)

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

<sup>\*</sup>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

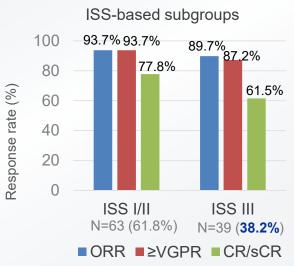
1. Chen W, et al. EHA 2024. 2024 Jun; Oral presentation S209

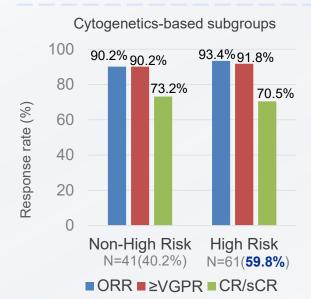
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#### **Zevor-cel: Outstanding Efficacy and Manageable Safety**









#### 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

- IIT<sup>1</sup>: ORR of 87.5%, sCR/CR rate of 79.2%.
- Phase I<sup>2</sup>: 2-year OS rate of 100%, 3-year OS rate of 92.9%.
- Pivotal phase II<sup>3,4</sup>: ORR of 92.2%, predicted
   30-month OS rate of 87.7% (in patients who achieved CR/sCR).

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

### **Higher safety, lower incidence of SAE**

#### ◆ In IIT, Phase I, and Phase II studies

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

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

#### **Zevor-cel: Commercialization in China**







- Zevor-cel was approved by the NMPA in 2024 for the treatment of R/R MM.
- Exclusive commercialization partner in mainland China:



certification and regulatory filings completed in

100+

20+

healthcare institutions

provinces / cities

111

valid orders in H1, 2025

#### CT071: Differentiated GPRC5D CAR-T with CARcelerate® Platform



#### **Product**



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

#### Manufacturing Time:



CT071 Conventional CAR T

80 cells % of CD3 T 10  $T_{CM}$  $T_{EM}$ T<sub>EFF</sub>

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

#### 



	0.1×10 <sup>6</sup> cells/kg (n=8)	0.3×10 <sup>6</sup> cells/kg (n=9)	All Patients (N=17)
R-ISS Stage, No. (%)			
II	4 (50.0)	8 (88.9)	12 (70.6)
III	4 (50.0)	0	4 (23.5)
Extramedullary Disease, No. (%)	2 (25.0)	2 (22.2)	4 (23.5)
High-risk Cytogenetics, No. (%)	6 (75.0)	6 (66.7)	12 (70.6)
Prior Lines of Therapy, median (range)	4 (1, 12)	5 (3, 7)	5 (1, 12)
ORR, No. (%)	8 (100)	8 (88.9)	16 (94.1)
CR/sCR rate, No. (%)	5 (62.5)	4 (44.4)	9 (52.9)
VGPR or better rate, No. (%)	5 (62.5)	5 (55.6)	10 (58.8)
MRD Negativity (<10 <sup>-6</sup> ) with CR/sCR subjects*, No. (%)	5 (100)	4 (100)	9 (100)
CRS, No. (%)	6 (75.0)	5 (55.6)	11 (64.7)
Grade 1, No. (%)	5 (62.5)	3 (33.3)	8 (47.1)
Grade 2, No. (%)	1 (12.5)	2 (22.2)	3 (17.6)
ICANS, No. (%)	0	0	0
AE leading to death, No. (%)	0	0	0

R/R MM: Relapsed/Refractory Multiple Myeloma; IIT: Investigator-initiated Trial; R-ISS: Revised International Staging System; ORR: Objective Response Rate; CR: Complete Response; sCR: Stringent Complete Response; VGPR: Very Good Partial Response; MRD: Minimal Residual Disease; CRS: Cytokine Release Syndrome; ICANS: Immune Effector Cell-associated Neurologic Syndrome; AE: Adverse Event

Cut-off date: Jun 21, 2024

<sup>1.</sup> Du J, et al. ASH 2024. 2024 Dec; Poster #3451

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



#### EHA**2025**

	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



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



Gastric Cancer	Incidence ~25.6K <sup>1</sup> • Resectable ~10.0K Mortality ~11.0K <sup>1</sup>	Incidence ~358.7K¹  • Resectable ~300.0K  Mortality ~260.4K¹
	5-year survival rate of advanced For advanced GC (3L+), ORR is	GC is 5-20%; 4.5%, mPFS < 2 months, mOS < 6 months (TAGS study) <sup>2</sup>
Pancreatic Cancer	Incidence ~60.1K <sup>1</sup> Mortality ~49.5K <sup>1</sup>	Incidence ~118.7K <sup>1</sup> Mortality ~106.3K <sup>1</sup>
	5-year survival rate of PC is about No effective SOC for PC (2L+)	

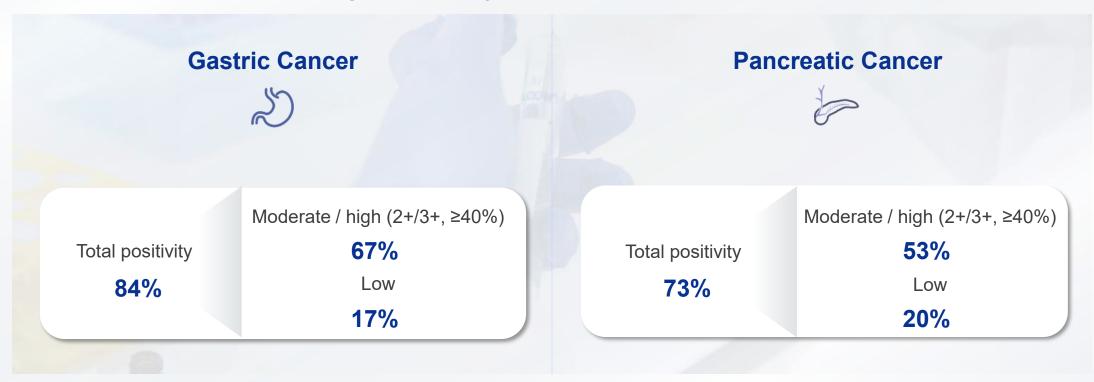
<sup>1.</sup> International Agency for Research on Cancer. Population factsheets. 2022

<sup>2.</sup> 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



<sup>\*</sup>Claudin18.2 expression is also observed in other solid tumors, e.g. in bile duct cancer, 24% of samples exhibit Moderate / high positivity (2+/3+, ≥40%).

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



#### **Product**



#### **Designations**



#### **Clinical Development Plan**



- Optimized scFv<sup>1</sup>
- 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; NDA submitted; Priority Review granted
- 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





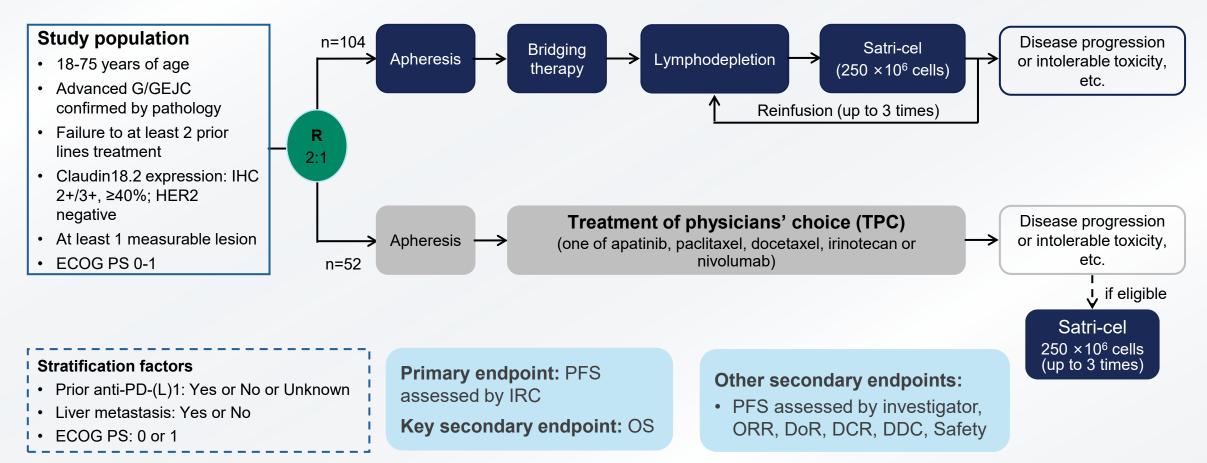


- 1. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003
- 2. Qi C, et al. *The Lancet* (2025). DOI: 10.1016/S0140-6736(25)00860-8

#### 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

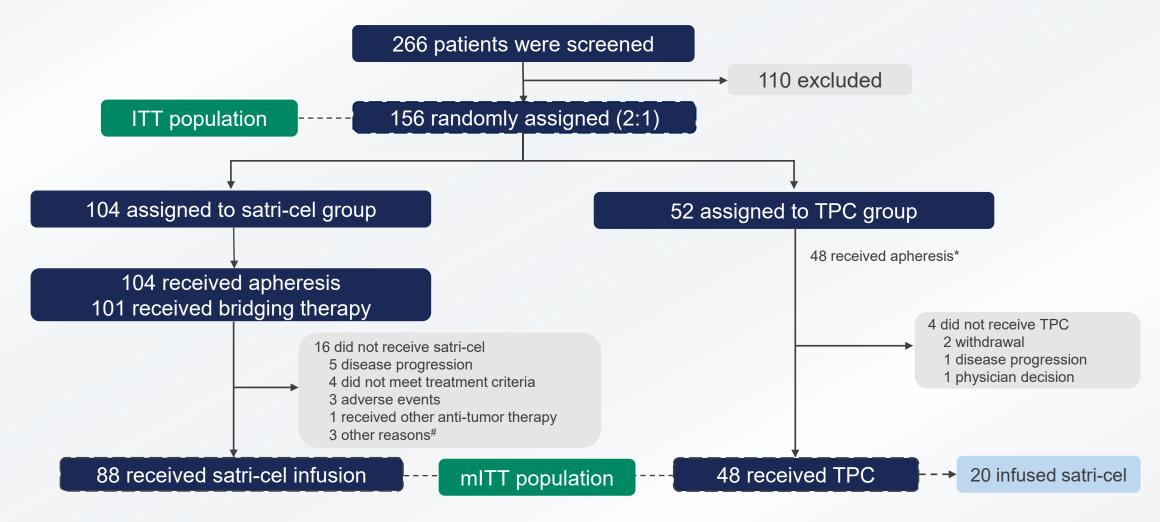
Cut-off date: Oct 18, 2024

<sup>1.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

<sup>2.</sup> 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

<sup>\*</sup>One was not apheresed per physician's decision and received TPC

<sup>#</sup>Three patients requested to withdraw from study treatment.

<sup>1.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

<sup>2.</sup> 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 ( <b>51.9</b> )
Lauren type, n (%)		
Intestinal type	21 (20.2)	12 (23.1)
Diffuse type	45 ( <b>43.3</b> )	26 ( <b>50.0</b> )
Mixed type	29 ( <b>27.9</b> )	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 (%) <sup>†</sup>		
Medium expression	24 (23.1)	10 (19.2)
High expression	80 (76.9)	42 (80.8)
Number of prior lines, n (%) <sup>‡</sup>		
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 ( <b>49.0</b> )	27 <b>(51.9</b> )
Metastatic organs, n (%)		
Peritoneal	72 ( <b>69.2</b> )	31 <b>(59.6</b> )
Liver	21 (20.2)	10 (19.2)
Lung	9 (8.7)	7 (13.5)
Bone	8 (7.7)	9 (17.3)

<sup>\*</sup> 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.

<sup>†</sup> 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%.

<sup>‡</sup> 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.

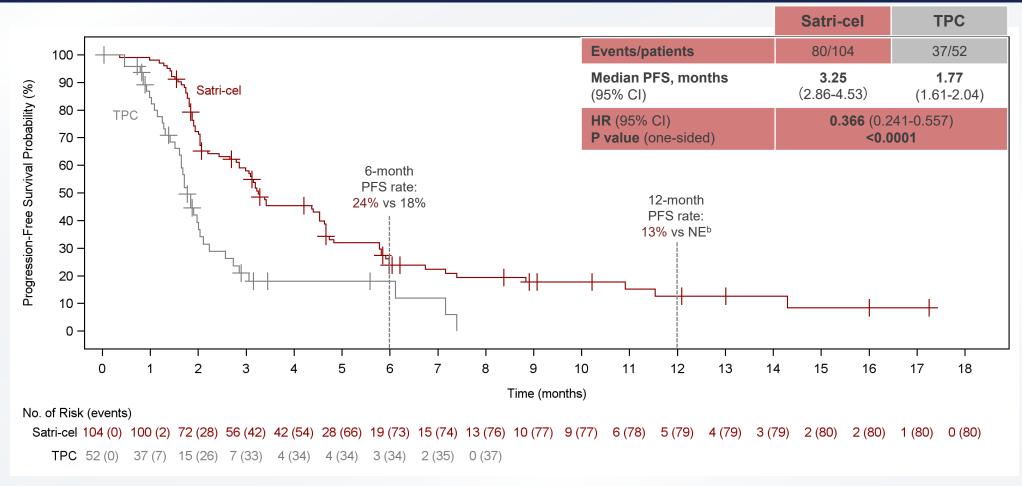
<sup>1.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

<sup>2.</sup> 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 gro

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

Median follow-up: 9.07 months (satri-cel group) vs 3.45 months (TPC group).

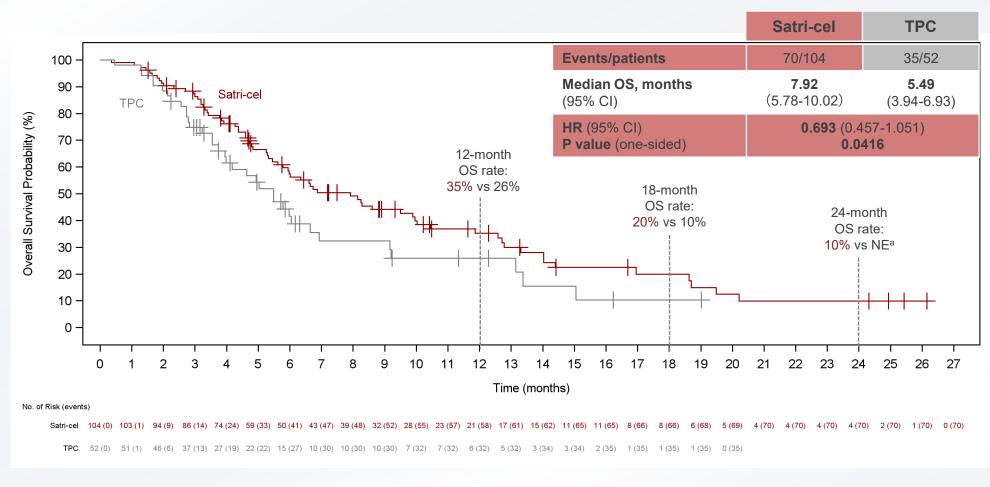
<sup>1.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

<sup>2.</sup> 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.

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

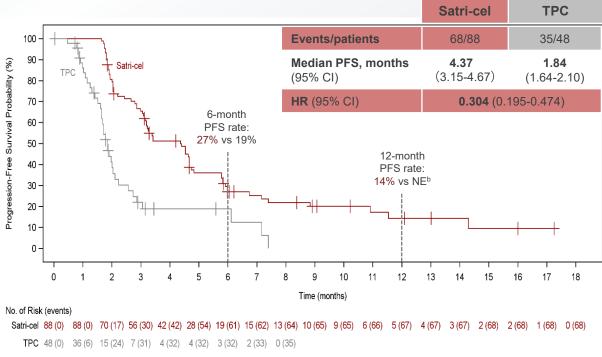
Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

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

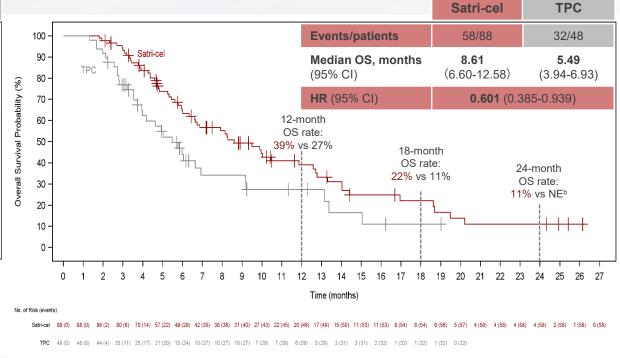


### In treated population (mITT), PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

#### PFS assessed by IRC<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.

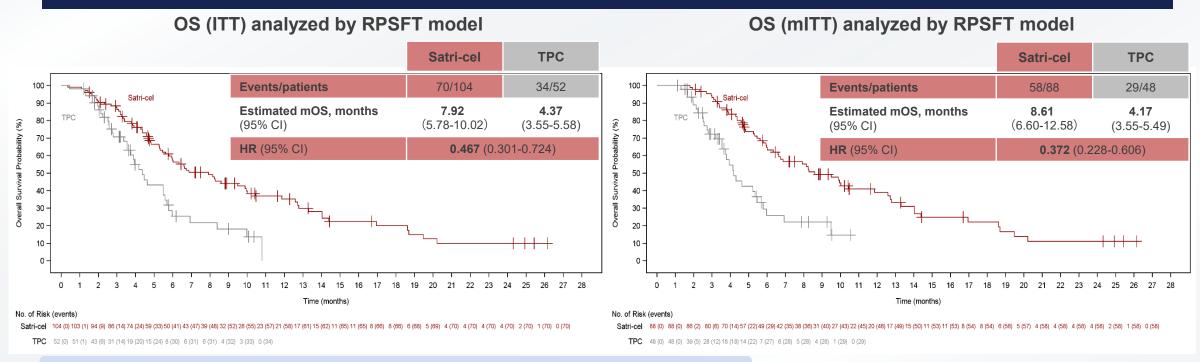
. Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

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 satri-cel, mOS reached 9.17 months (95% CI 6.64–12.58).

<sup>1.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

<sup>2.</sup> 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%) <sup>[1]</sup>	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

<sup>1.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

<sup>2.</sup> 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.

<sup>.</sup> Qi C, et al. ASCO 2025. 2025 May; Oral presentation #4003

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

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



	China investigator-initiated trial (NCT03874897) <sup>1,2</sup>	Phase Ib in China (NCT04581473) <sup>3</sup>	Phase 1b (NCT044	
	ASCO 2024, Nature Medicine	ASCO 2022	ASCO G	il 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	

<sup>\*51</sup> G/GEJA patients with target lesions at baseline received satri-cel monotherapy.

<sup>\*\*59</sup> G/GEJA patients received satri-cel monotherapy.

<sup>\*\*\*</sup>One patient was related to the investigational disease (lung metastasis of GC) and fully recovered after corticosteroids treatment.

Qi C, et al. ASCO 2024. 2024 Jun; Oral presentation #2501
 Qi C, et al. Nat Med (2024). DOI: 10.1038/s41591-024-03037-z2

<sup>3.</sup> Qi C, et. al. ASCO 2022. 2022 Jun; Poster #4017

<sup>4.</sup> 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

### 01 **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 GC 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

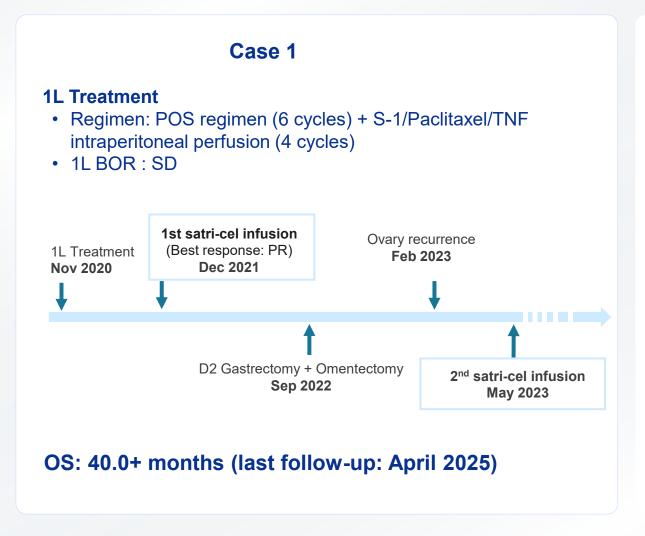
#### **Satri-cel Efficacy Highlights**

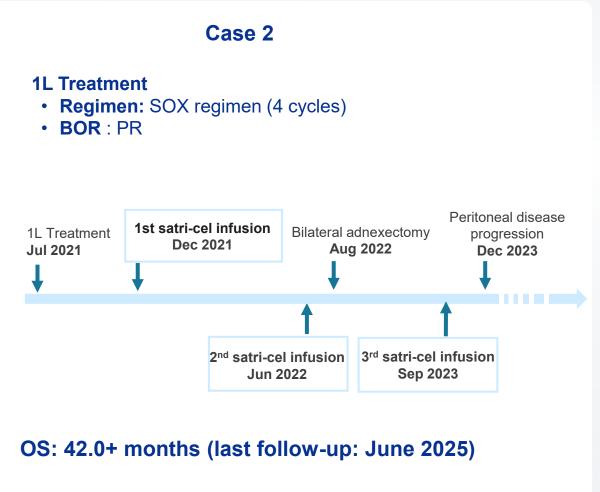
- ORR 100% in 4 patients with target lesions,
   TTR (Time to Response) Week 4
- 1 NN patient remained stable beyond 15 months
- 2 pts subsequently underwent surgical resection after satri-cel infusion, and remain alive until now.

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 GC Patients Underwent Surgical Resection, and Remain in Long-term Survival at the Latest Follow-up







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



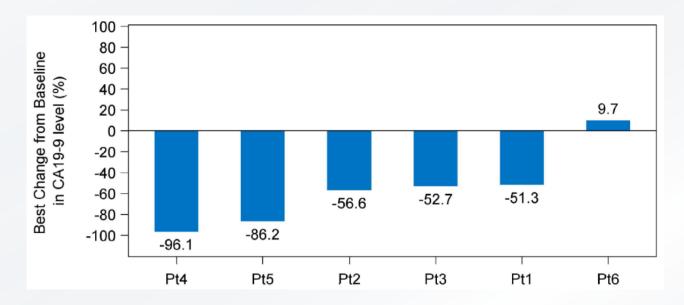
As of April 11, 2025 (data cut-off date), 6 PC patients with median follow-up of 6.05 months:

mDFS, mOS not reached

9-month DFS rate from surgery 83.3%

All patients developed Grade 1 or 2 CRS

No ICANS reported



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



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

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



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

Incidence

~43.5K

~30.9K Mortality

~367.7K Incidence

Mortality ~316.5K

#### **Liver Cancer 5-year survival rate**

	Global <sup>2</sup>	US <sup>3</sup>	China⁴
Liver Cancer, all stages	18%	20%	12%

<sup>1.</sup> International Agency for Research on Cancer. Population factsheets. 2022

<sup>2.</sup> Lin L, et al. *Liver Cancer*. 2020 Sep;9(5):563-582

<sup>3. 2022</sup> American Cancer Society medical information

<sup>4.</sup> 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**

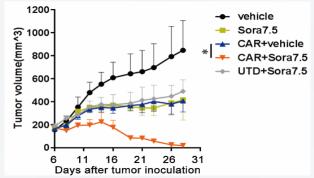
## GPC3 CAR-T in Combination with Small Molecules Against HCC: First publication in *Molecular Therapy*

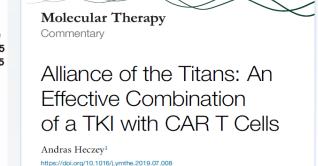


> Mol Ther. 2019 Aug 7;27(8):1483-1494. doi: 10.1016/j.ymthe.2019.04.020. Epub 2019 Apr 29.

#### 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>







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

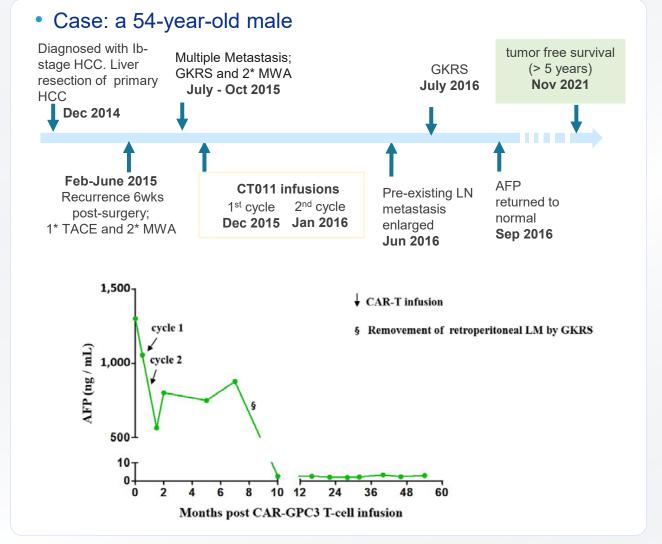








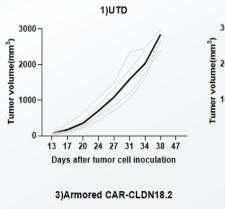
Patients stayed tumor free till latest follow-up on Apr 11, 2025

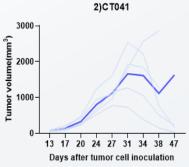


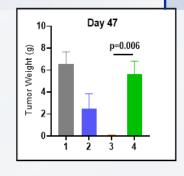
# Next-Gen CAR-T Development: Tackling Key Challenges in Solid Tumors

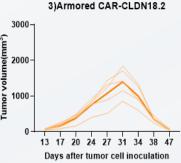


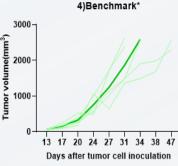
Next-gen Claudin18.2 CAR-T shows enhanced antitumor activity in GC models



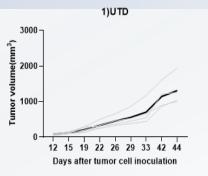


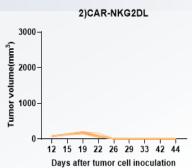


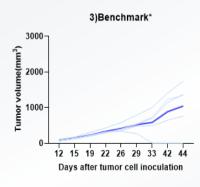


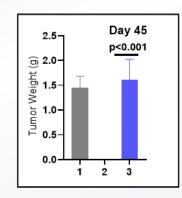


# Next-gen NKG2DL CAR-T shows robust anti-tumor activity in HCC models



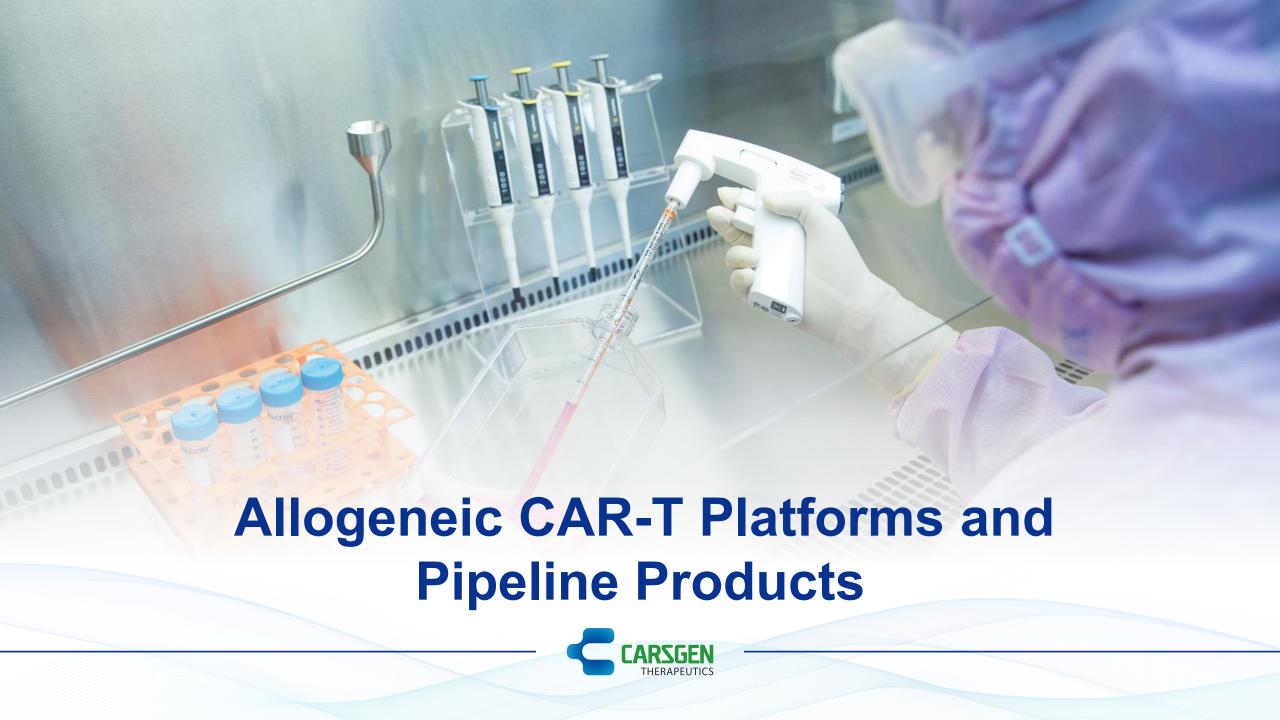






Satri-cel-derived Armored CAR-T demonstrates enhanced therapeutic efficacy

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



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



		Allogeneic BCMA CAR-T Autologous BCMA CAR-T		
Treatment and outcomes	tcomes ALLO-715 P-BCMA-ALLO1 <sup>2</sup> cilta-ce	cilta-cel		
	3.2 x10 <sup>8</sup> cells, N=24 <sup>1</sup>	All Arm**: 0.25-6 x10 <sup>6</sup> cells/kg, N=72	Arm C**:2 x10 <sup>6</sup> cells/kg N=23	0.5-1 x10 <sup>6</sup> cells/kg, N=97 <sup>3</sup>
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****

<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.

<sup>\*\*</sup>Four arms in total, Arm C (cy 750 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10<sup>6</sup> and Arm B (cy 1000 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10<sup>6</sup> , Arm S (cy 300 mg/m²/day +Flu 30 mg/m²/day) P-BCMA-ALLO1 Dose 2 × 10<sup>6</sup> .

<sup>\*\*\*</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.

<sup>\*\*\*\*</sup>Based on a median duration of follow-up of 18 months, mDOR=21.8 months.

<sup>1.</sup> Allogene Therapeutics. 2021. ASH 2021 Presentation. Accessed Nov 5, 2024

<sup>2.</sup> Poseida website news releases of phase 1 early results; Poseida Therapeutics. 2024. International Myeloma Society (IMS) 21st Annual Meeting and Exposition

<sup>3.</sup> 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		
	<b>ALLO-715</b>	cilta-cel	zevor-cel	
	UNIVERSAL Phase I1*	CARTITUDE-1 <sup>2</sup>	LUMMICAR-1 Phase 1 <sup>3</sup>	
Median C <sub>max</sub> (copies/ug gDNA)	6,419*	47,806	202,543	
Lymphodepletion Regimen	<ul> <li>Fludarabine: 30 mg m²*3 days;</li> <li>Cyclophosphamide: 300 mg m²*3days;</li> <li>ALLO-647 mAb**: 13mg/20mg/30mg*3days</li> </ul>	<ul> <li>Fludarabine: 30 mg m²*3 days;</li> <li>Cyclophosphamide: 300 mg m²*3 days;</li> </ul>	Fludarabine: 25 mg m²*3 days; Cyclophosphamide: 300 mg m²*3 days	

<sup>\*</sup>Data from all patients (N=24) receiving the FCA regimen with 3.2 x108 cells.

<sup>\*\*</sup>ALLO-647: A humanized anti-CD52 monoclonal antibody for the depletion of CD52-positive host lymphocytes.

<sup>1.</sup> Mailankody S, et al. Nat Med 29, 422–429 (2023)

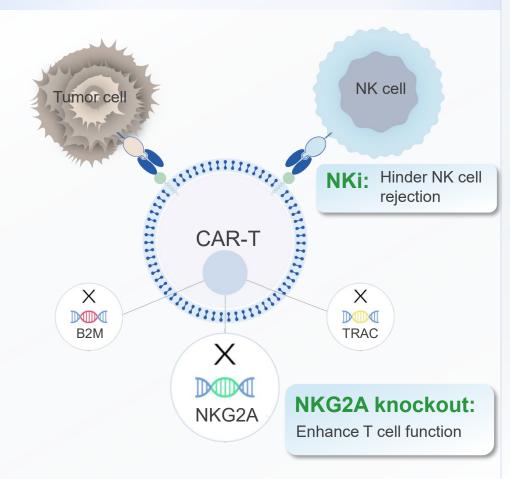
<sup>2.</sup> ciltacabtagene autoleucel [Prescribing Information]. Janssen Biotech

<sup>3.</sup> 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.

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



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

Patient (Diagnosis)	ISS stage	# of prior lines	Refractorine ss to PI/ IMiD*	% Baseline NKG2A expression NK cells	Best overall response	DoR (mo)	Peak CAR copy number (copies/µg gDNA)
PT 1 (MM)	ı	2	1	23	SD	NA	BLQ
PT 1-reinf (MM)	l	2	'	23	30	INA	5,102
PT 2 (MM)	I	2	2	38	sCR	23	482,749
PT 3 (MM)	III	3	2	12	SD	NA	BLQ
PT 4 (MM)		2		NIA	PR	4	PI O
PT 4-reinf (MM)	III 3	2	NA	PR	6.9	BLQ	
#PT 5 (pPCL)	NA	3	2	46	sCR	20	280,863

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



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

<sup>#</sup> This patient was treated under compassionate use

<sup>\* 2</sup> indicates double class refractoriness (to a PI and an IMiD), 1 indicates PT 1 patient refractory to a PI.

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

<sup>1.</sup> Fu C. et al. ASH 2024, 2024 Dec: Poster #4843

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



### **THANK-u Plus™ Platform**

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

#### CT0596

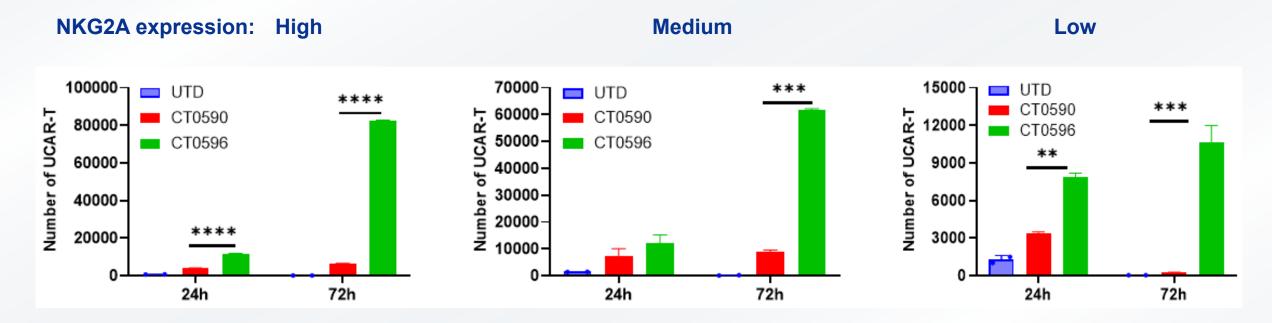
 Based on THANK-u Plus<sup>™</sup>, CT0596—an allogeneic BCMA-targeted CAR-T therapy was developed for the treatment of R/R MM or PCL.

### **Clinical Development**

- CT0596 is under evaluation in an IIT for the treatment of R/R MM or PCL:
- ✓ As of May 6, 2025, 8 patients with R/R MM have been infused.
- 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.

## **Patient Baseline Characteristics in IIT**

### Data Cut-off: June 24, 2025

	Patients (N=8)		
Multiple Myeloma	8 (100%)		
Median Age	63.5		
Immunoglobulin Type at Initial Diagnosis, n (%)			
IgG	2 (25.0%)		
IgA	4 (50.0%)		
κ Light Chain	2 (25.0%)		
R-ISS Stage, n (%)			
I	0		
II	5 (62.5%)		
III	3 (37.5%)		
High-Risk Cytogenetics, n (%)	gh-Risk Cytogenetics, n (%)		
Yes	1 (12.5%)		
No	3 (37.5%)		
Missing	4 (50.0%)		
Extramedullary Disease, n (%)	1 (12.5%)		
Median Prior Lines of Therapy	4.5		
Prior Autologous Stem Cell Transplantation	5 (62.5%)		



### Lymphodepletion Dose

- 6 patients received the full-dose lymphodepletion regimen (i.e., fludarabine 30 mg/m²/day and cyclophosphamide 500 mg/m²/day for 3 consecutive days, as per protocol).
- 2 patients had their lymphodepletion doses adjusted due to investigator concerns about potential severe hematological toxicity or pre-existing impaired creatinine clearance. The specific adjustments were as follows:
  - ✓ 1 patient: cyclophosphamide dose reduced by 30% only, with fludarabine dose unchanged.
  - 1 patient: both fludarabine and cyclophosphamide doses reduced by 25%.

#### Cell Infusion Dose

 $1.5 \times 10^{8}$  cells dose cohort: 1 patient

 $3.0 \times 10^{8}$  cells dose cohort: 5 patients

 $4.5 \times 10^{8}$  cells dose cohort: 2 patients

## **CT0596 Demonstrated a Manageable Safety Profile**



- Cytopenias were reported in all 8 patients.
- Grade ≥3 treatment-related cytopenias:
  - ✓ Lymphopenia: [n=8]
  - ✓ Neutropenia: [n=7]
  - ✓ Leukopenia: [n=8]
  - ✓ Thrombocytopenia: [n=3]
- Four patients experienced Grade 1 CRS, with no Grade 3 or higher CRS observed.
- The time to CRS onset was 2 (range: 1-8) days post-infusion, with a median duration of 6 (range: 2-10) days.
- No cases of ICANS or GvHD were observed.
- No DLTs, no study discontinuation due to AE, no deaths due to AE.

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

## CT0596 Induced Deep and Durable Responses



- All 8 infused patients were all evaluable for efficacy, with the median follow-up of 2.56 months (range: 0.9-5.9).
- 5 patients achieved PR or above: 3 CR/sCR (all 3 received full lymphodepletion dose), 1 PR, and 1 VGPR.
- 4 out of 6 patients with full lymphodepletion dose achieved PR or above. 6 patients achieved MRD-negativity at Week 4.
- Hematological responses deepened over time in MRD-negative patients. No patients got progression disease. Furthermore, Patient 01 has maintained sCR and MRD-negative for nearly 6 months.

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



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

	pPCL-01	pPCL-02	
Patient	62-year-old male, IgG-λ type	70-year-old male, κ light chain type	
Prior Therapies	ASCT + triple classes of drugs (PI, IMiD, CD38 mAb)	Triple classes of drugs (PI, IMiD, CD38 mAb)	
CAR-T Treatment	Two infusions, ~2 months apart	Single infusion	
Safety	Grade 2 CRS, Grade 4 cytopenia, lung infection	Grade 1 CRS, Grade 4 neutropenia and thrombocytopenia	
Pharmacokinetics	C <sub>max</sub> : <b>161,971</b> copies/μg gDNA; Maintained at 10³ by Week 8	C <sub>max</sub> : <b>151,654</b> copies/µg gDNA	
Efficacy	Achieved <b>sCR</b> at Week 4 & 8; bone marrow MRD-negative (<10 <sup>-6</sup> ) at Week 4	Achieved <b>sCR</b> at Week 4, 8, & 12; bone marrow MRD-negative (<10 <sup>-6</sup> ) at Week 4 & 12	

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

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



#### **THANK-u** Plus™ Platform

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

#### CT1190B

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

### **Clinical Development Progress and Plans**

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

### **Enrollment of CT1190B IIT**



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

### **Lymphodepletion Dose Exploration Phase:**

- 3 FL patients (Cell dose: 3.0 × 10<sup>8</sup>: 1 patient; 4.5 × 10<sup>8</sup>: 2 patients)
- 2 DLBCL patients (Cell dose: 1.5 × 10<sup>8</sup>: 1 patient; 4.5 × 10<sup>8</sup>: 1 patient)
- 1 MCL patient (Cell dose: 4.5 × 10<sup>8</sup>: 1 patient)

# Recommended Lymphodepletion Dose: Fludarabine 30 mg/m²/day for 3 days + Cyclophosphamide 1000 mg/m²/day for 2 days

- 2 MCL patients (Cell dose: 6.0 × 10<sup>8</sup>)
- 6 DLBCL patients (Cell doses: 3.0 × 10<sup>8</sup>: 1 patient; 4.5 × 10<sup>8</sup>: 1 patient;
   6.0 × 10<sup>8</sup>: 4 patients)

## **CT1190B Demonstrated Efficacy and Safety**



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

- > Lymphodepletion Regimen: Fludarabine 30 mg/m<sup>2</sup> × 3 days + Cyclophosphamide 500 mg/m<sup>2</sup> × 3 days
- All three FL patients achieved CR, resulting in an ORR of 100% and a CRR of 100%. One FL patient had failed immunochemotherapy, a PI3K inhibitor, chemotherapy + autologous HSCT, and CD3/CD20 bispecific antibody therapy. Another FL patient had failed immunochemotherapy + autologous HSCT and CD19 CAR-T therapy. The peak expansion copy number reached 10³-10⁴ copies/µg gDNA.

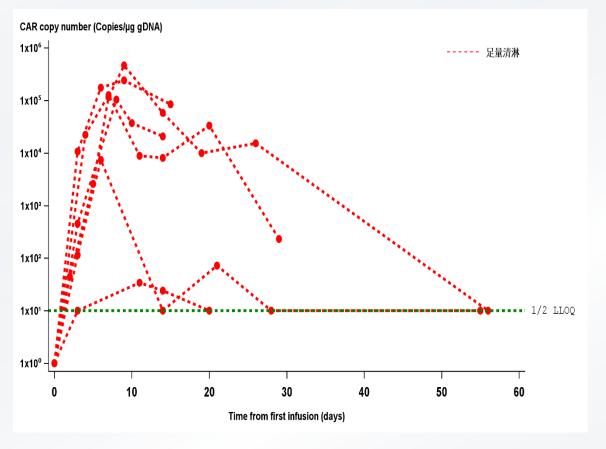
## > Lymphodepletion Regimen: Fludarabine 30 mg/m<sup>2</sup> × 3 days + Cyclophosphamide 1000 mg/m<sup>2</sup> × 2 days

- 8 patients were enrolled under this regimen, including 2 MCL patients (cell dose: 6 × 10<sup>8</sup>) and 6 DLBCL patients (cell doses: 3 × 10<sup>8</sup>: 1 patient; 4.5 × 10<sup>8</sup>: 1 patient; 6 × 10<sup>8</sup>: 4 patients).
  - ✓ 6 patients were evaluable for efficacy, showing an ORR of 83.3% and a CRR of 66.6%, including 4 CR and 1 PR. Two DLBCL patients infused with 6×10° cells had not reached the efficacy assessment timepoint.
  - ✓ Both MCL patients achieved CR. Among the DLBCL patients: 2 achieved CR, 1 achieved PR (this patient had failed autologous CD19 CAR-T manufacturing), and 1 had PD. The two DLBCL patients not yet evaluable for efficacy showed a peak expansion of 10⁵ copies/µg gDNA.
  - ✓ In the 6 × 10<sup>8</sup> cell dose cohort (4 patients), 3 achieved CR.

## Pharmacokinetics at the Recommended Dose



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



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

## Registration and Development Plan for CT0596 and CT1190B



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

#### **CT0596**

- Potential Indications: R/R PCL, R/R MM
- Planned initiation of Phase IB registration study in 2026
- Planned initiation of pivotal registration study in 2027

#### CT1190B

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

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



## **Experienced Senior Management Team**





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







Huamao Wang, PhD Co-founder and COO



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