CARSGEN THERAPEUTICS

Key Technological R&D to Overcome Challenges in CAR-T Therapy Development

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CARsgen Therapeutics (Stock Code: 2171.HK)

Making Cancer Curable

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Content

- Underlying Rationale and Establishment of the THANK-u Plus™ Technology Platform
- Next-Generation Technology Platform for Solid Tumors
- Application Potential of LADAR® Technology
- New Allogeneic Pipeline and Its Preclinical Studies

Allogeneic CAR-T Platforms

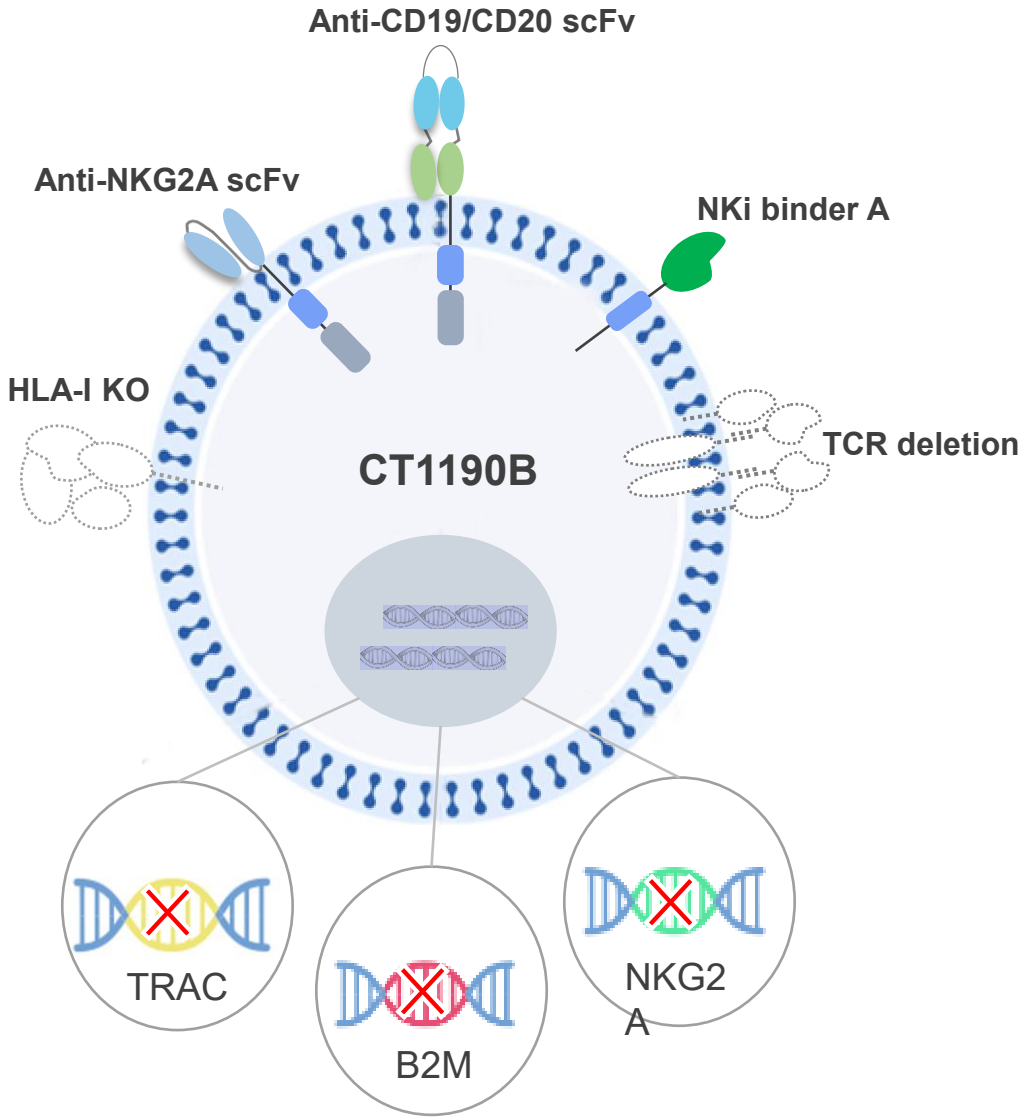
Company	CARsgen Therapeutics	Allogene Therapeutics	Poseida Therapeutics	Caribou Biosciences	Bioheng Therapeutics	SANA Biotechnology	BRL Medicine	Crispr Therapeutics
Technology	TCR+HLA-I+/-2 +/- NKG2A KO+Nki Binder+NK-targeted CAR	TCR+CD52 KO, CD52 antibody may be required in lymphodepletion.	TCR +B2M KO	Approach 1: TCR+PD-1 KO, combined with a more intensive lymphodepletion regimen; Approach 2: TCR+B2M KO + HLA-E, HLA matching may be required	TCR+HLA-I/II KO，Nki Binder	TCR+HLA-I/II KO +CD47	TCR+HLA A/B，HLA-II，PD-1 KO+PD-L1 ECD	TCR+B2M+ Regnase-1+TGFbR2 KO

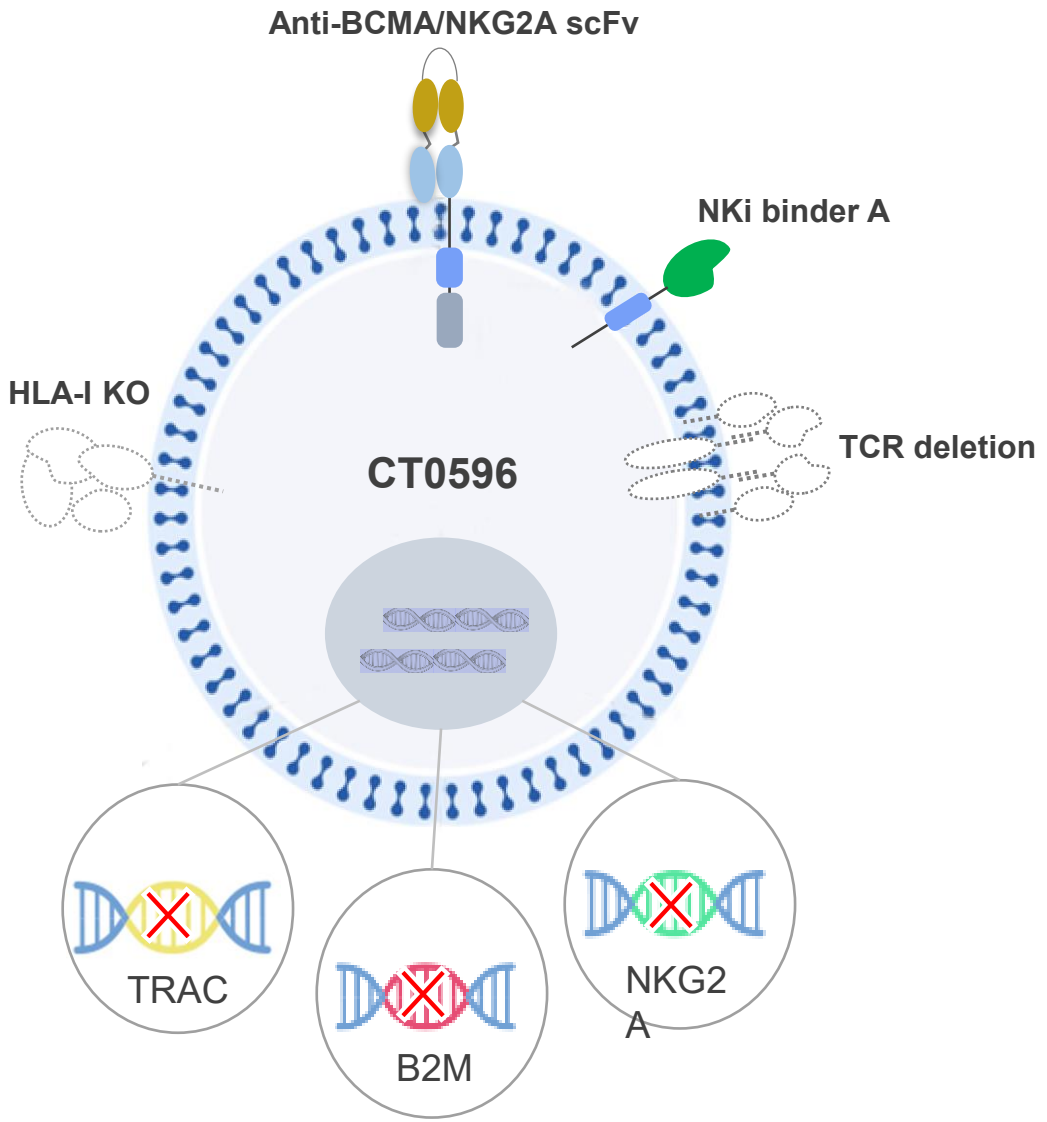
KO: Knock-out; Nki: NK inhibitor; B2M KO and HLA-I KO have the same meaning.

Insights from CT0590 Clinical Data

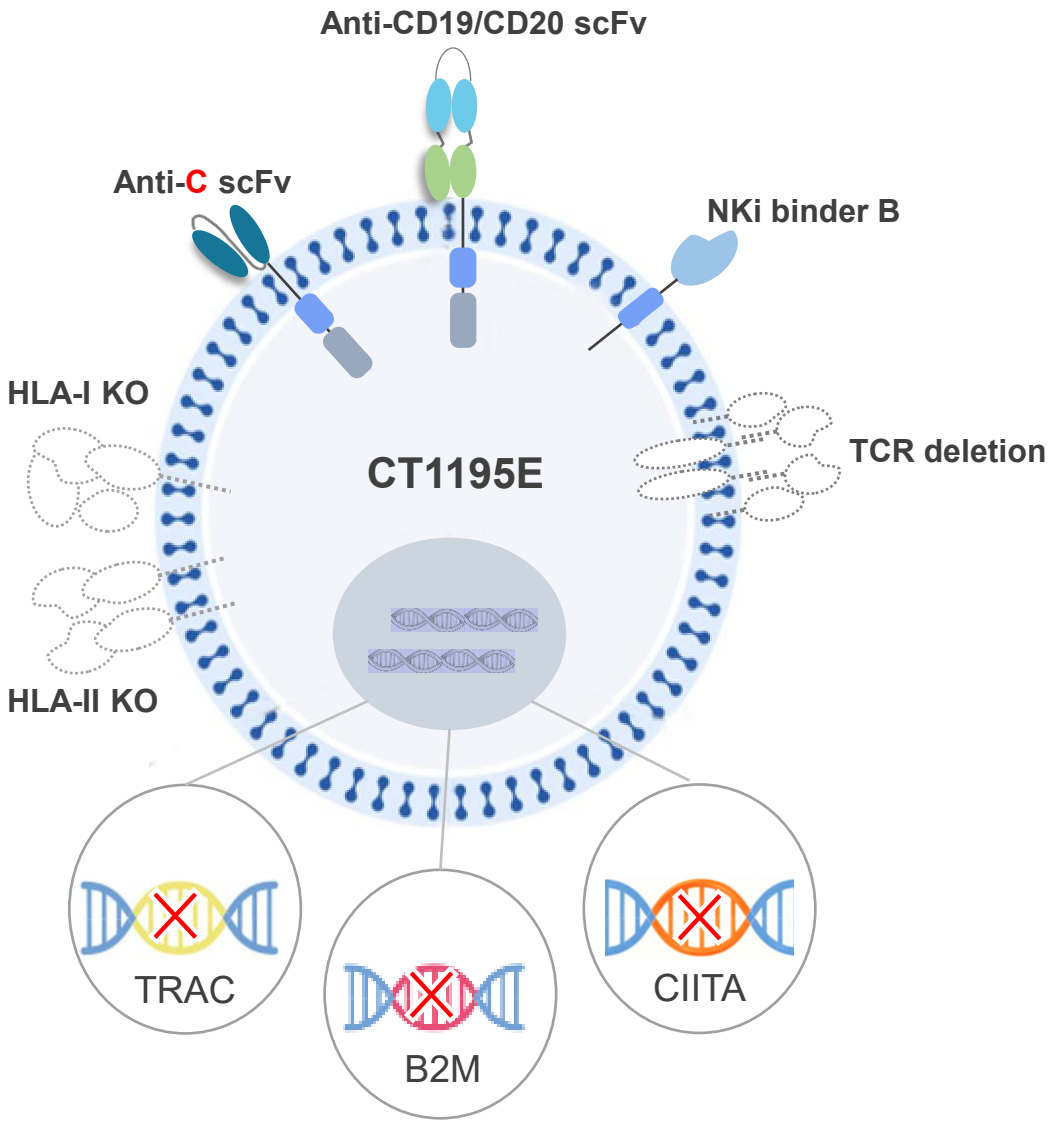
- NKG2A CAR-T cells showed robust expansion in two patients, but failed to expand in two others—one of the patient achieved expansion only after a dose escalation. This suggests that a CAR targeting only NKG2A may be insufficient to induce robust expansion in all patients.
- In patients with strong expansion, the durability of response is at least comparable to that of autologous CAR-T therapy.
- The expression level of NKG2A may influence the efficacy.
- What other reasons could be involved?
- Cryopreserved, thawed cells administered in vivo might face rapid clearance by NK cells. Adding a blocker to create a "buffer" could be a strategy to further enhance the anti-rejection effect.
- The second strategy is to improve the recognition of NK cells. Identify an antigen with broader expression than NKG2A to clear NK cells more effectively .

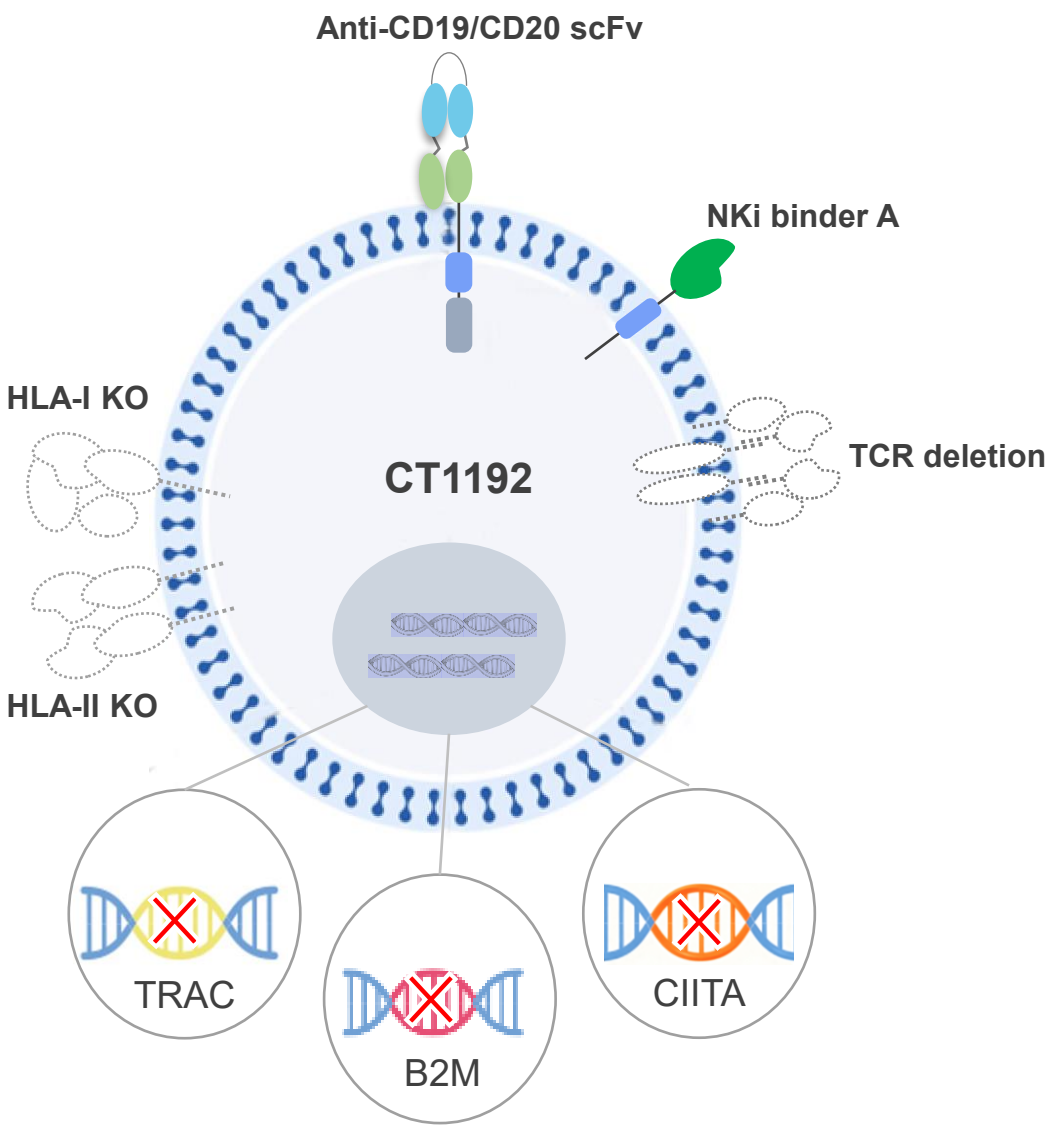
CARsgen's Novel Strategy for Allogeneic CAR-T



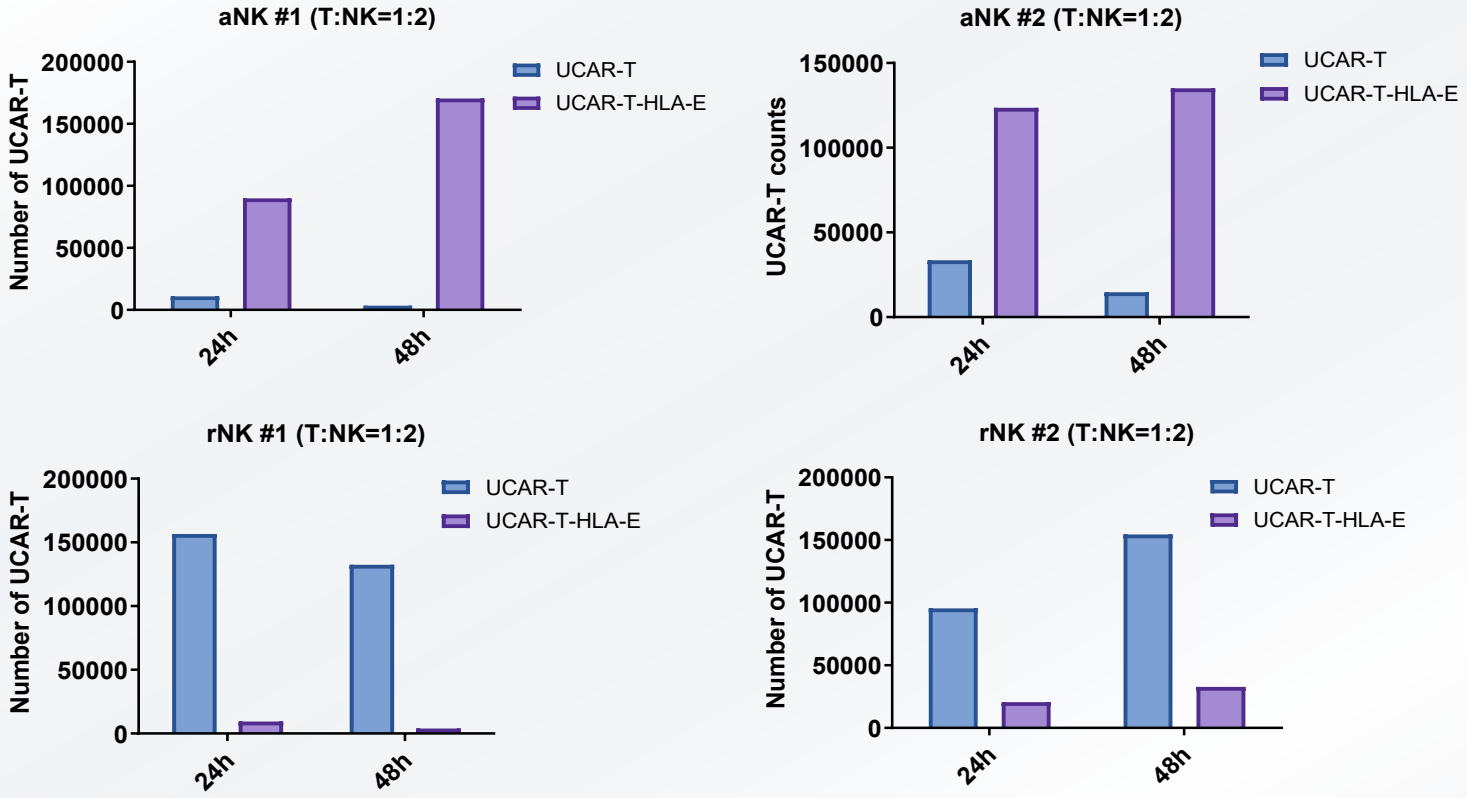


CARsgen's Novel Strategy for Allogeneic CAR-T



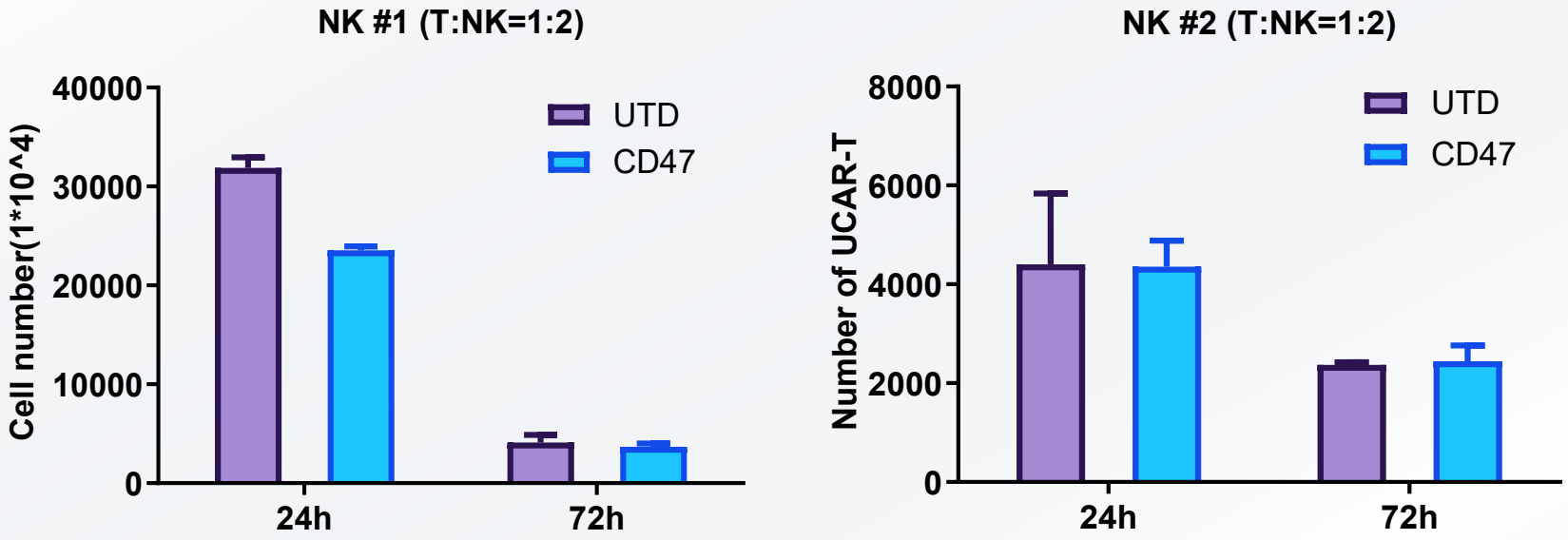


Goal 1: To Identify a Potent Blocker for Activated NK Cells



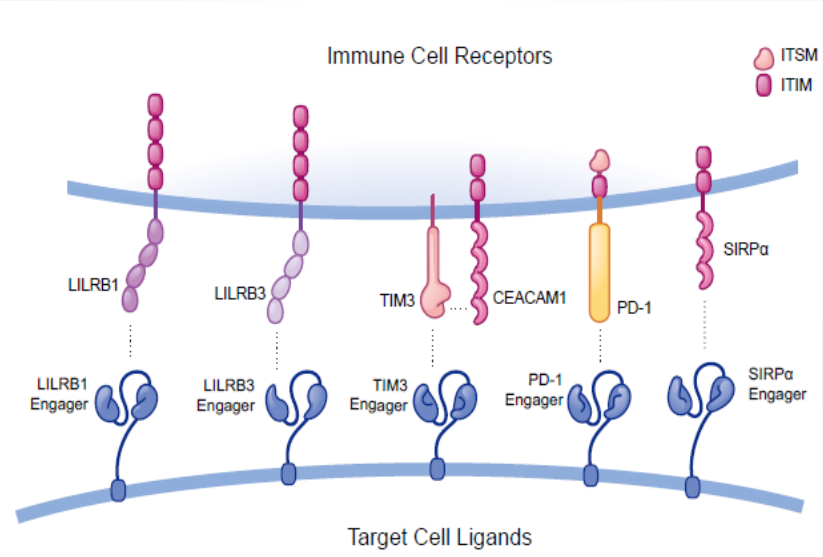
While HLA-E overexpression in UCAR-T cells confers some resistance to activated NK cells, it potentially enhances their clearance by resting NK cells.

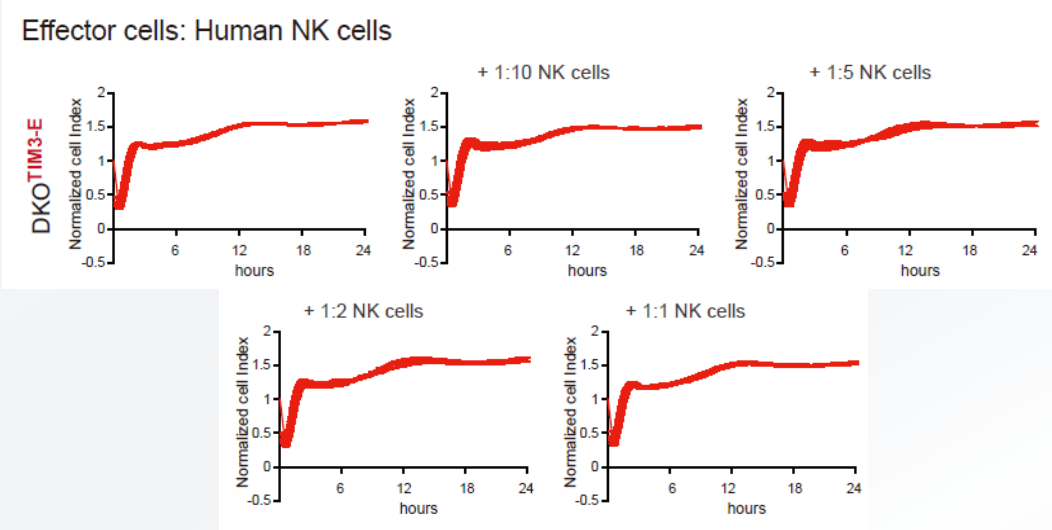
T Cells Overexpressing CD47 are Ineffective in Resisting NK Cell Rejection



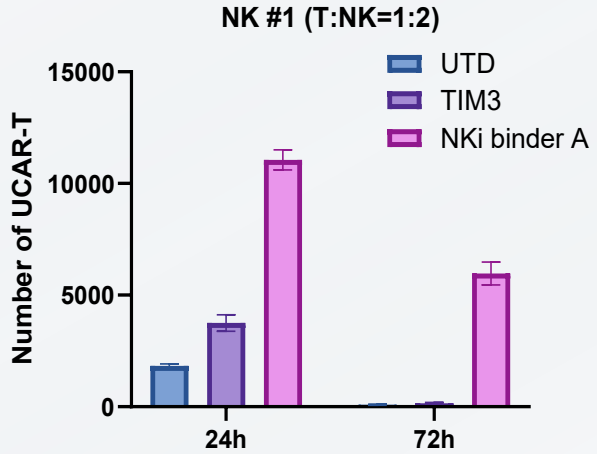
In co-culture assays with NK cells at 24 and 72 hours, CD47-overexpressing T cells did not demonstrate a significant enhancement in resistance to NK cell-mediated killing.

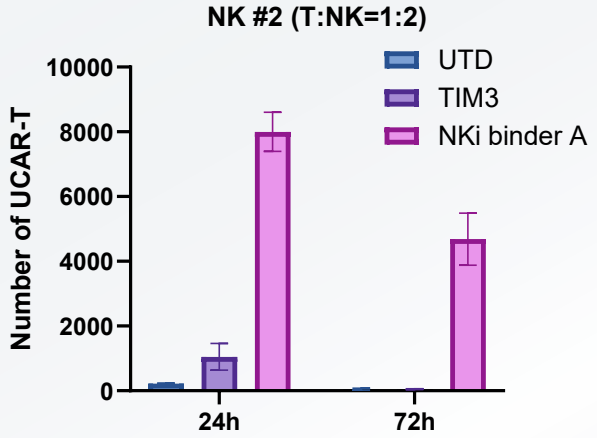
NKi Binder A Confers Strong Protection to Allogeneic CAR-T Cells Against NK Cell-Mediated Rejection

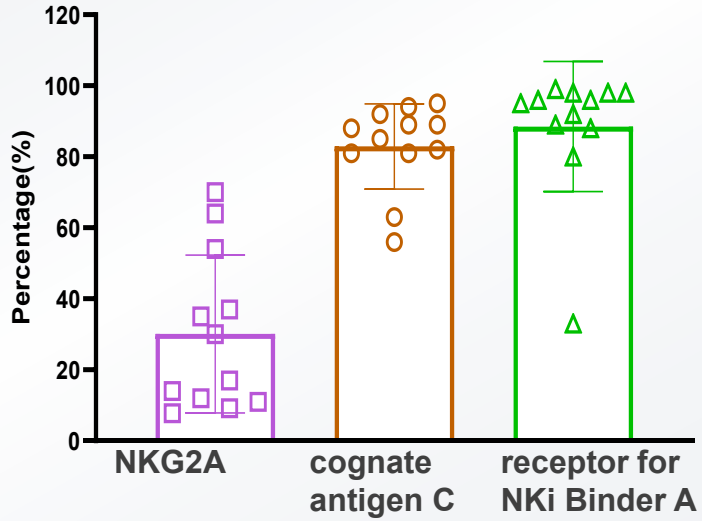




Cell Stem Cell . 2023;30(11):1538-1548.e4



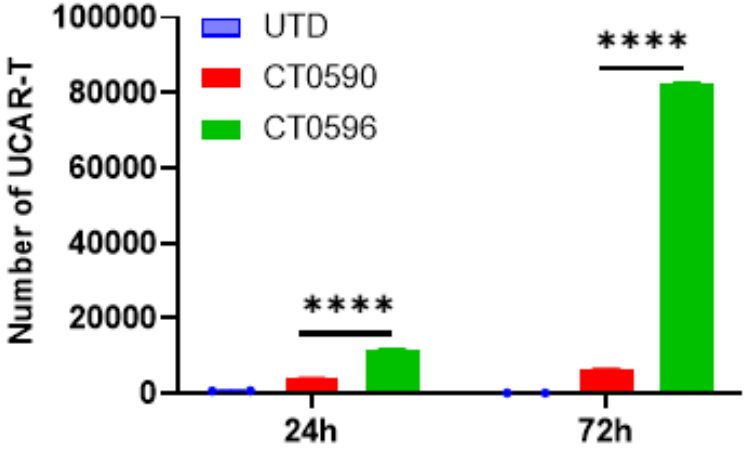




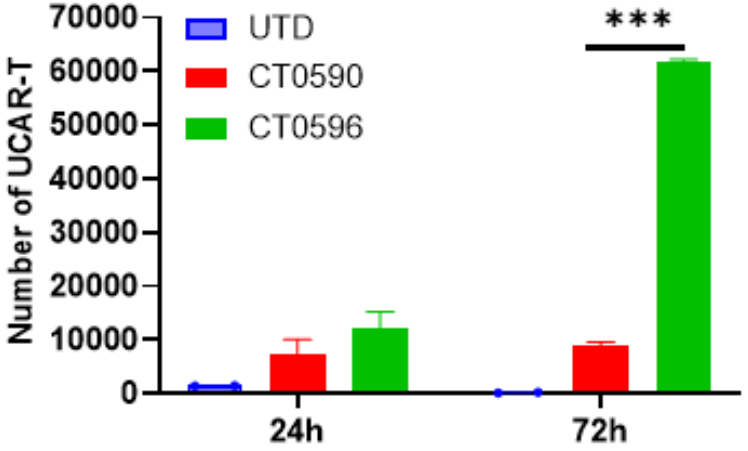
The receptor for NKi Binder A and its cognate antigen C are highly expressed on the surface of NK cells (as validated in NK cells from 12 donors).

Robust and Sustained Expansion of U-CART Across Varying NKG2A Expression Levels Achieved by a Combination of NKi Binder A and an NKG2A CAR

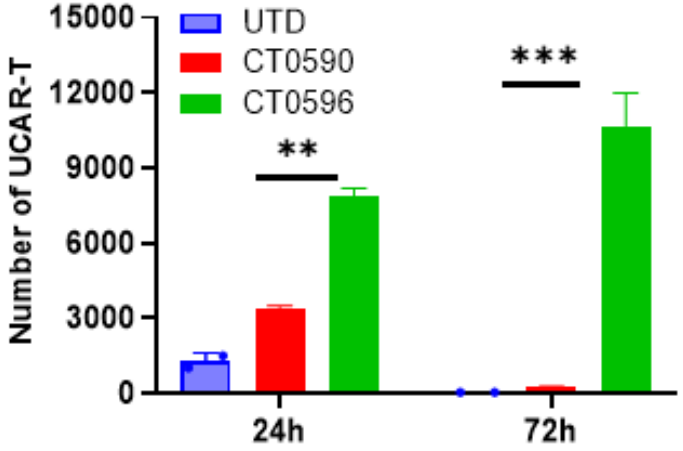
High NKG2A expression



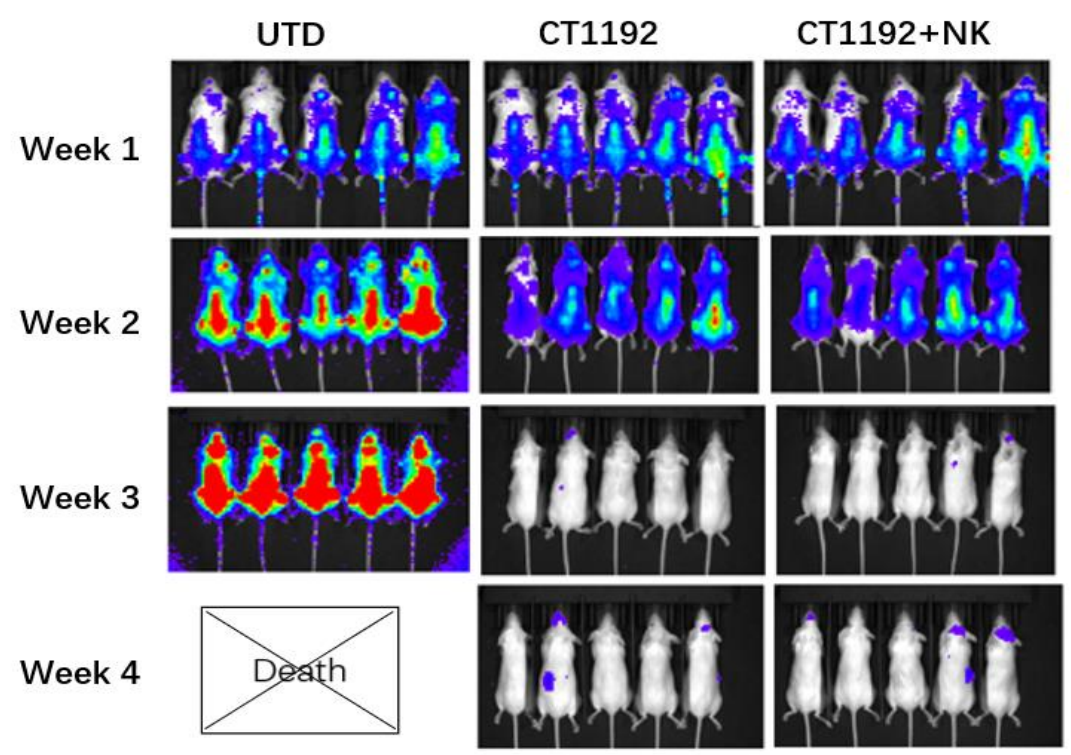
Moderate NKG2A expression

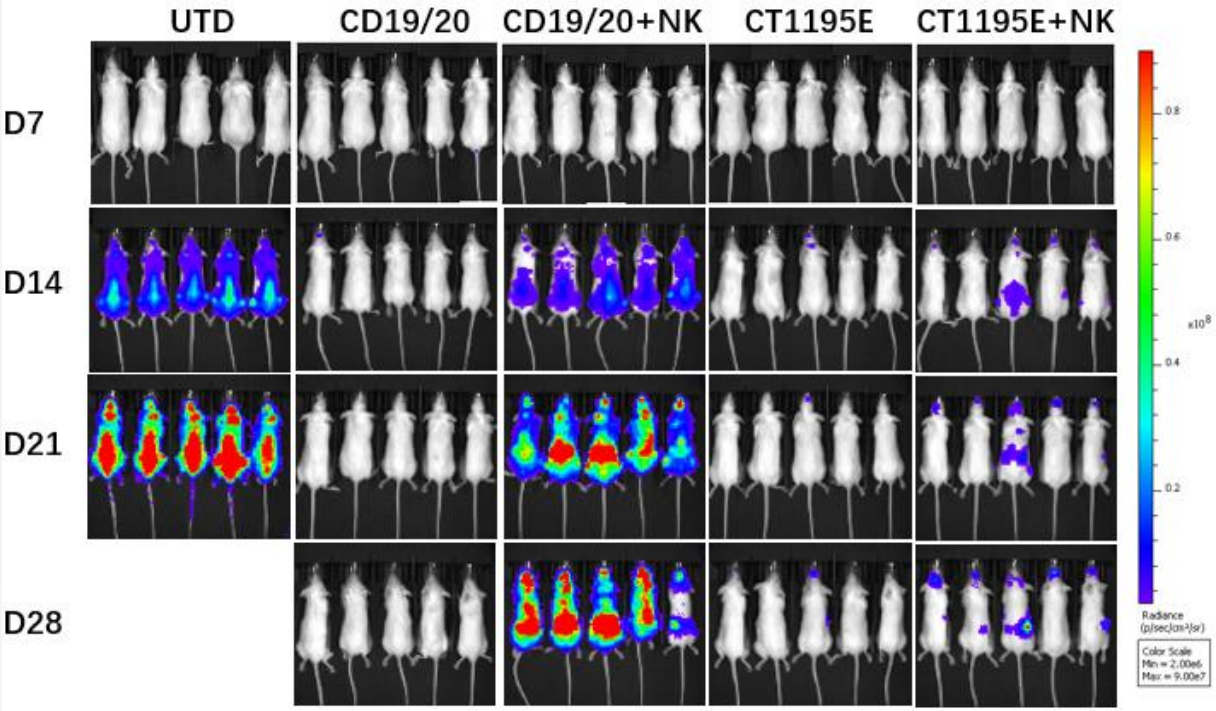


Low NKG2A expression



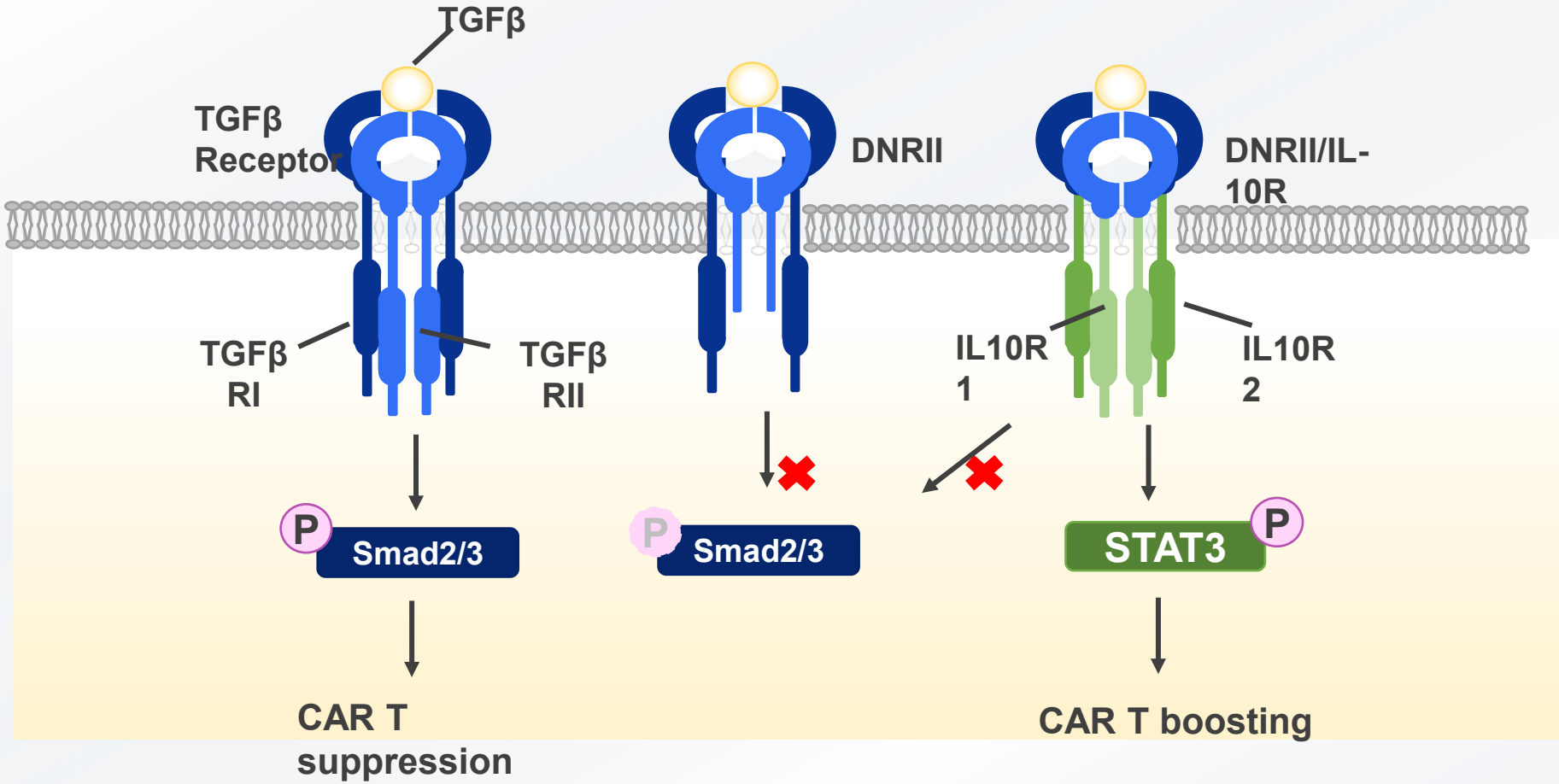
Both CT1192 and CT1195E Demonstrate Robust NK Cell Resistance and Anti-Tumor Efficacy





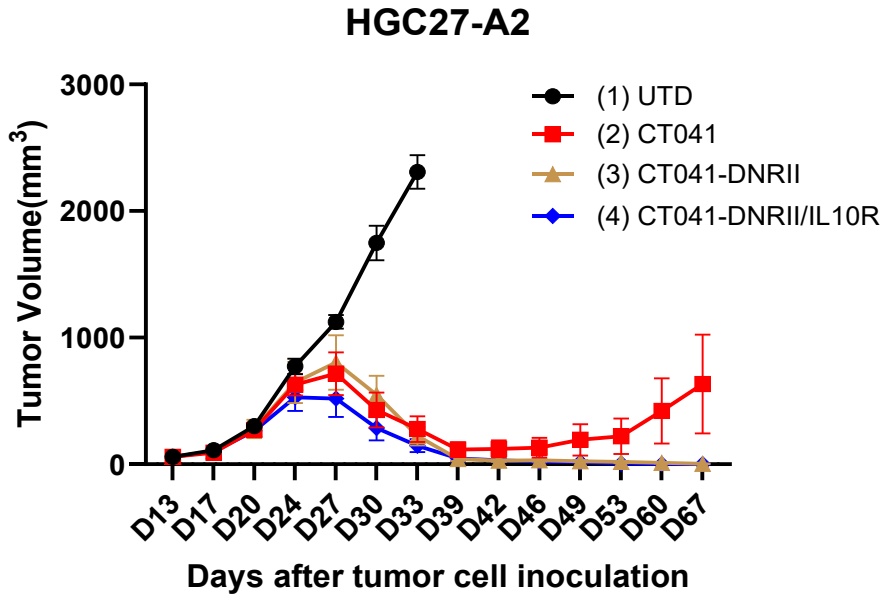
Novel Technologies and Strategies for Solid Tumors

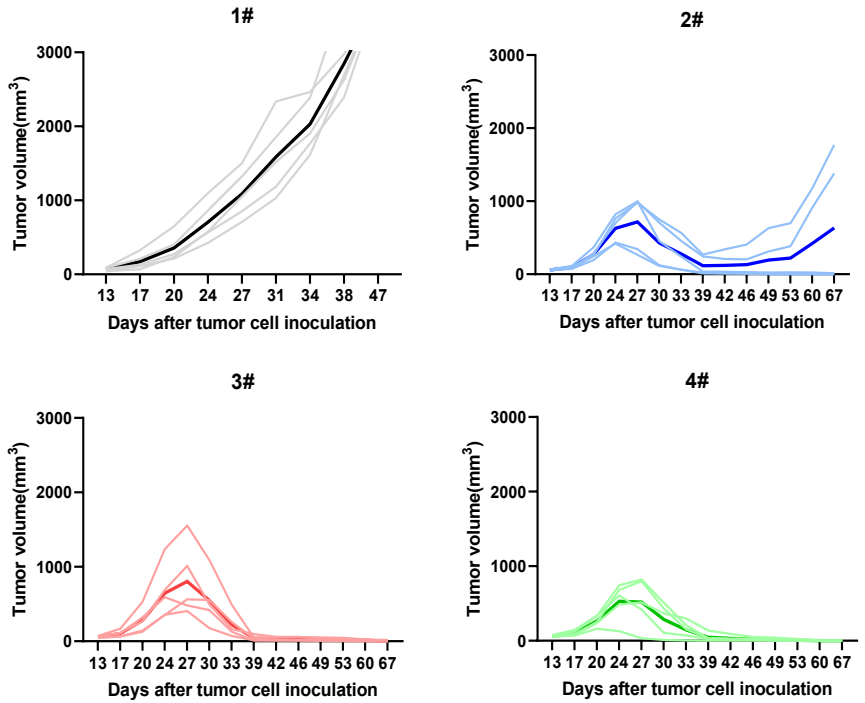
Zhao Y, et al. IL-10-expressing CAR T cells resist dysfunction and mediate durable clearance of solid tumors and metastases. Nat Biotech, 2024

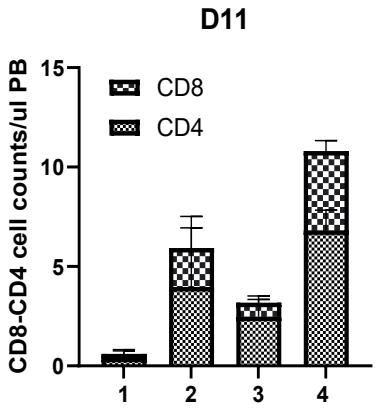


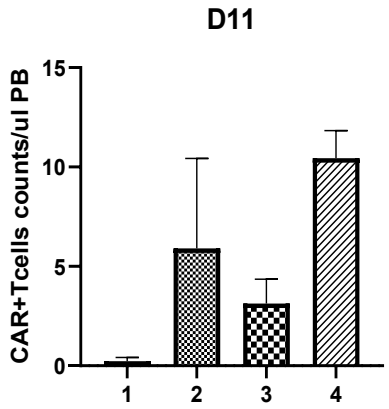
Schematic Diagram of the TGFβII/IL-10R Converter

In Vivo Efficacy of Different-Generation CLDN18.2-Targeting CAR-T Cells in Tumor-Bearing Mice





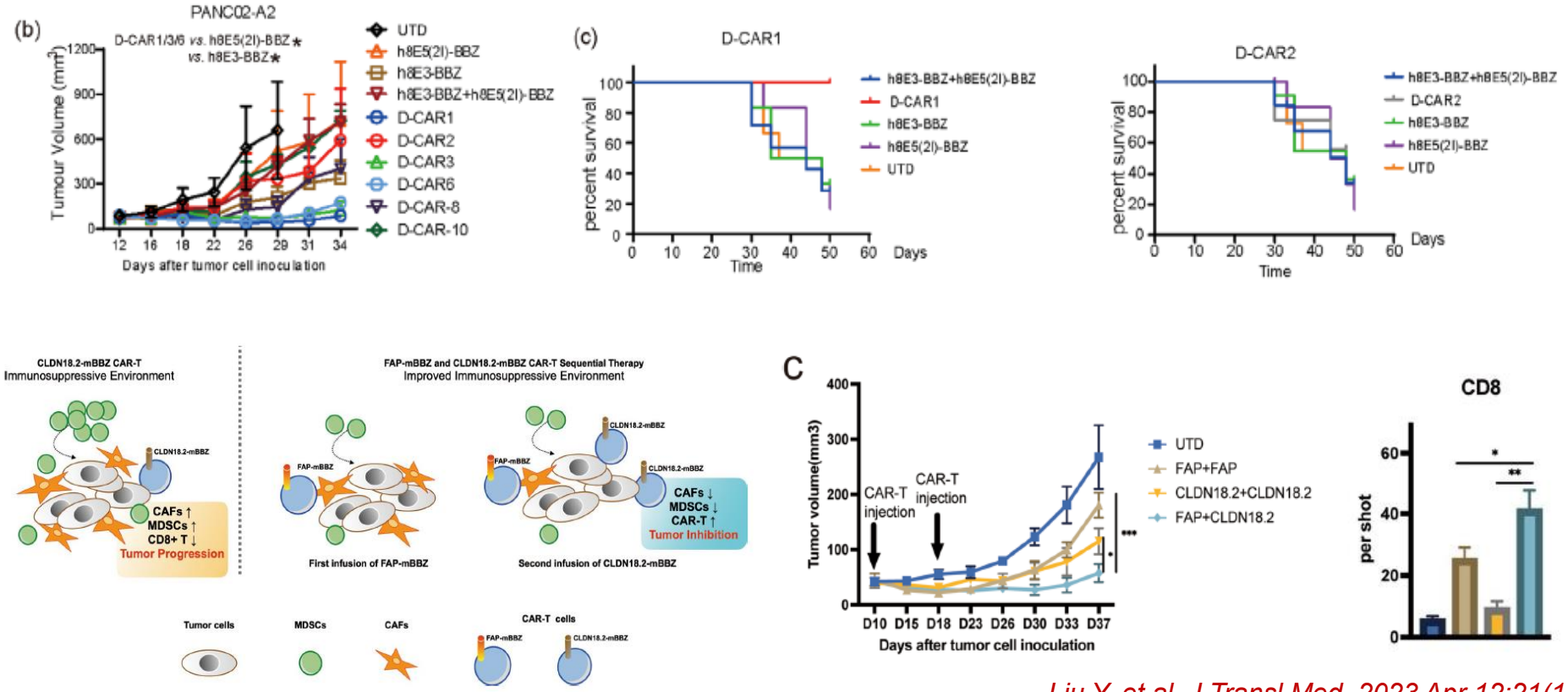




1. UTD
2. CT041
3. CT041-DNRII
4. CT041-DNRII/IL10R

Targeting Cancer-Associated Fibroblasts to Potentiate CAR-T Cell Efficacy in Solid Tumors

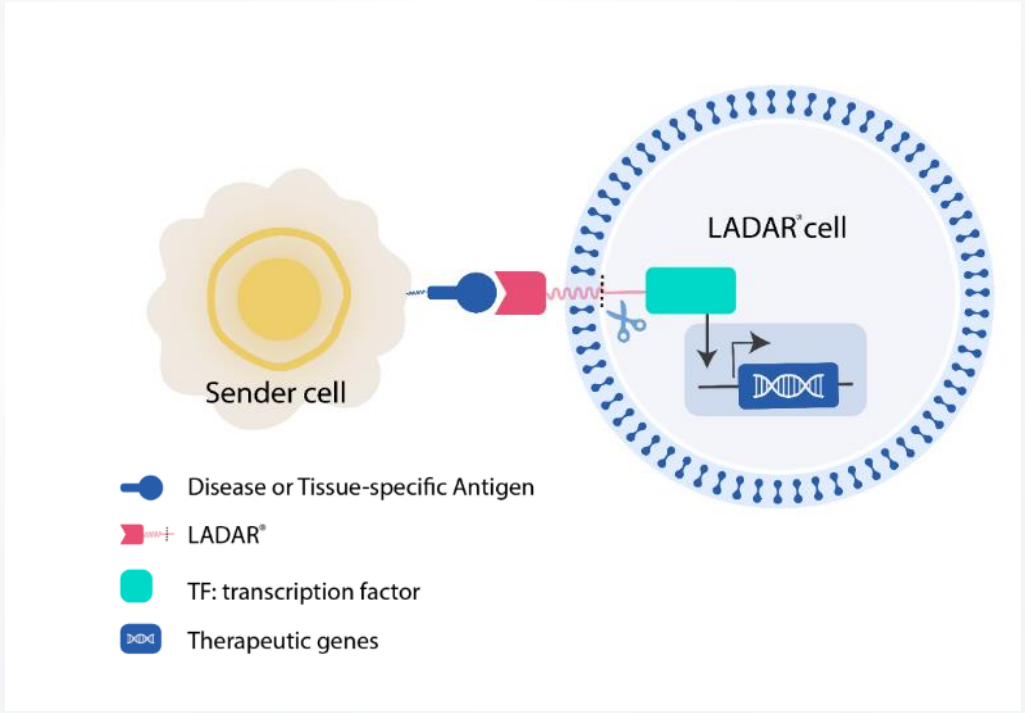
Addressing fibroblasts in the tumor microenvironment represents a promising strategy to unlock the therapeutic potential of CAR-T cells and other agents. FAP (Fibroblast activating protein alpha)

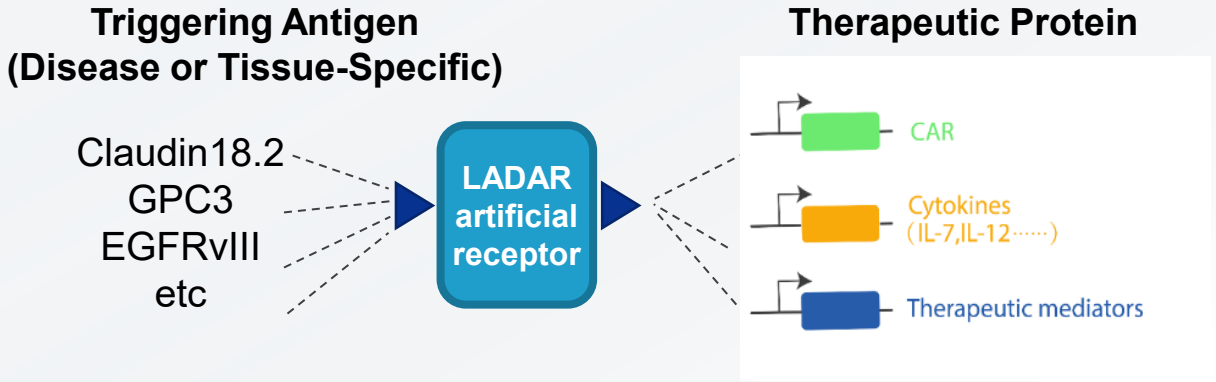


Liu Y, et al. J Transl Med. 2023 Apr 12;21(1):255.

Sun R, et al. Br J Pharmacol. 2024 Nov;181(22):4628-4646.

LADAR®: Technology Platform for Precise Targeting





LADAR® Technology
Local Action Driven by Artificial Receptor

LADAR®, like SynNotch , induces the expression of a therapeutic protein in the presence of its specific triggering antigen. This leads to localized activity of the therapeutic protein, thereby:

- Significantly **reducing the risk of side effects**, such as on-target, off-tumor toxicity.
- Having the potential to **unlock more targets for cell therapy.**

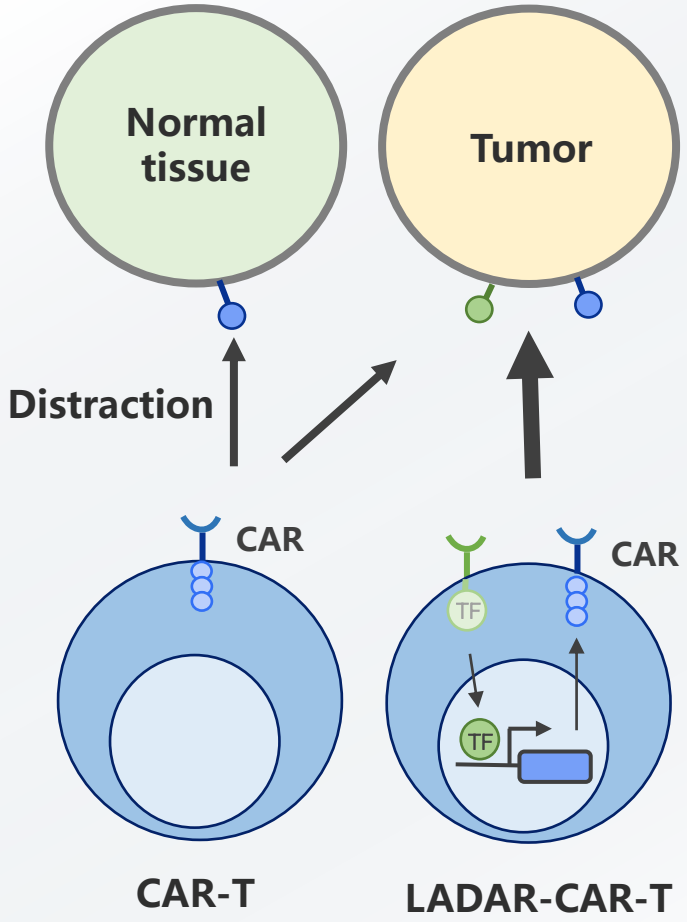
Advantages Over SynNotch*:

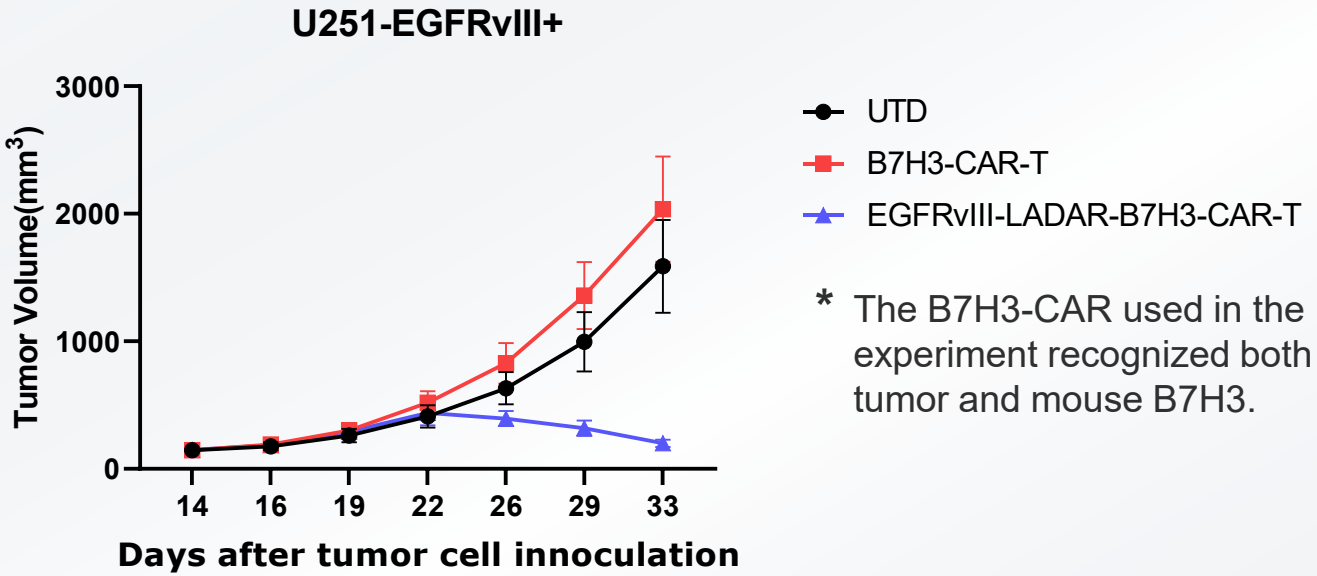
- **LADAR® is significantly smaller than SynNotch (saving over 200 amino acids in extra space)**, enabling the accommodation of larger therapeutic proteins, such as next-generation CARs.
- **Markedly improved sensitivity** to low levels of triggering antigen expression.

LADAR® for Localized CAR and Therapeutic Protein Expression

Applications of the LADAR system in CAR-T therapies

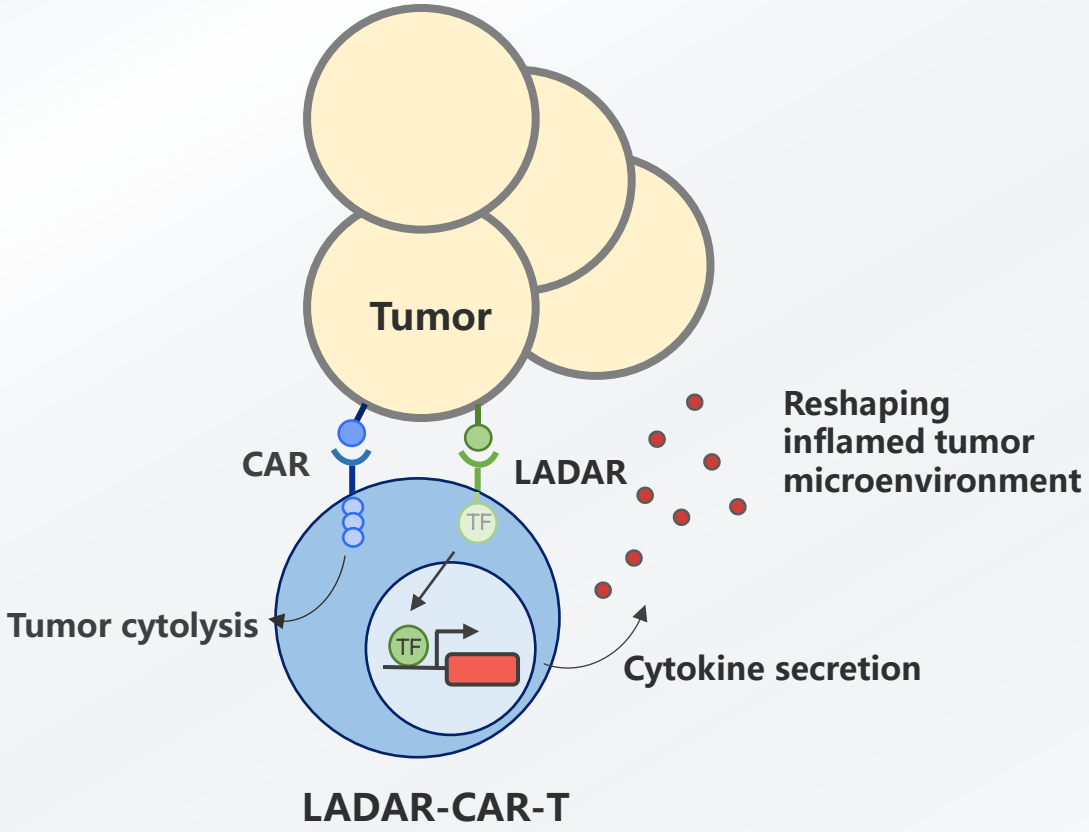
Dual receptor AND-gate LADAR-CAR-T cells with precise tumor killing (*in vivo* effects)

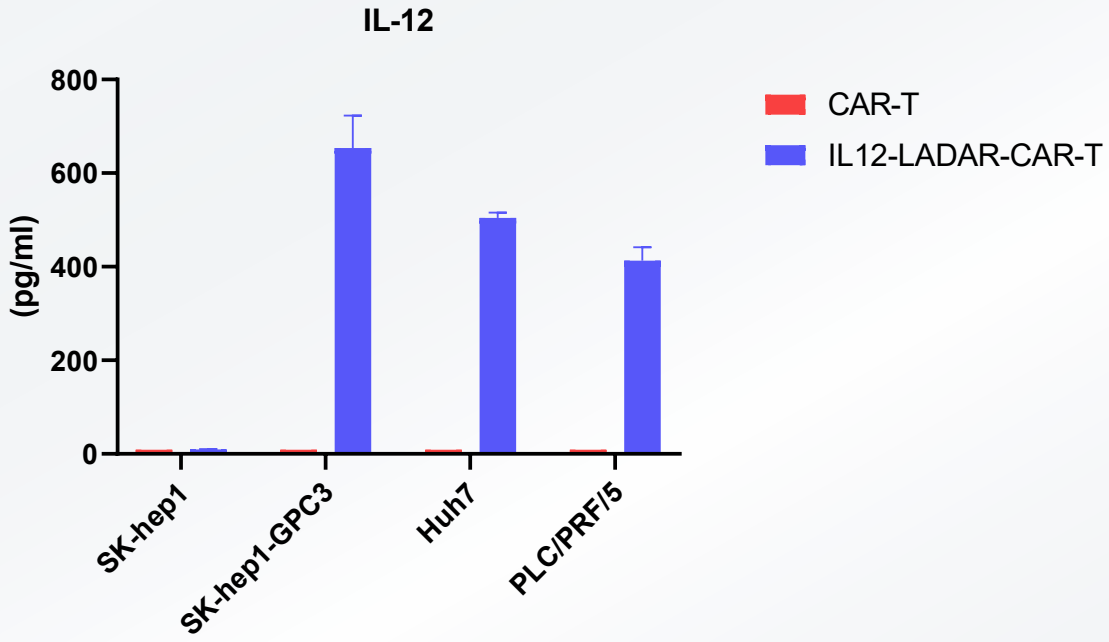




* The B7H3-CAR used in the experiment recognized both tumor and mouse B7H3.

LADAR® Enables Precise, Localized Expression of Cytokines and Other Therapeutic Proteins





Allogeneic CAR-T Candidates for Multiple Targets

CAR-T for solid tumors： CLDN18.2, GPC3, DLL3, B7H3, FAP, NKG2DL…

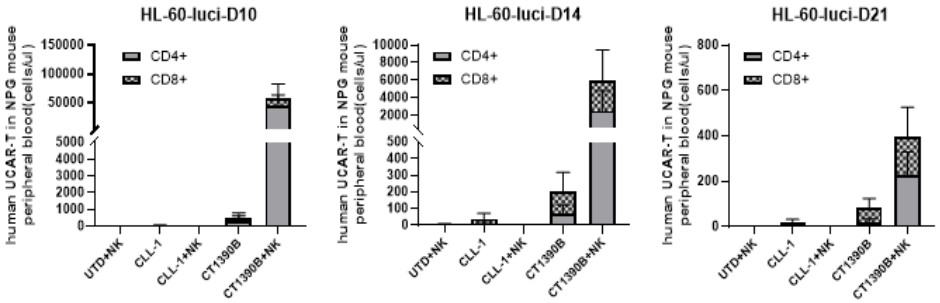
CAR-T for hematologic malignancies： NKG2DL， CLL1, CD19/BCMA,BCMA/GPRC5D, CD19/CD20…

CAR-T for autoimmune diseases： CD19/CD20, CD19/BCMA, BCMA

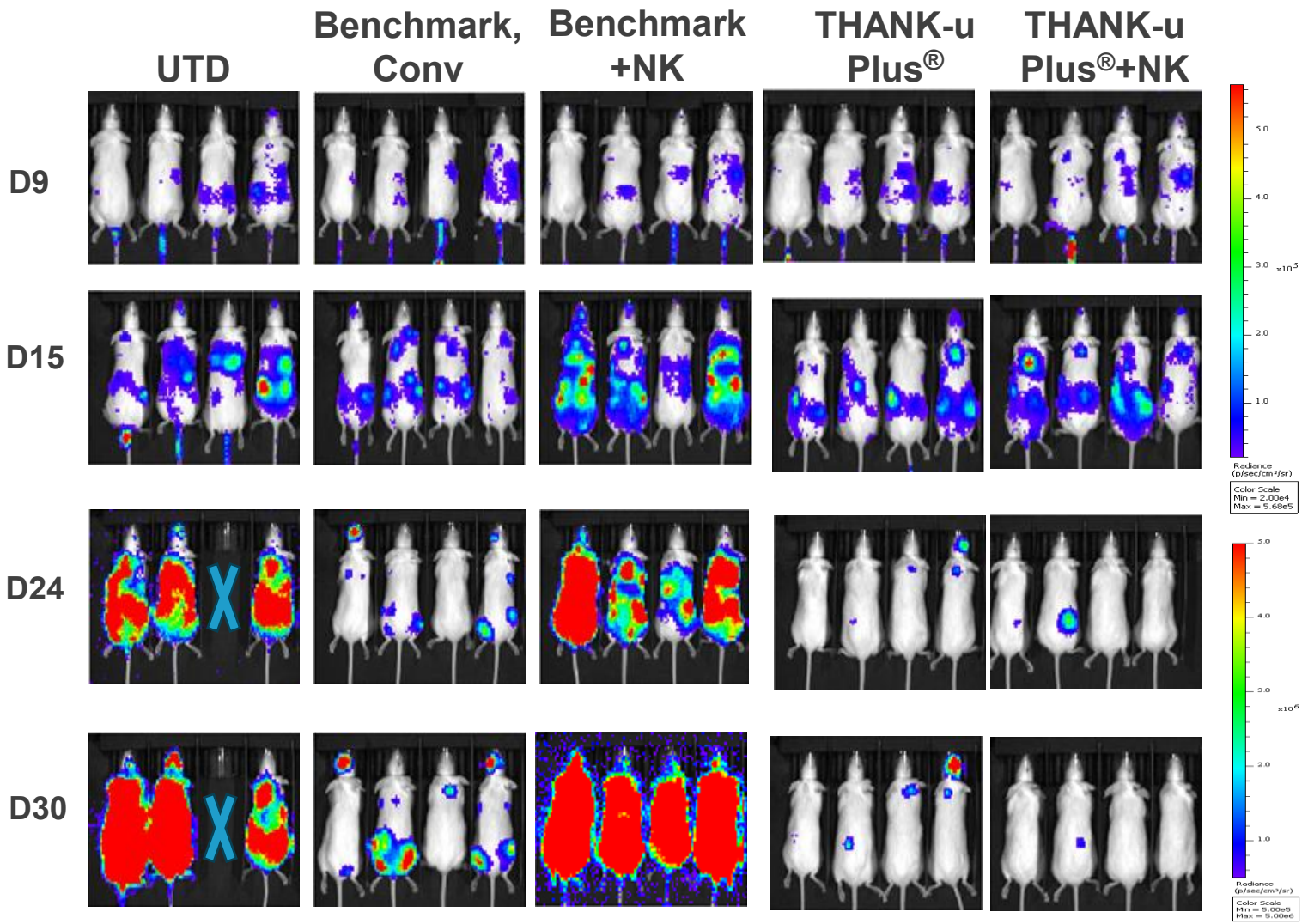
CLL1-Targeted Allogeneic CAR-T CT1390B Effectively Eliminates Acute Myeloid Leukemia Cells

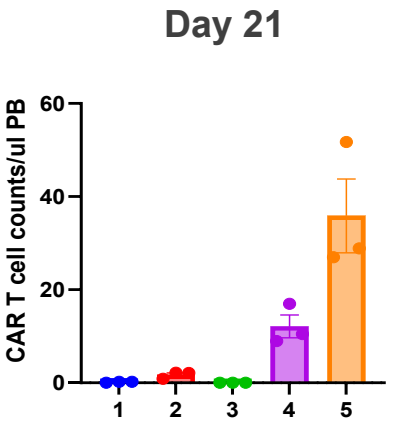
CT1390B demonstrates significant anti-tumor efficacy, regardless of the presence or absence of NK cells.

In the presence of NK cells, CT1390B exhibits superior survival compared to conventional CLL1-targeted UCAR-T cells.



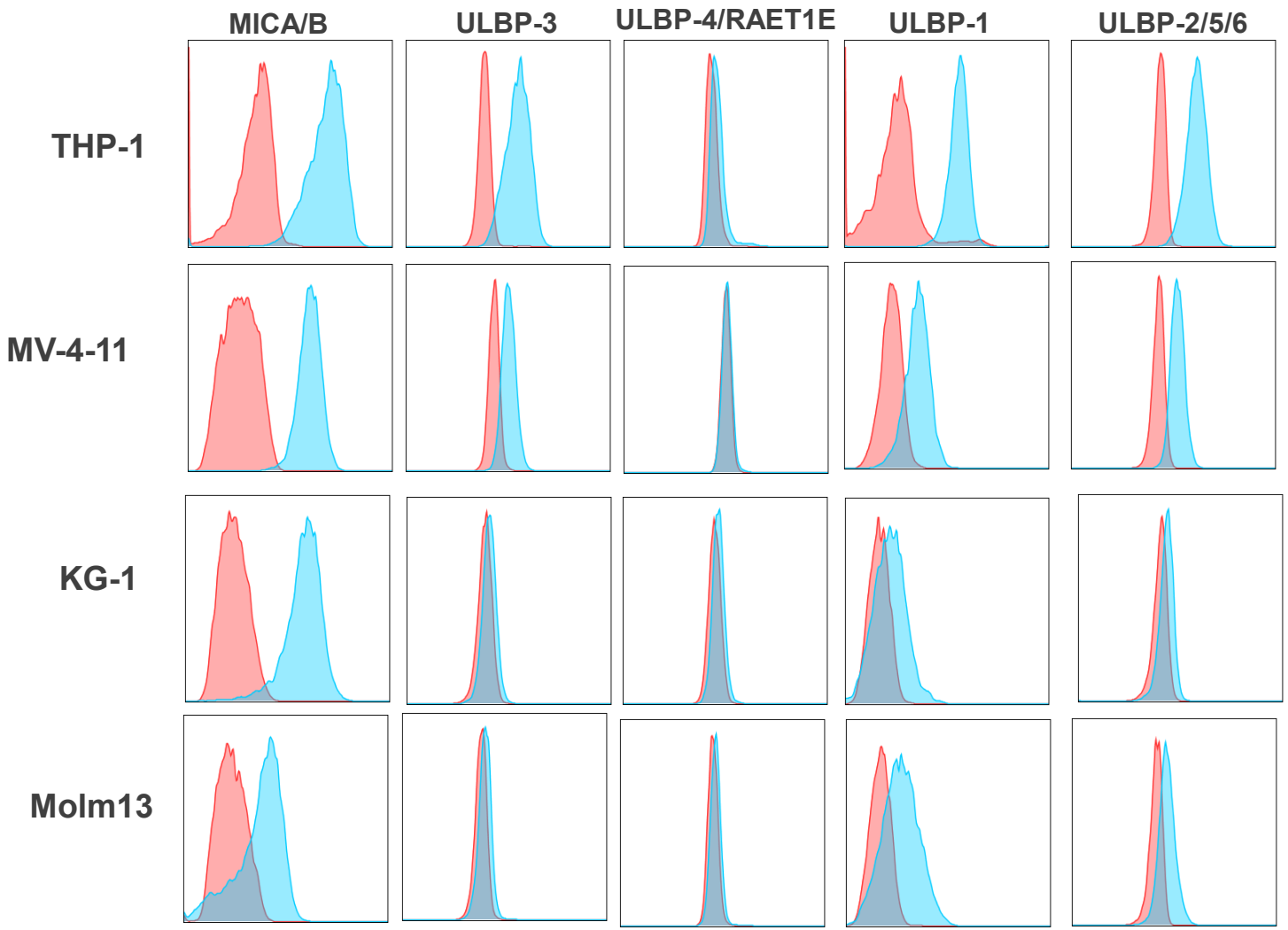
NKG2D UCAR-T Effectively Eliminates Acute Myeloid Leukemia Cells



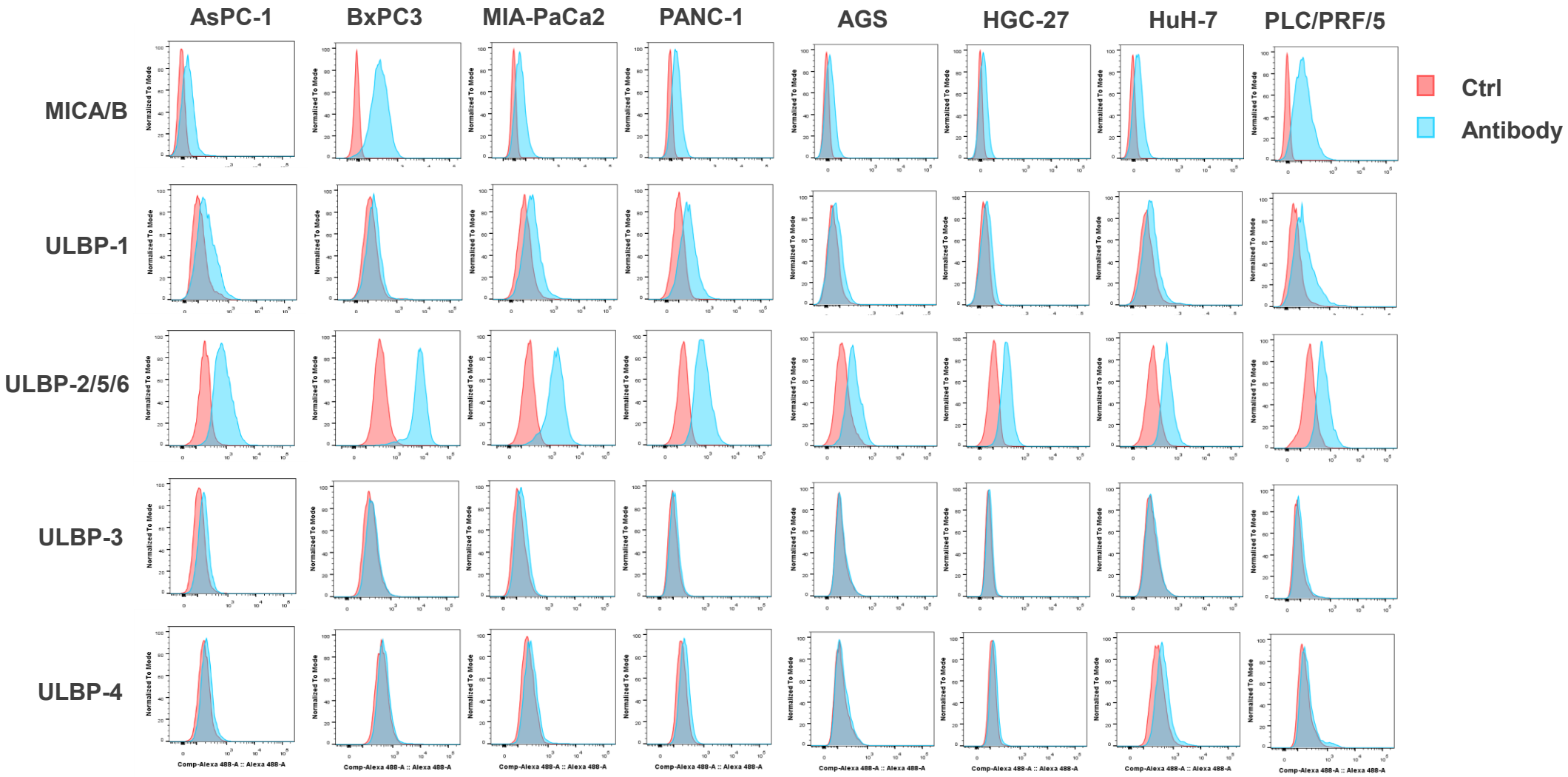


1. UTD
2. Benchmark (Conv.)
3. Benchmark +NK
4. THANK-u Plus®
5. THANK-u Plus® +NK

NKG2DL is Universally Expressed Across AML Cell Lines

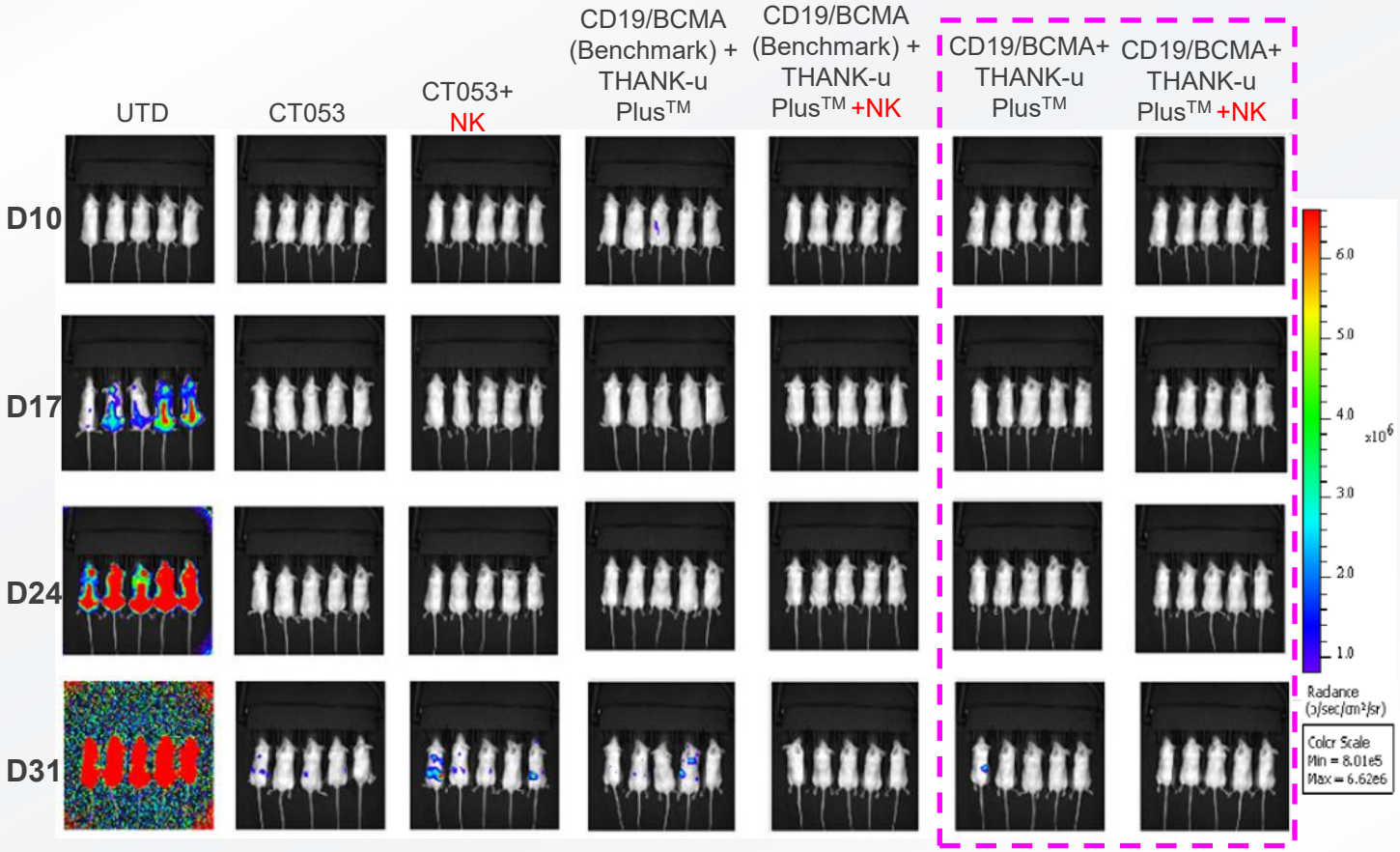


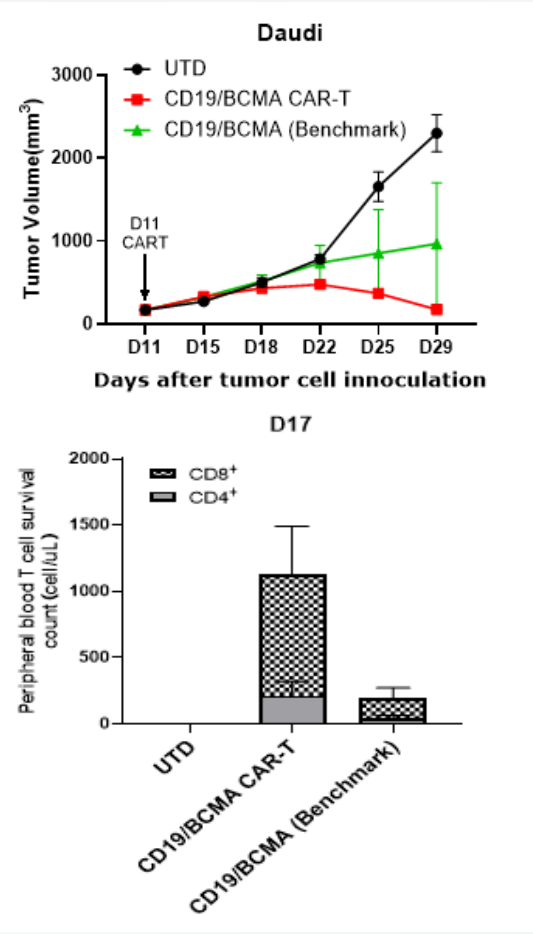
NKG2DL Expression is Detected in All Tumor Cell Lines Tested



A Potential Best-in-Class BCMA/CD19 CAR-T

Feng J, et al. Co-infusion of CD19-targeting and BCMA-targeting CAR-T cells for treatment-refractory systemic lupus erythematosus: a phase 1 trial, Nat Med, 2025. **12 out of 15 (80%) patients achieved a DORIS response within 3 months.**

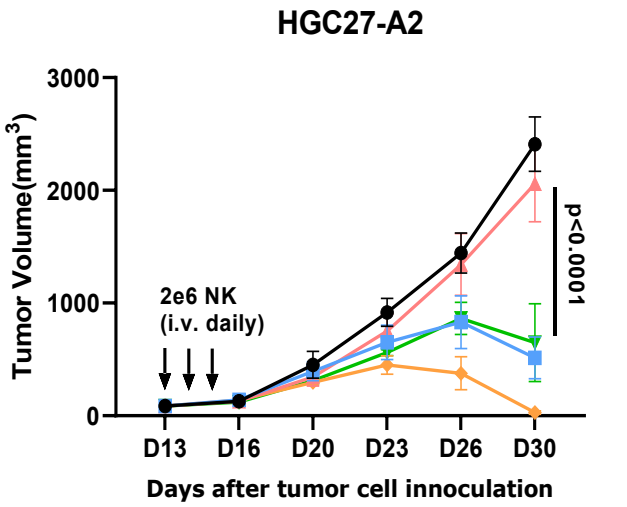




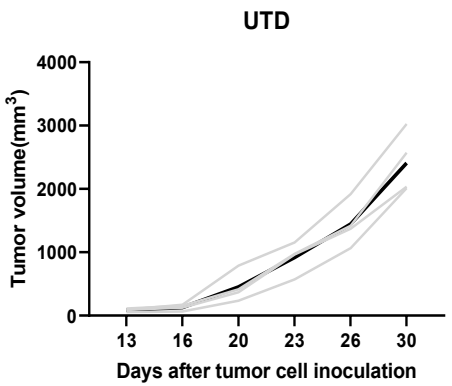
MM.1S tumor model

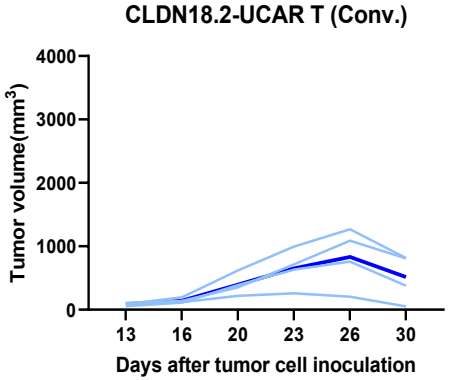
For autoimmune diseases, the ability to target both CD19 and BCMA may be critical. Therefore, developing a CAR product capable of addressing both targets is of great importance.

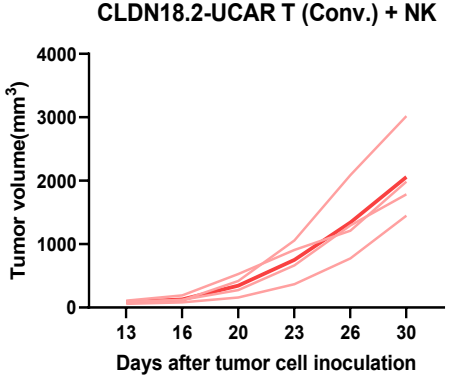
Preclinical Efficacy Evaluation of Allogeneic CLDN18.2 CAR-T

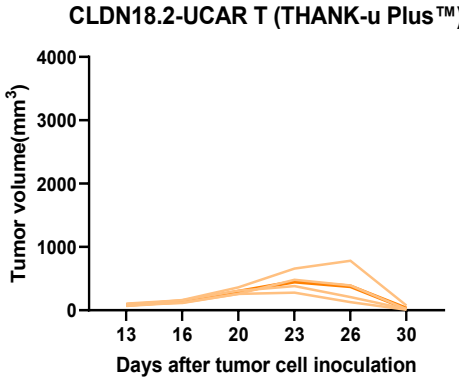


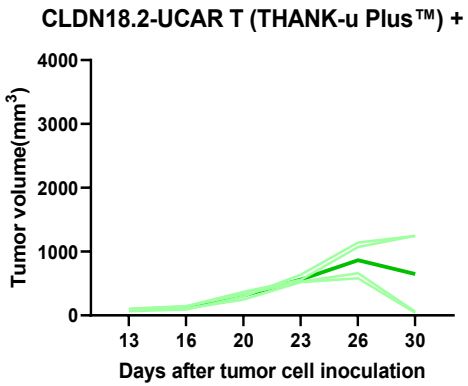
1. UTD
2. CLDN18.2-UCAR-T (Conv.)
3. CLDN18.2-UCAR-T (Conv.)+NK
4. CLDN18.2-UCAR T (Plus)
5. CLDN18.2-UCAR T (Plus)+NK

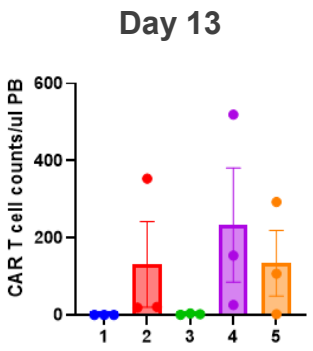












1. UTD
2. CLDN18.2-UCAR-T (Conv.)
3. CLDN18.2-UCAR-T (Conv.)+NK
4. CLDN18.2-UCAR T (Plus)
5. CLDN18.2-UCAR T (Plus)+NK

Summary and Outlook

- Our proprietary allogeneic CAR-T strategy holds promise for better addressing the challenges in the widespread application of CAR-T therapy.
- Next-generation strategies for solid tumors, such as Armored CAR-T, FAP targeting, and combination/sequential therapy with other agents, may further enhance efficacy.
- BCMA-CD19 dual-targeting CAR-T has the potential to increase the DORIS response rate in autoimmune diseases.
- Allogeneic CAR-T targeting CLL-1 and CD38 show potential for application in AML.
- NKG2D-based allogeneic CAR-T holds broad potential across various tumors, and our CAR construct is a potential best-in-class candidate.
- The LADAR® technology may solve the challenge of localized expression for CARs and other therapeutic proteins, thereby expanding the application scenarios for cell therapy.

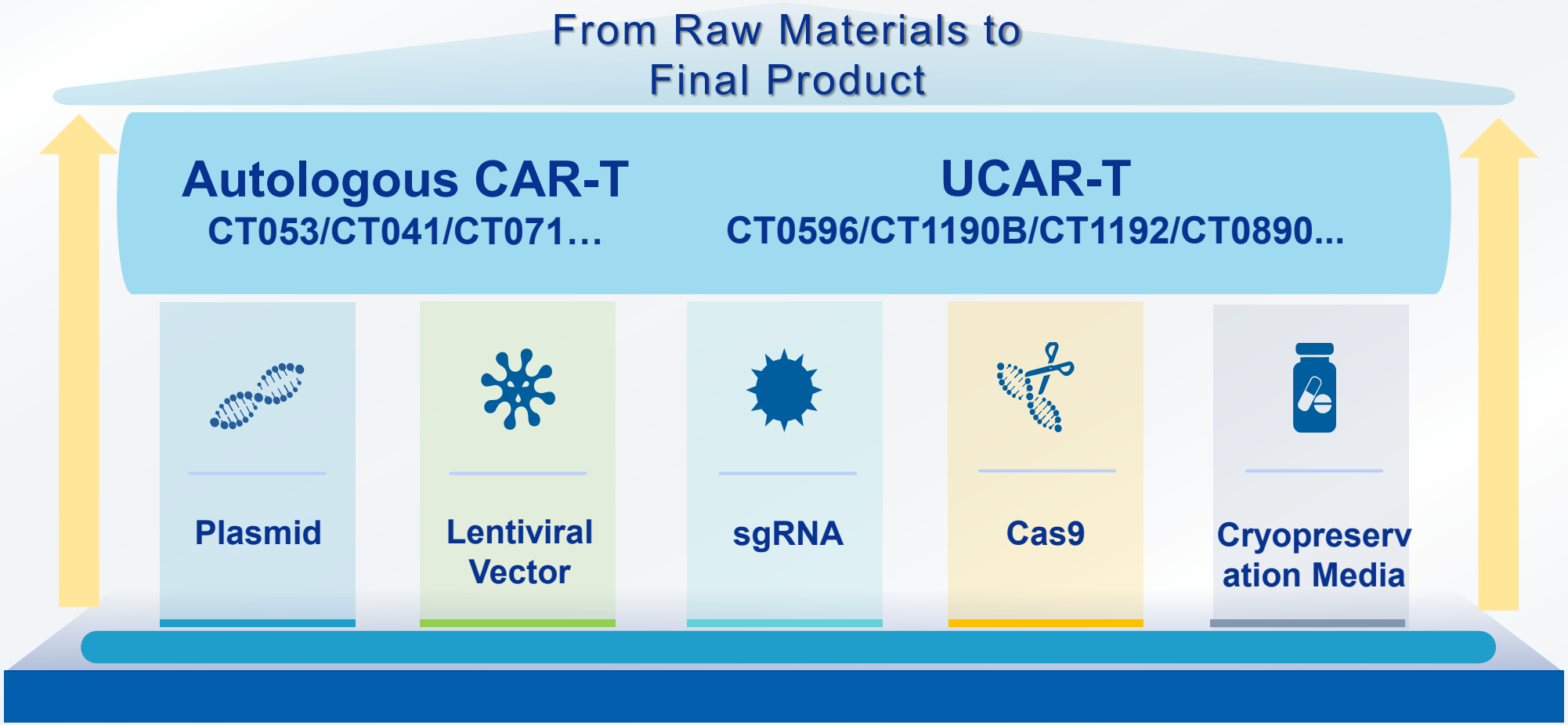
CARSGEN THERAPEUTICS

Comprehensive CMC Enablement for CAR-T: From Development to Industry

November 19, 2025

An Integrated CAR-T CMC Platform: Process Development and Analytical Testing

Full-Platform Process Development



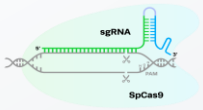
Full-Platform Process Development: Plasmid, Viral Vector, sgRNA & Cas9 Process Platforms

Plasmid Platform

- Utilizes an **Animal-Origin Free (AOF) single-use** fermentation process.
- Capable of supplying material for hundreds of **lentiviral vector production** batches.

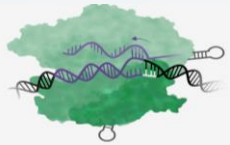
Lentiviral Vector Platform

- Batch production capacity reaches up to **10^{12}** TU.
- Can supply sufficient vector for **hundreds of CAR-T cell production batches**.



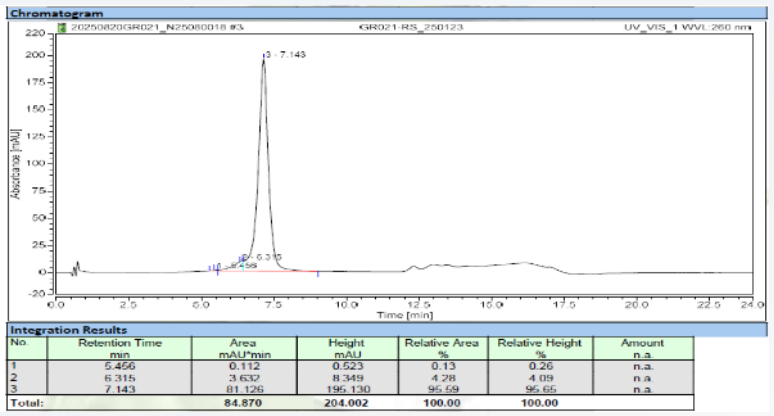
sgRNA

- Features dual-end chemical modifications.
- Purity exceeds **95%**.

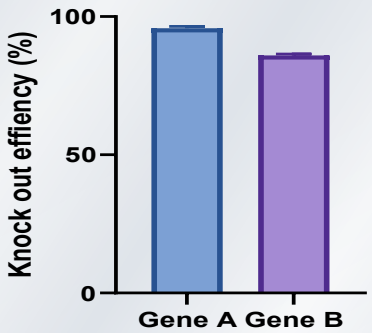


Cas9

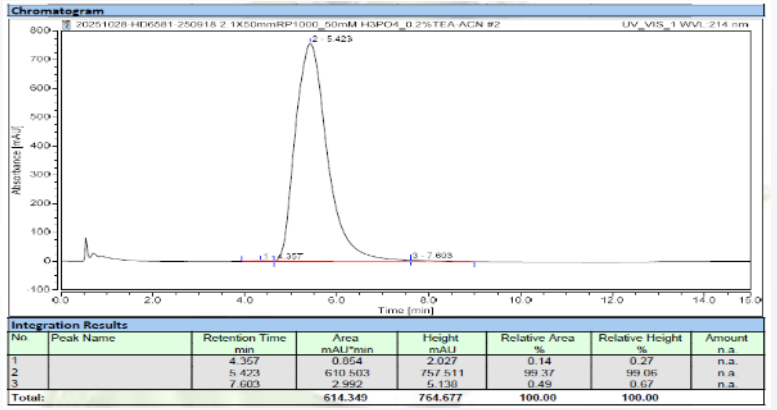
- High-activity spCas9.
- Purity exceeds **95%**.



Purity: 96.65%

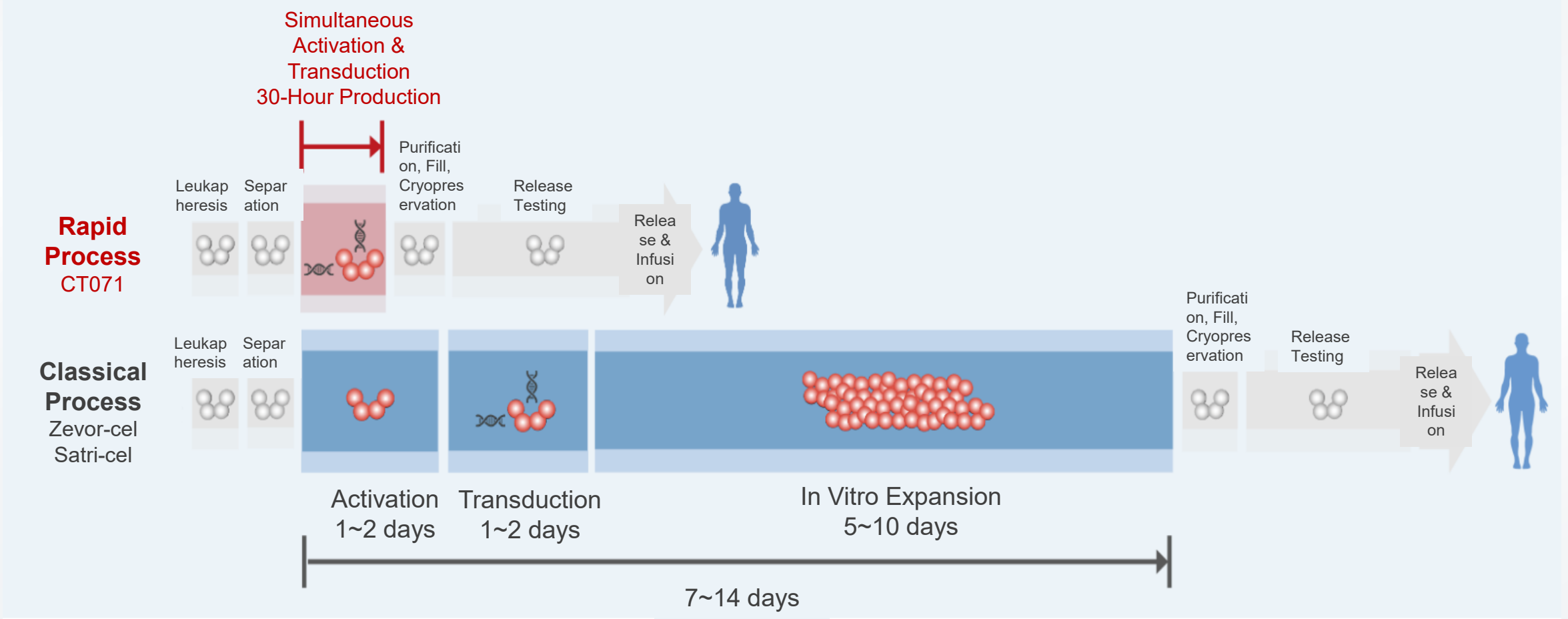


High Knockout Efficiency

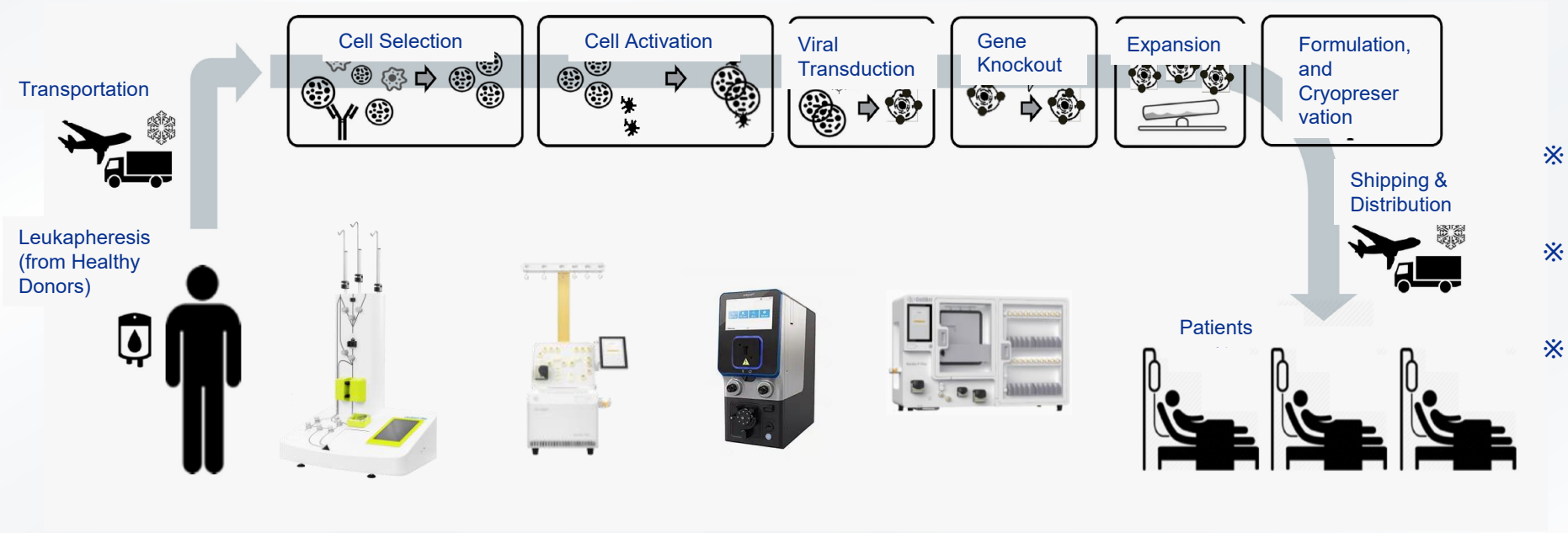


Purity: 99.06%

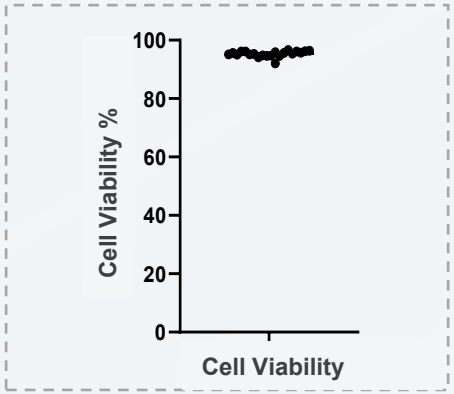
Full-Platform Process Development: Autologous CAR-T Process Platform

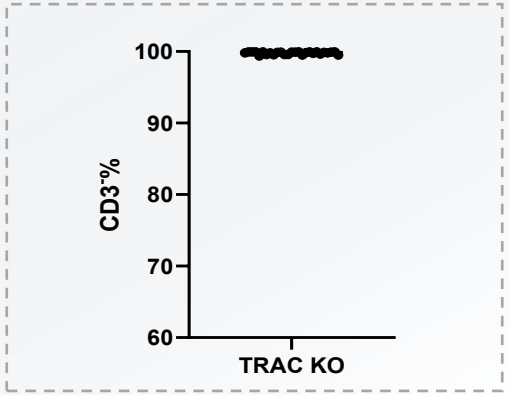


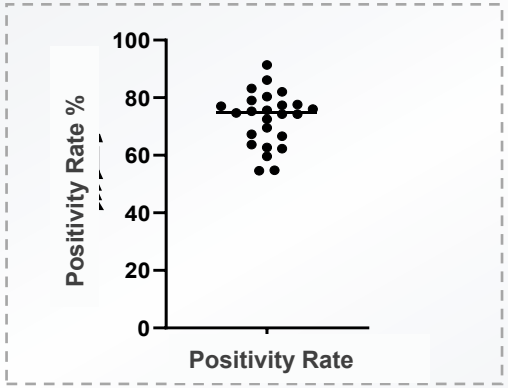
Full-Platform Process Development: UCAR-T Process Platform

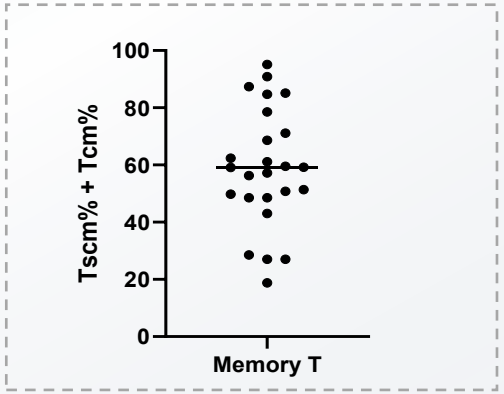


- ※ Fully Closed Processing System
- ※ Automated Key Unit Operations
- ※ Batch Capacity: Up to 100 Doses



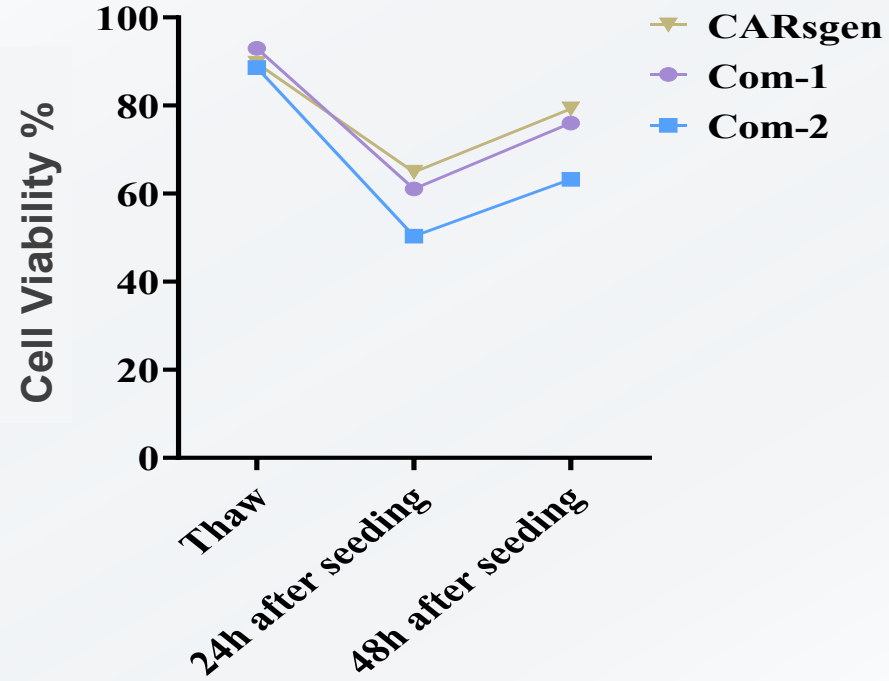


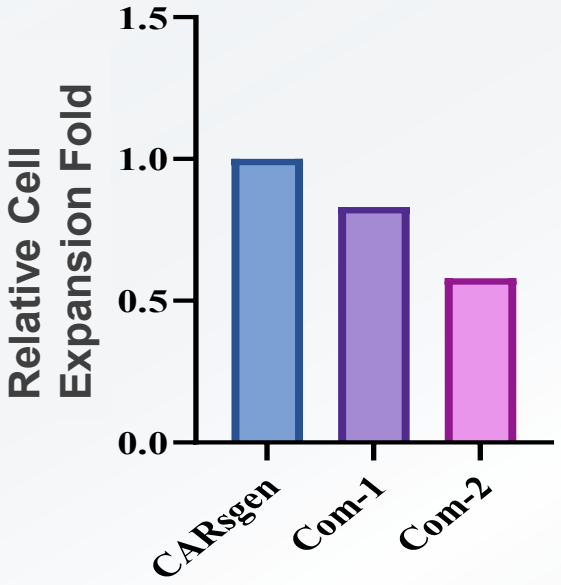




Full-Platform Process Development: Proprietary Cell Cryopreservation Medium

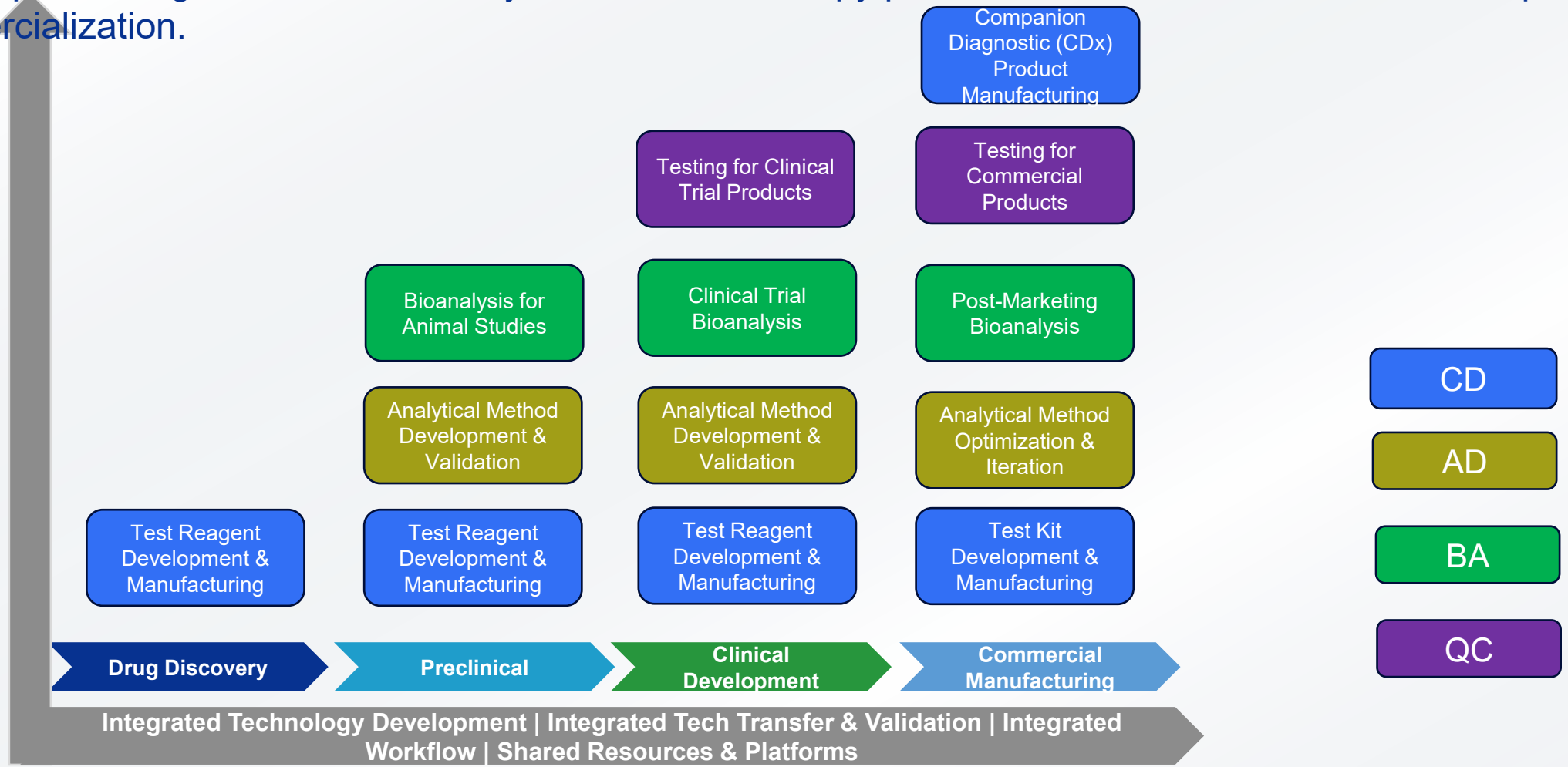
The in-house developed cryopreservation medium ensures long-term stability and quality of CAR-T cell products.





Full-Platform Analytics and Quality Control: An Integrated Analytical Testing Platform

Our platform provides comprehensive, precise, and efficient analytical methods and testing data, ensuring robust support throughout the entire lifecycle of our cell therapy products, from R&D and clinical development to commercialization.



Claudin18.2 Detection Kit Development: Addressing the Unmet Need for a Companion Diagnostic (Class III Medical Device)

Early Product Development; Establishment of CARsgen Diagnostics

2020

2021

Mar 9, 2021: Project Initiation & Analytical Performance Study Commenced; Oct 2021 – Dec 2021: Design Transfer Completed

Nov 2022: Type Testing for Registration Completed

2022

2023

Mar 2023: Kit Clinical Trial Initiated

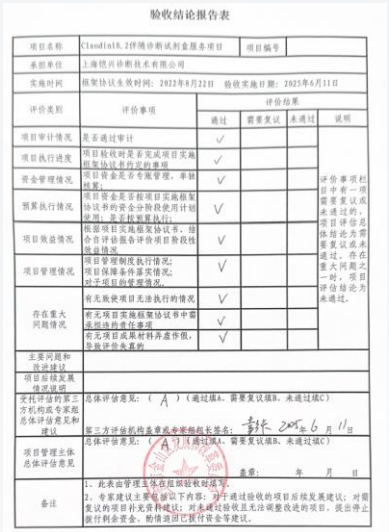
Jun 2024: ISO 13485 Certification Obtained; Aug 2024: Kit Clinical Trial Completed

2024

2025

Jun 2025: Companion Drug Submission for Market Approval; Sep 2025: Kit Submission for Market Approval

发明专利证书



验收结论报告表

From Apr 2021 to Dec 2024: Executed a Shanghai Municipal Development Guiding Fund Project, passing the final project acceptance review in May 2025.

· 718 · 中华病理学杂志 2025 年 7 月第 54 卷第 7 期 Chin J Pathol, July 2025, Vol. 54, No. 7

·共识与指南·

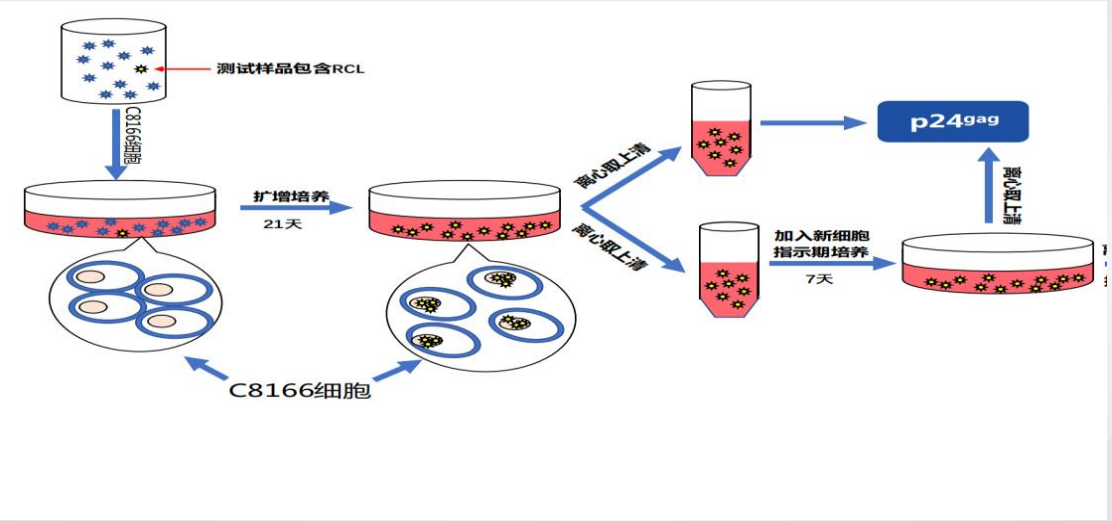
胃癌 Claudin18.2 临床检测专家共识(2025 版)

《胃癌 Claudin18.2 临床检测专家共识(2025 版)》专家委员会

研究项目	NCT 号	癌种	药物	抗体克隆号	CLDN18.2 阳性判读标准
SPOTLIGHT[24]	NCT03504397	胃癌	Zolbe+mFOLFOX6	43-14A(Ventana)	IHC 2+/3+≥75% 肿瘤细胞
GLOW[23]	NCT03653507	胃癌	Zolbe+CAPOX	43-14A(Ventana)	IHC 2+/3+≥75% 肿瘤细胞
Qi 等[19]	NCT03874897	实体瘤	CAR T 细胞	14F8(CARsgen)	IHC 2+/3+≥40% 肿瘤细胞

Jul 2025: This detection kit was included in the *Expert Consensus on Clinical Testing for Claudin18.2 in Gastric Cancer*.

RCL (Replication Competent Lentivirus) Testing (Indicator Cell Culture Assay)



- Compliant with FDA regulatory requirements
- Extended 28-day culture period
- High detection sensitivity

Enabled by our integrated testing platform:

- In-house developed test kits
- Internally established and validated methods

Analytical Development, AD

Integrated Multi-National Regulatory Compliance

Meets the multi-faceted GxP requirements of NMPA, FDA, and EMA

Comprehensive Multi-Dimensional Testing System

Encompassing dozens of test items including physicochemical characterization, biological activity, potency, content, and impurities

Full Lifecycle Support

Covering method development, qualification, validation, transfer, change control, and re-validation

Central Technology Integration Hub

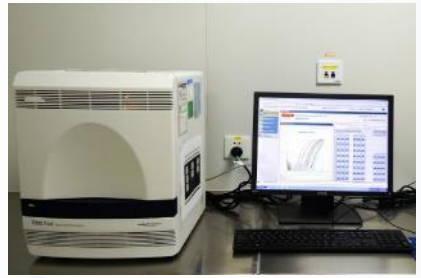
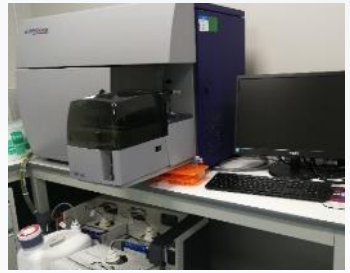
Connecting method development, quality control, and bioanalysis

Supported 2 BLAs, nearly 10 INDs, and 20+ IIT studies. Developed and validated over 100 analytical methods. Completed testing for more than 50,000 samples.

Bio-sample Analysis, BA





Compliance

- GLP/GCP as the foundational framework
- Adherence to FDA 21 CFR Part 58+.
- Dual compliance with ICH E6 (R2) & M10 guidelines.
- Reinforced by ISO 9001 certification.

Technical Capabilities

- Comprehensive sample processing expertise for diverse matrices: whole blood, serum, plasma, tissue, ascites, pleural fluid, etc.
- Established a full-spectrum analytical platform encompassing: molecular, Immunoassay, Cell-based, and Histochemical assays.

Scale

- Successfully processed single batches exceeding 1,800 samples (blood + tissue)
- Cumulative testing volume has surpassed 100,000 samples

Quality Control, QC

Reference Standards & In-house Control Materials Management

Culture Media & Reagent Management

Instrument & Equipment Management

OOS/OOT/AD Management

Testing & Monitoring

Method Qualification and Validation

Stability Study Management

- Products: CAR-T, Lentiviral Vectors, Plasmid
- Materials: Leukapheresis Material, Excipients, Raw Materials, Packaging Materials, etc.
- Utilities: Process Water, Process Gases, etc.
- Clean Environment Monitoring, etc.

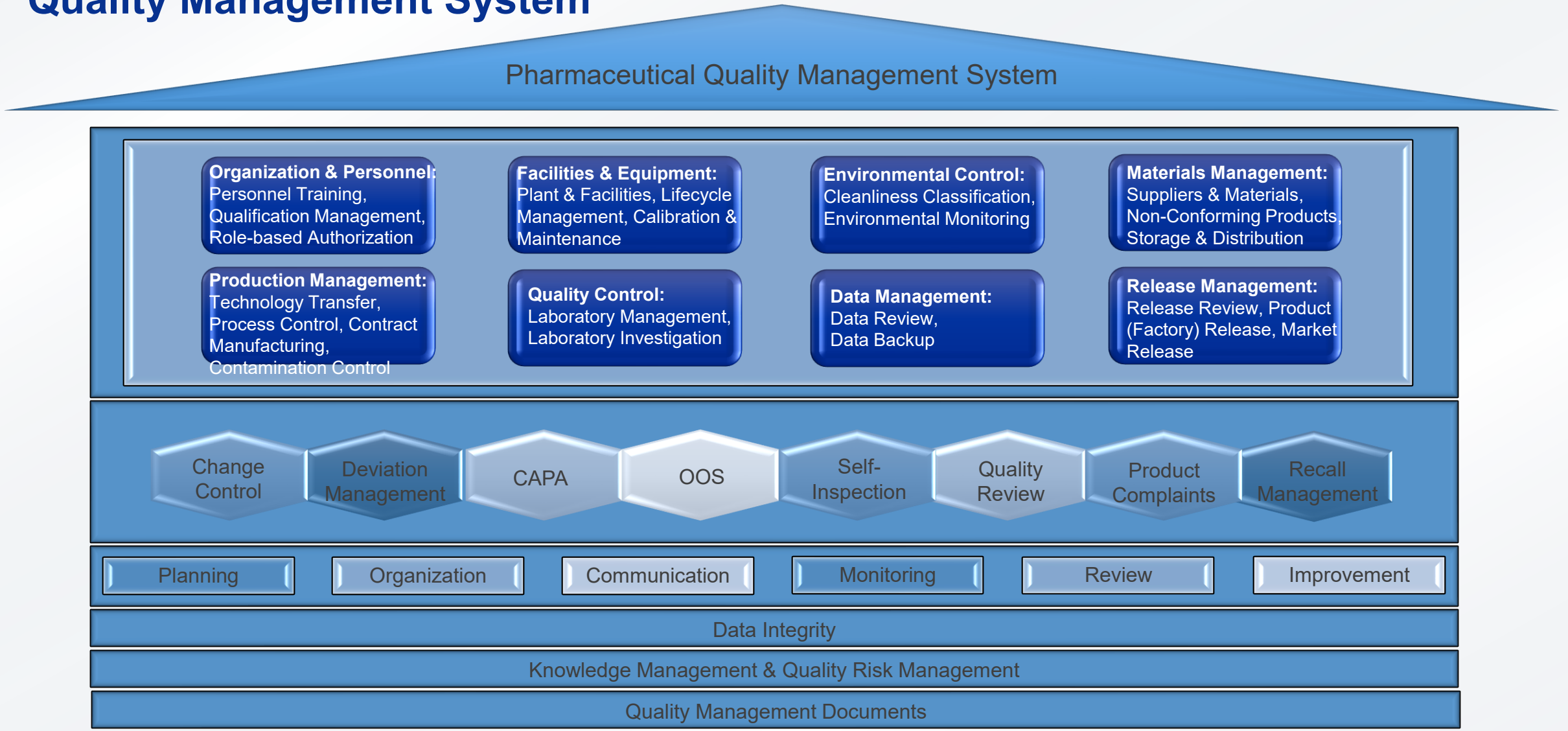
- Bioassay Platform: Cytotoxicity, FACS
- Biochemical Analysis Platform: ELISA, qPCR
- Physicochemical & Microbiology Platform

Full-Spectrum Compliance and Quality System

Full-Spectrum Compliance and Quality System

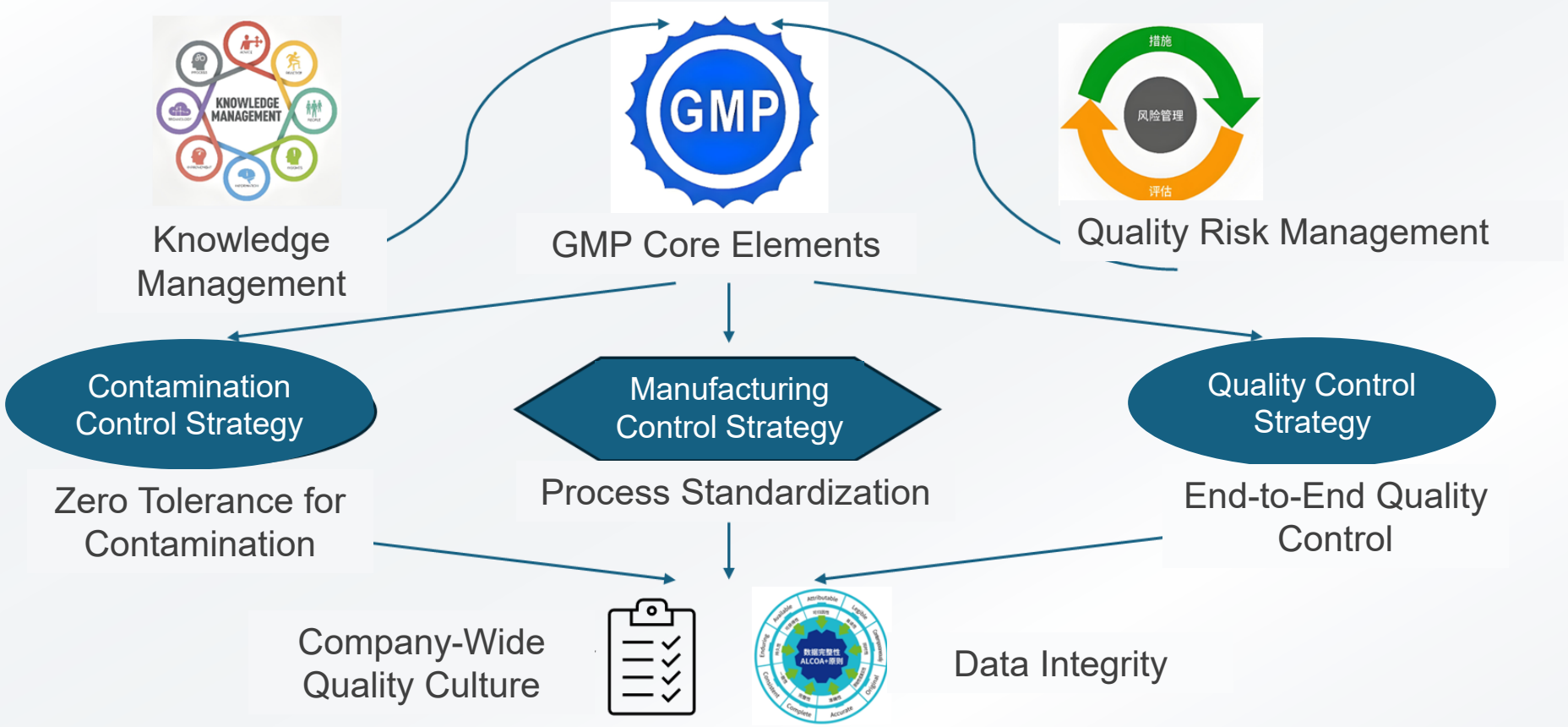
- Pharmaceutical Quality Management System
- Technology Transfer Management System
- Regulatory Submission and Inspection Management System
- Information System Management System
- EHS Management System (Environment, Health, and Safety)

Full-Spectrum Compliance and Quality System: Pharmaceutical Quality Management System

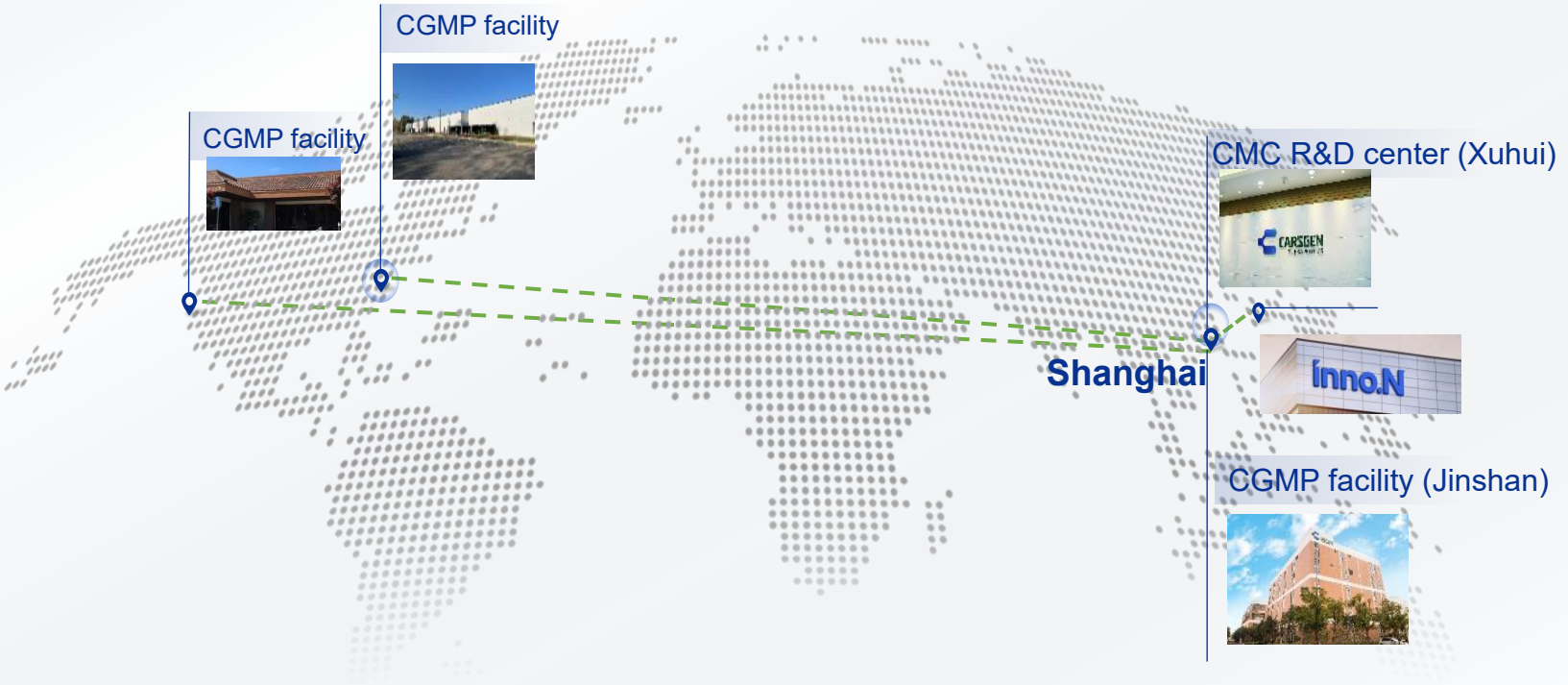


Full-Spectrum Compliance and Quality System: Pharmaceutical Quality Management System

Control Strategy for Cell Therapy Products



Full-Spectrum Compliance and Quality System: Technology Transfer Management System



Technology Transfer Experience & Achievements

- Executed 2 domestic site transfers (from Xuhui to Jinshan)
- Completed technology transfer to 2 US-based CDMOs
- Performed technology transfer for 3 projects to the US RTP facility
- Conducted 1 License-out technology transfer

Conducted Gap analysis prior to transfer to assess the suitability and feasibility of new facility infrastructure, equipment, materials, environment, and process testing methods.

Optimized the technology transfer strategy to enable rapid deployment and smooth implementation of new processes at the receiving site.

Validated and confirmed the manufacturing process and production site during pivotal clinical studies.

Initiated commercial production, ensuring process controllability and robustness post-approval.

Full-Spectrum Compliance and Quality System: Global Regulatory Submission System

Supported by multiple prestigious designations, accelerating the R&D process

- **China:** 2 Breakthrough Therapy designations, 2 Priority Reviews, 1 Conditional Approval.
- **FDA:** 2 Orphan Drug designations, 2 RMAT designations.
- **EMA:** 1 Orphan Drug designation, 1 PRIME designation

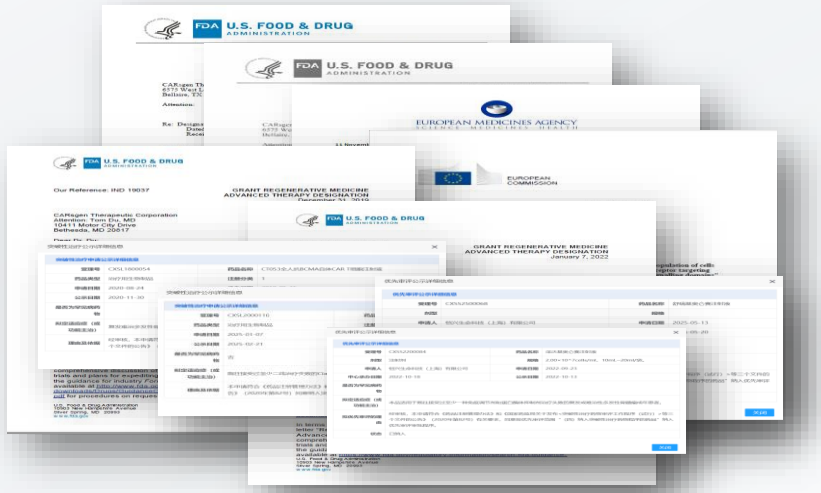
Coverage of Chinese and international registration applications

China Progress

- INDs: 8 submissions ➤ All Approved
- NDAs: 2 submissions ➤ 1 Approved / 1 Under Review
- Supplemental Applications: 3 during clinical trials ➤ All Approved; 3 post-approval ➤ 1 Approved / 2 Under Review

International Progress

- FDA INDs: 3 submissions ➤ All Approved
- Health Canada CTAs: 2 submissions ➤ All Approved



Full-Spectrum Compliance and Quality System: Information System Management System

From Digitalization to Intelligentization: Building an Efficient, Reliable, and Continuously Evolving Modern Manufacturing Operation System.

WMS (Warehouse Management System)

Value: Enables precise management of material inventory and automated distribution, ensures continuous supply for production, and mitigates the risk of production stoppages due to material shortages.

MES (Manufacturing Execution System)

Value: Provides transparency into production progress, real-time monitoring of equipment status, and error-proofing control of process standards, significantly enhancing overall manufacturing efficiency.

DMS & TMS (Document Management System & Training Management System)

Value: Centrally manages standard documents such as SOPs, ensures personnel qualifications and training comply with regulations, and fundamentally secures the quality foundation.

End-to-End Traceability System

Value: Achieves seamless traceability from patient leukapheresis, cell transportation, production, QC release, to final infusion, ensuring clear product origin, controlled processes, and definitive destination.

Intelligent Evolution: Generative AI Empowers a Leap in System Value

By deploying proprietary large language models, we infuse intelligence into our solid digital foundation, achieving a transition from "control" to "proactive anticipation".

- For Production (MES+): Intelligent production scheduling that dynamically optimizes plans and improves equipment utilization.
- For Quality: Root cause analysis that rapidly identifies key factors in complex quality issues and helps pinpoint optimal (golden) production batches.
- Core Advantages: On-premises deployment ensures data security, with stable and rapid response times that meet the stringent requirements of the production environment.

Full-Spectrum Compliance and Quality System: EHS Management System to Ensure Comprehensive Protection

EHS Management

Emergency Response

Establish a robust safety emergency management system with simulation drills.

Safety in Production

Implement comprehensive safety measures across all operations, protecting both the company and personnel.

Biosafety

Implement robust hardware and software measures for biosafety, along with personnel protection protocols.

Occupational Health

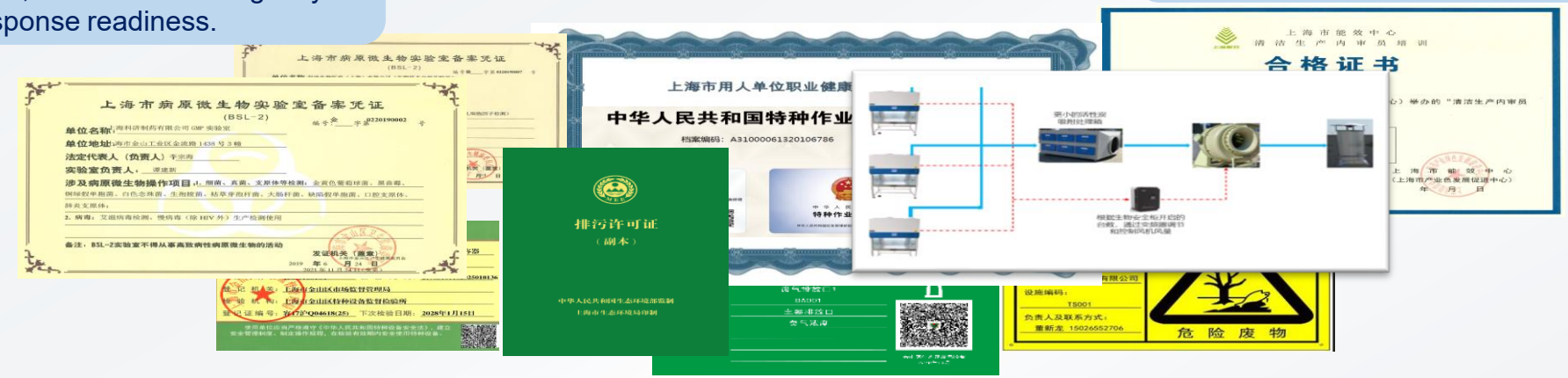
Promote awareness and activities to foster a culture of "I want safety, I know how to be safe."

Fire Safety

Maintain fire protection facilities and equipment, conduct regular drills, and ensure emergency response readiness.

Environmental Protection

Ensure environmental compliance, promote energy conservation and emissions reduction, and support green development initiatives.



Industrial Evolution and Scaling

CARSGEN
THERAPEUTICS

Commercial Production: Comprehensive and Integrated Manufacturing Capabilities

Shanghai Jinshan Facility

In 2019, this site was granted China's **first** Drug Manufacturing License for a CAR-T cell therapy.

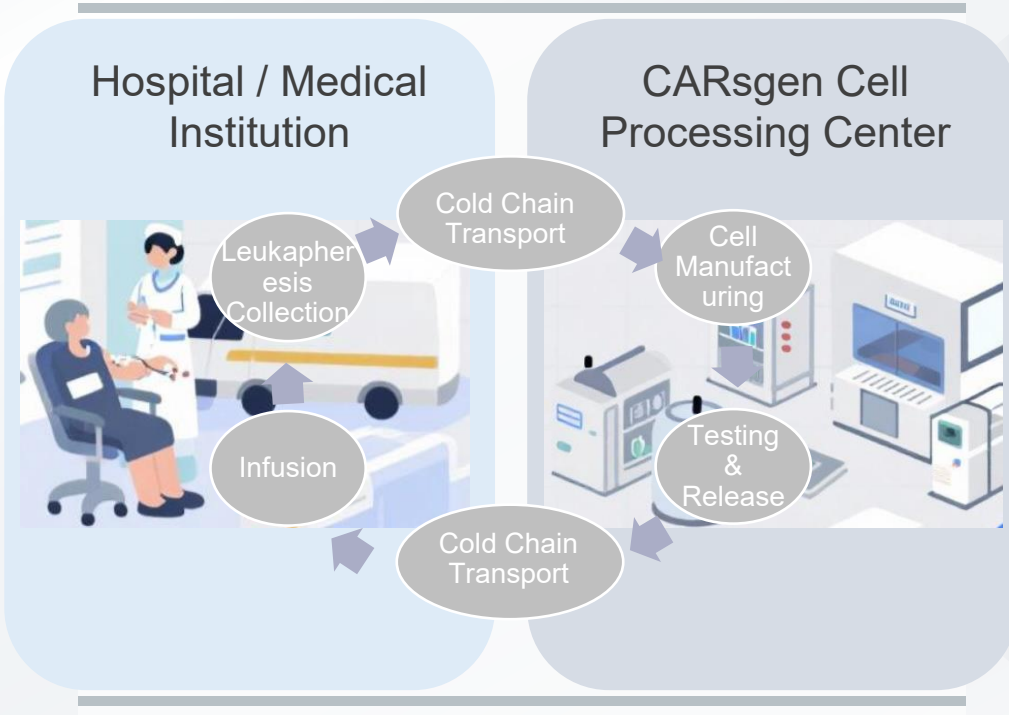
The designed production capacity can support CAR-T treatment for up to **2,000 patients** annually.

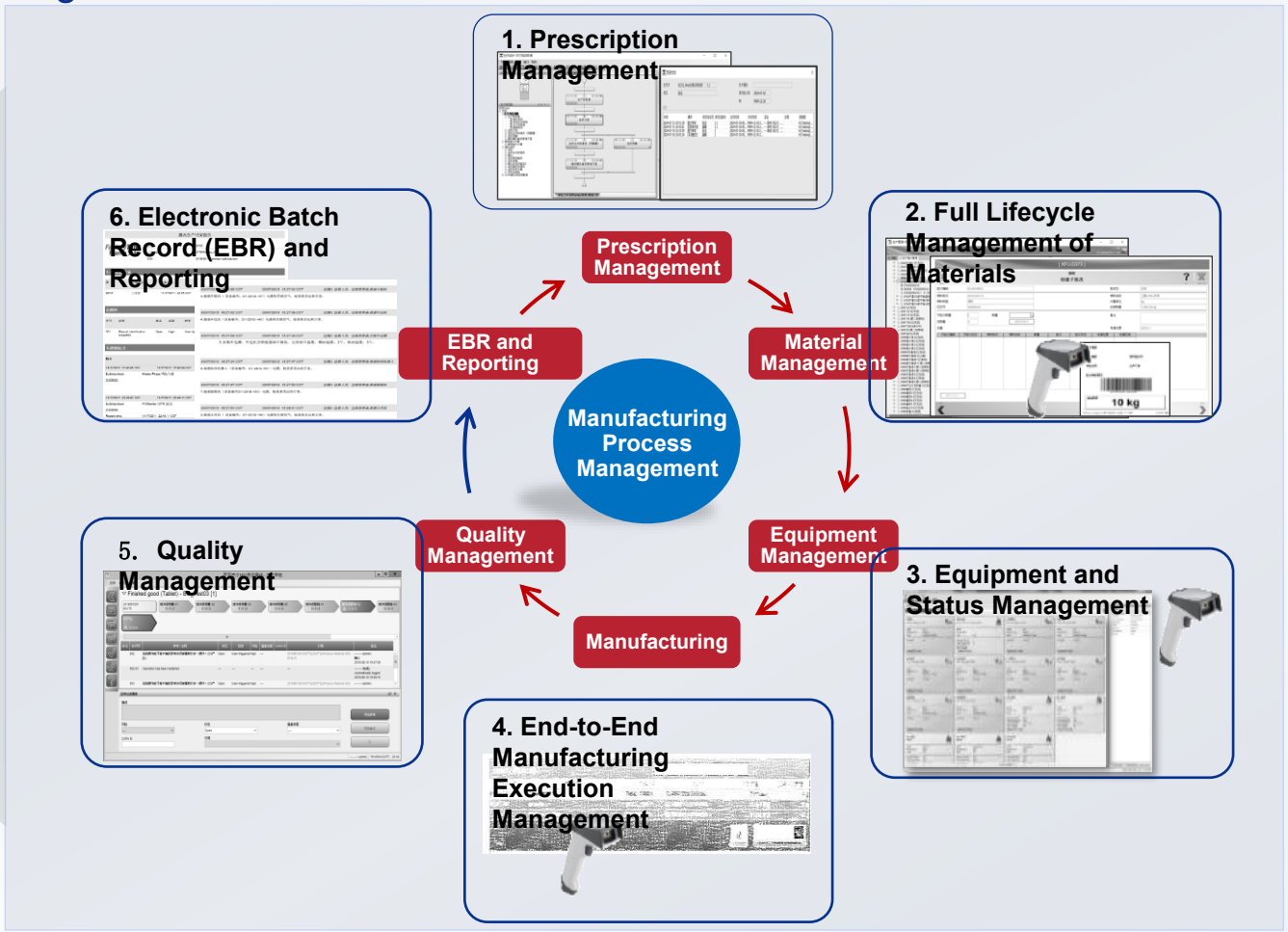
Integrated Smart Cell Manufacturing Center

The future facility will be an Integrated Smart Cell Manufacturing Center capable of producing both autologous and allogeneic CAR-T therapies, with **a projected capacity of tens of thousands of patient doses per year**.

Industrialization Breakthrough: The CMC Smart Manufacturing Platform

Our digital platform enables seamless, end-to-end management and data visualization from "Raw Material" to "Patient," driving an efficient and reliable productivity engine.





Industrialization Breakthrough: Closed, Automated, Integrated Process Development Platform

CARSGEN THERAPEUTICS

Closed

Automation

Integrated

- Production area cleanliness grade B to C
- Reduced production space required
- Increased production success rate
- Reduced number of personnel per batch

Supply chain management

- Optimal selection
- Strategic partnerships

Thermo SCIENTIFIC, cytiva, MaxCyte, Miltenyi Biotec, CORNING, TERUMO TERUMO MEDICAL CORPORATION, Lonza, LEPURE乐纯生物, T&L 同立海源 BIOTECHNOLOGY, 金斯瑞生物科技, 中博瑞康 Sino-Biocan, 赛桥生物 CELLBRI, Eureka bio 深研生物科技, Etta Biotech 壹达生物科技, ExCell 依科赛

CAR-T Industrialization Evolution and Future Prospects

Empowering CAR-T CMC development through multi-dimensional capabilities including full-platform technology and systematic approaches, enabling **global regulatory compliance, large-scale production, and rapid market commercialization**.

Looking ahead, we will focus on **process automation, digitalized management, and industry chain collaboration** to further reduce production costs, enhance product quality, and improve patient access to therapies. This commitment drives China's CAR-T industry toward global leadership, bringing hope for a cure to more cancer patients.

CARSGEN THERAPEUTICS

Data-Driven, Evidence-Based: A Practical Review of Allogeneic CAR-T Clinical Data Across Multiple Cancers

November 19, 2025

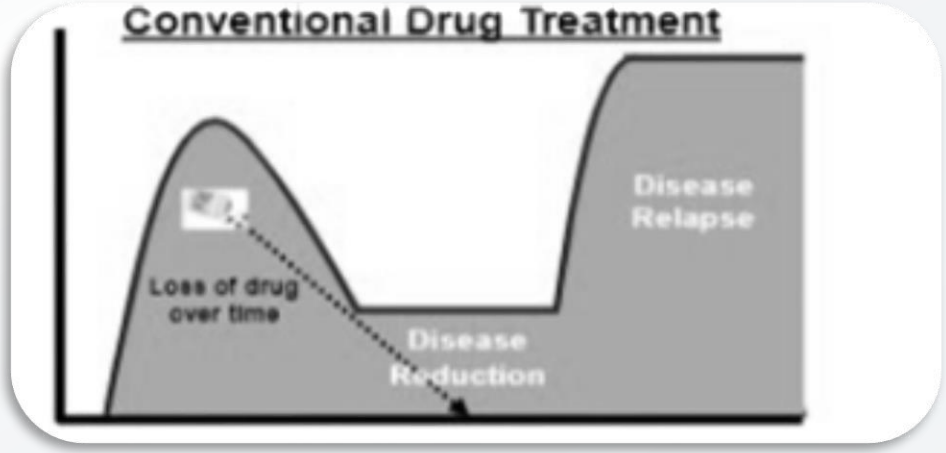
CONTENT

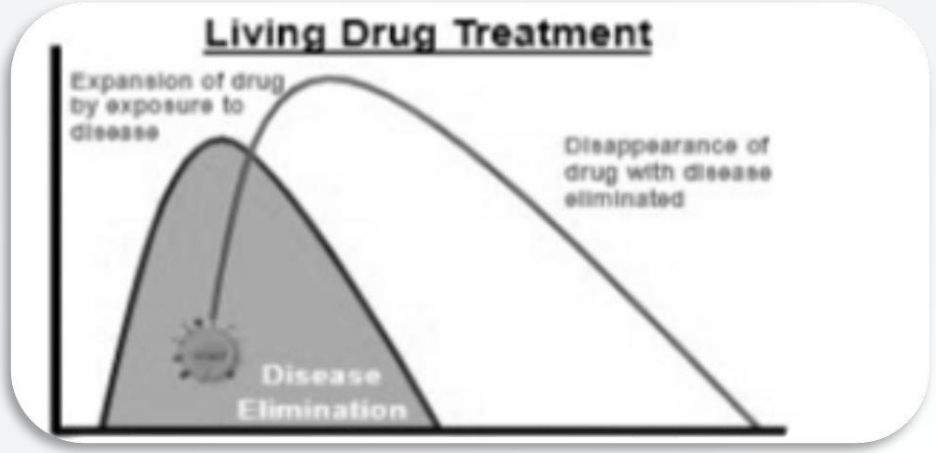
- Significant Features of CAR-T Cells as Living Drugs
- Core Advantages of Allogeneic CAR-T and Key Clinical Application Considerations
- CARsgen's Pioneering Solutions
- Early Efficacy of CARsgen's Technology Platform Across Various Indications
- Scalability of CARsgen's Technology Platform

Significant Features of CAR-T Cells as Living Drugs

CARSGEN THERAPEUTICS

CAR-T Cells Are "Living" Drugs, Fundamentally Distinct from Other Therapeutic Modalities



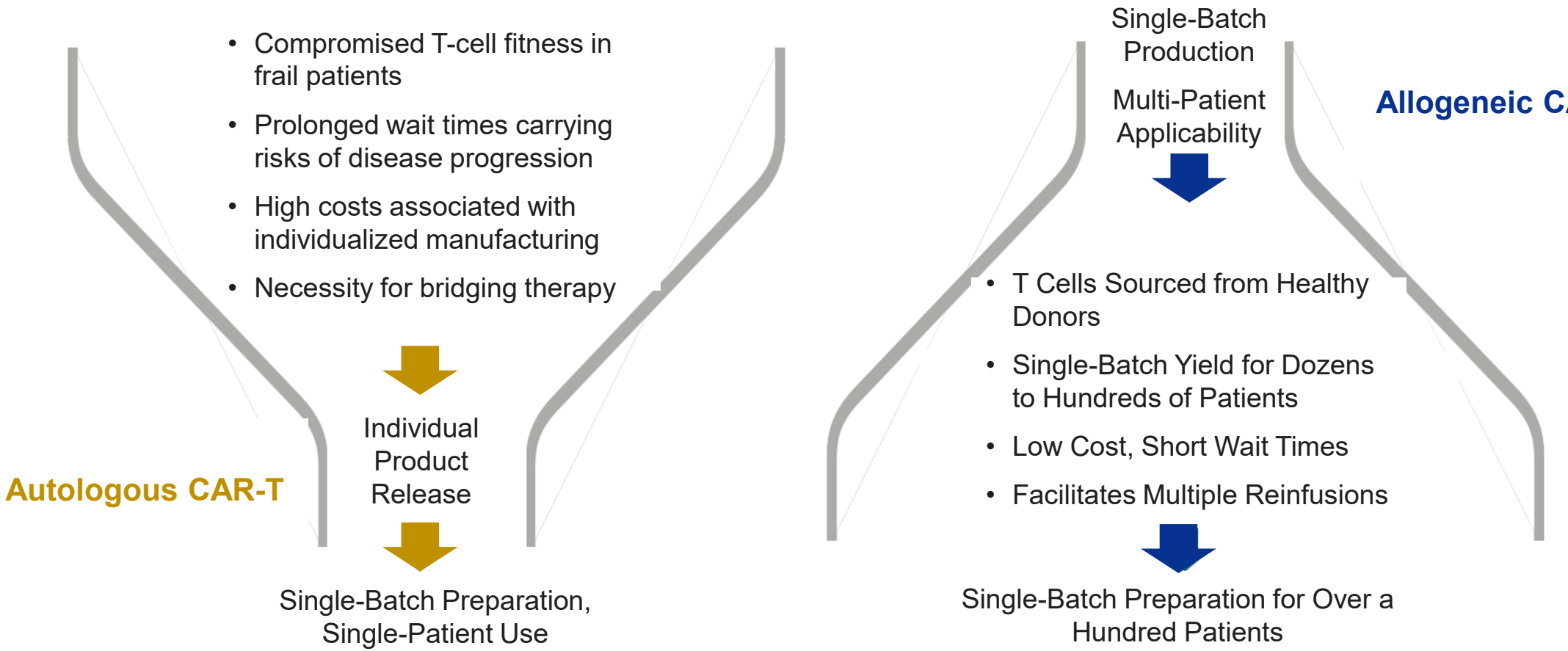


- The greatest appeal of CAR-T as a living drug lies in its capacity for expansion. Unlike traditional medications that require repeated administration to maintain therapeutic concentrations, CAR-T cells possess self-amplifying capabilities.
- Establishing an advantageous Efficacy-to-Target (ET) ratio is crucial for achieving deep clearance of target cells.

Core Advantages of Allogeneic CAR-T and Key Clinical Application Considerations

CARSGEN
THERAPEUTICS

Allogeneic CAR-T: Overcoming Industry Bottlenecks with Rapid Production, Lower Costs, and Off-the-Shelf Availability to Significantly Improve Patient Access



Multiple Constraints in Product Supply and Marketization

Robust Supply Capacity and High Market Potential

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.

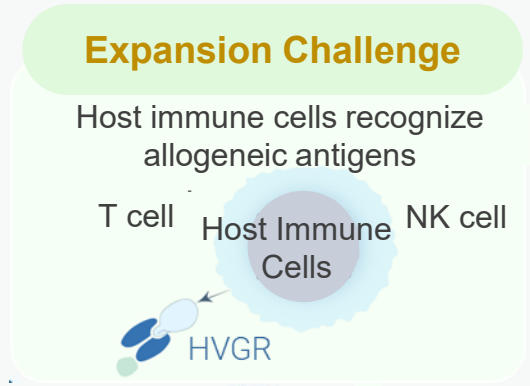
Autologous and Allogeneic BCMA CAR-T in Multiple Myeloma

	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

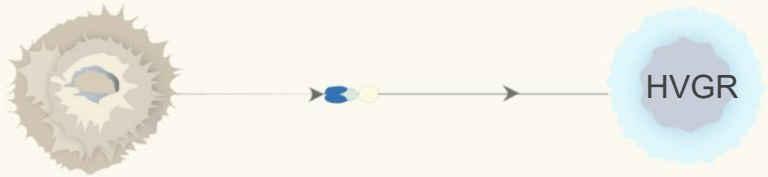
*Data from all patients (N=24) receiving the FCA regimen with 3.2 $x10^8$ cells.
**ALLO-647: A humanized anti-CD52 monoclonal antibody for the depletion of CD52-positive host lymphocytes.

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

Allogeneic CAR-T Faces HVGR Challenges in Clinical Applications

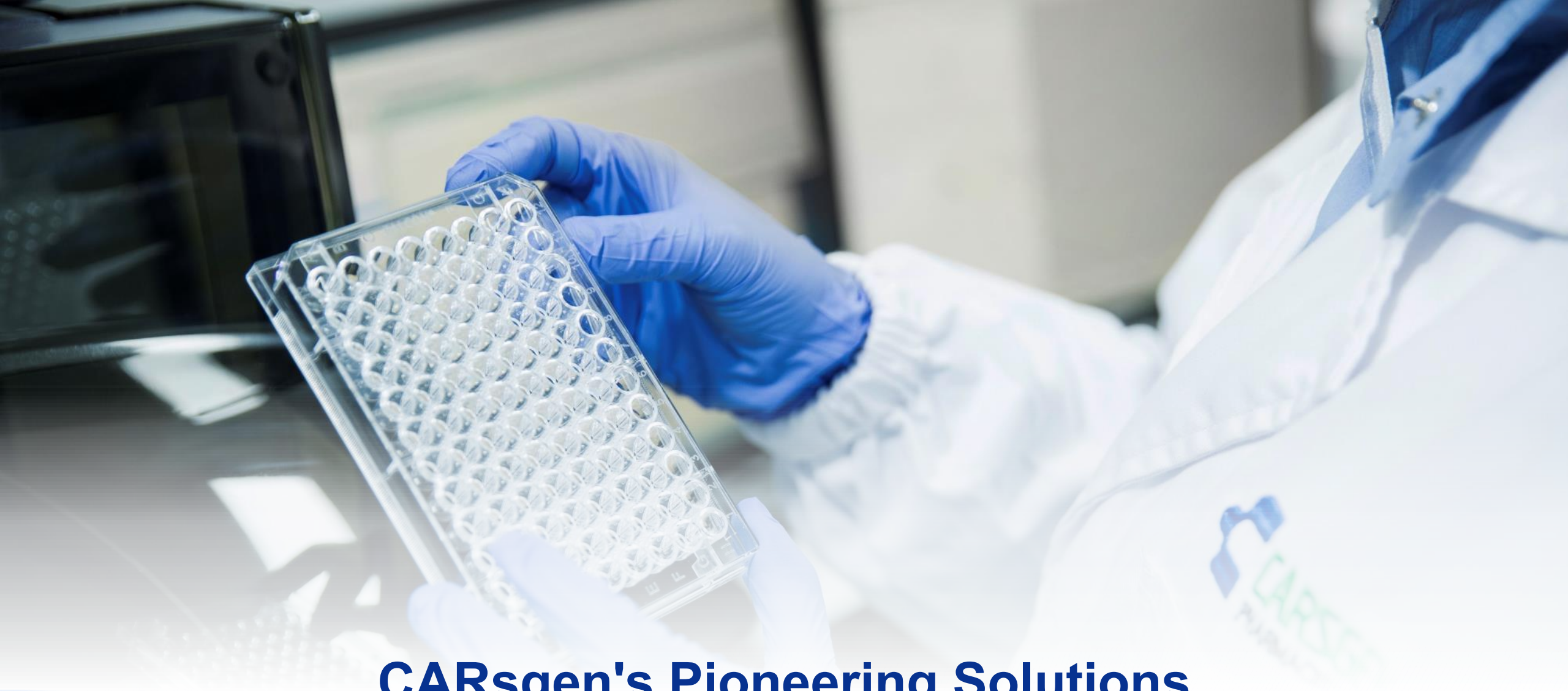


Relationship with Gene Editing



Key: Combination Gene Editing + Lymphodepletion to Induce Temporary Immune Tolerance Avoid HVGR

- The primary bottleneck in the clinical application of allogeneic CAR-T is Host-versus-Graft Response (HVGR).
- HVGR impairs the expansion of allogeneic CAR-T cells, preventing the establishment of a favorable effector-to-target ratio and compromising the clearance of target cells.
- Current mainstream gene editing strategies primarily focus on evading immune recognition by T cells, mainly through knockout of HLA class I and/or class II molecules. However, knocking out HLA class I molecules can enhance host NK cell-mediated recognition of the allogeneic cells, potentially exacerbating rejection. While intensifying lymphodepletion regimens (using higher doses or additional agents) can enhance the induction of immune tolerance, it concurrently exposes patients to significantly increased risks of infection.
- An ideal strategy to counter HVGR should simultaneously resist rejection mediated by both T cells and NK cells, thereby creating a favorable window for CAR-T expansion.

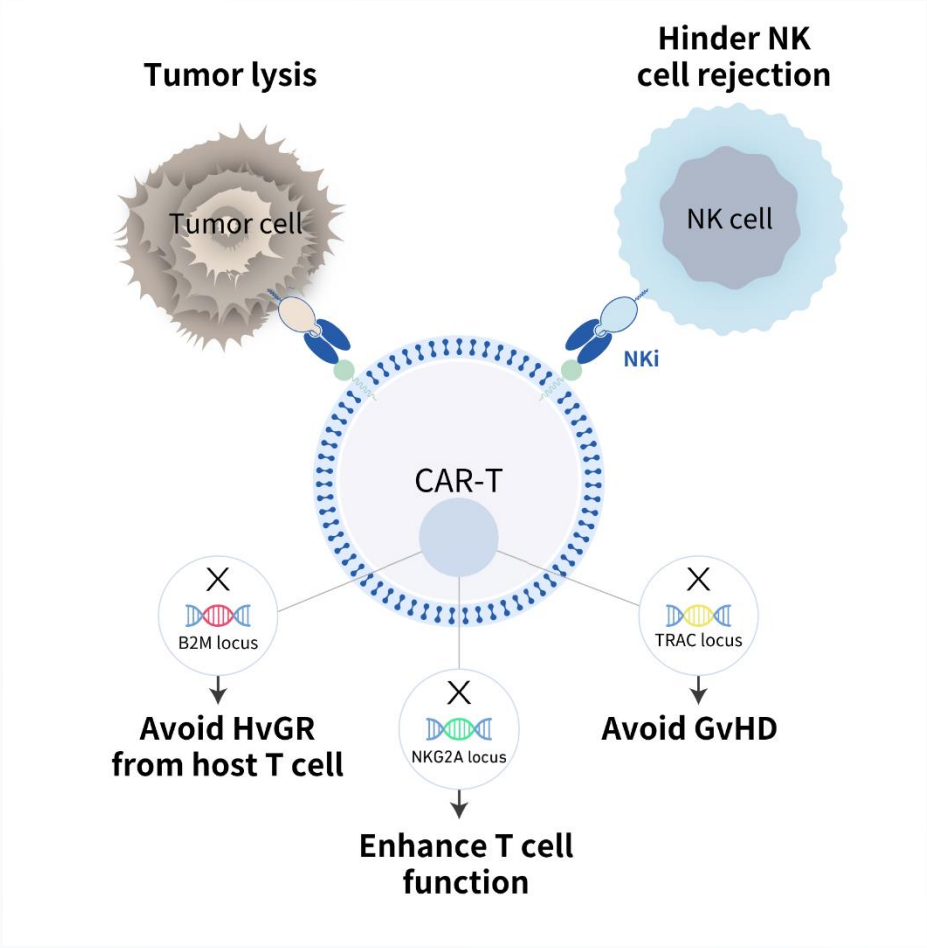


CARsgen's Pioneering Solutions

CARSGEN THERAPEUTICS

THANK-uCAR® or THANK-u Plus™: Innovative Allogeneic CAR-T Platform Aimed to Address HvGR

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.
- THANK-u Plus™ incorporates an additional inhibitory signaling module compared to THANK-uCAR®, enhancing resistance to NK cell-mediated elimination and expanding its application scope.

Early Efficacy of CARsgen's Technology Platform Across Various Indications

CARSGEN THERAPEUTICS

CT0590 (BCMA): First-Generation Product Built on the THANK-uCAR® Platform

Patient (Diagnosis)	Dose (cells)	High risk cytogenetics Y/N	# of prior lines	% Bone marrow smear plasma cell at baseline	% Baseline NKG2A expression NK cells	Best overall response	DOR (mo)	Peak CAR copy number (copies/μg gDNA)
PT 1 (MM)	50×10^6	Y	2	8	23	SD	NA	BLQ
PT 1-reinf (MM)	300×10^6			NA				5102
PT 2 (MM)	300×10^6	Y	2	94.5	38	**sCR**	**23**	**482749**
PT 3 (MM)	300×10^6	Y	3	6	12	SD	NA	BLQ
PT 4 (MM)	450×10^6	Y	3	6	NA	PR	4	BLQ
PT 4-reinf (MM)	450×10^6			25		PR	6.9	
#PT 5 (pPCL)	300×10^6	N	3	80	46	**sCR**	**20**	**280863**

This patient was treated under compassionate use

Data cut-off : 22-Apr-2024

- As of April 22, 2024, a total of 5 patients had been enrolled. Two patients achieved sCR, with **DoR ≥ 20 months and CAR copy numbers ≥ 200,000 copies/μg gDNA**. One patient achieved partial response (PR), while another patient achieved PR but objective response remained unconfirmed due to Covid-19.
  - ✓ Patient 2 remained in remission at data cutoff, with **DoR > 23 months**, and reached peak CAR copy number (**482,749** copies/μg gDNA) on day 19 post-infusion.
  - ✓ Patient 5, diagnosed with primary plasma cell leukemia (pPCL), achieved **DoR of 20 months**, with peak CAR copy number (**280,863** copies/μg gDNA) recorded on day 15 post-infusion.
- In a subgroup analysis of the autologous BCMA CAR-T product CARVYKTI CARTITUDE-1 trial, patients with high-risk cytogenetic abnormalities showed mDoR of **20.1** months, while those with ≥60% plasma cells achieved mDoR of **23.1** months.
- **No** incidents of immune effector cell-associated neurotoxicity syndrome (ICANS) or graft-versus-host disease (GvHD) were reported. There were **no** dose-limiting toxicities (DLTs), **no** treatment discontinuations due to adverse events (AEs), and **no** AE-related deaths.

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

CT0596 (BCMA): Second-Generation Product Built on the THANK-u Plus™ Platform

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 June 24, 2025, 8 R/R MM patients who had received at least 3 prior lines of therapy 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:
  - ✓ Five patients achieved PR or better: among them, 3 reached CR/sCR (all three received full-dose lymphodepletion therapy), 1 achieved PR, and 1 achieved Very Good Partial Response (VGPR).
  - ✓ Among the 6 patients who received full-dose lymphodepletion therapy, **4 achieved PR or better**. All 6 patients achieved minimal residual disease (MRD)-negative status by Week 4.
  - ✓ With extended follow-up, hematologic responses are expected to deepen further in MRD-negative patients. No disease progression has been observed in any patient, and Patient 01 has maintained sCR with sustained MRD-negative status for nearly 6 months.
  - ✓ The three previously reported patients with CR or better responses remain in remission. One patient initially assessed as PR has now achieved VGPR, demonstrating a progressively deepening response approaching CR.

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_{max}: **161,971** copies/μg gDNA; Maintained at 10^3 by Week 8	C_{max}: **151,654** copies/μg gDNA
Efficacy	Achieved **sCR** at Week 4 & 8; bone marrow MRD-negative ($<10^{-6}$) at Week 4	Achieved **sCR** at Week 4, 8, & 12; bone marrow MRD-negative ($<10^{-6}$) 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**.

pPCL: Primary Plasma Cell Leukemia; sCR: Stringent Complete Response; ASCT: Autologous Stem Cell Transplantation; PI: Proteasome Inhibitor; IMiD: Immunomodulatory Drug; CRS: Cytokine Release Syndrome; MRD: Minimal Residual Disease

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

THANK-u Plus™ Platform

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

CT1190B

- Based on the THANK-u Plus™ 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.

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/m² × 3 days + Cyclophosphamide 500 mg/m² × 3 days

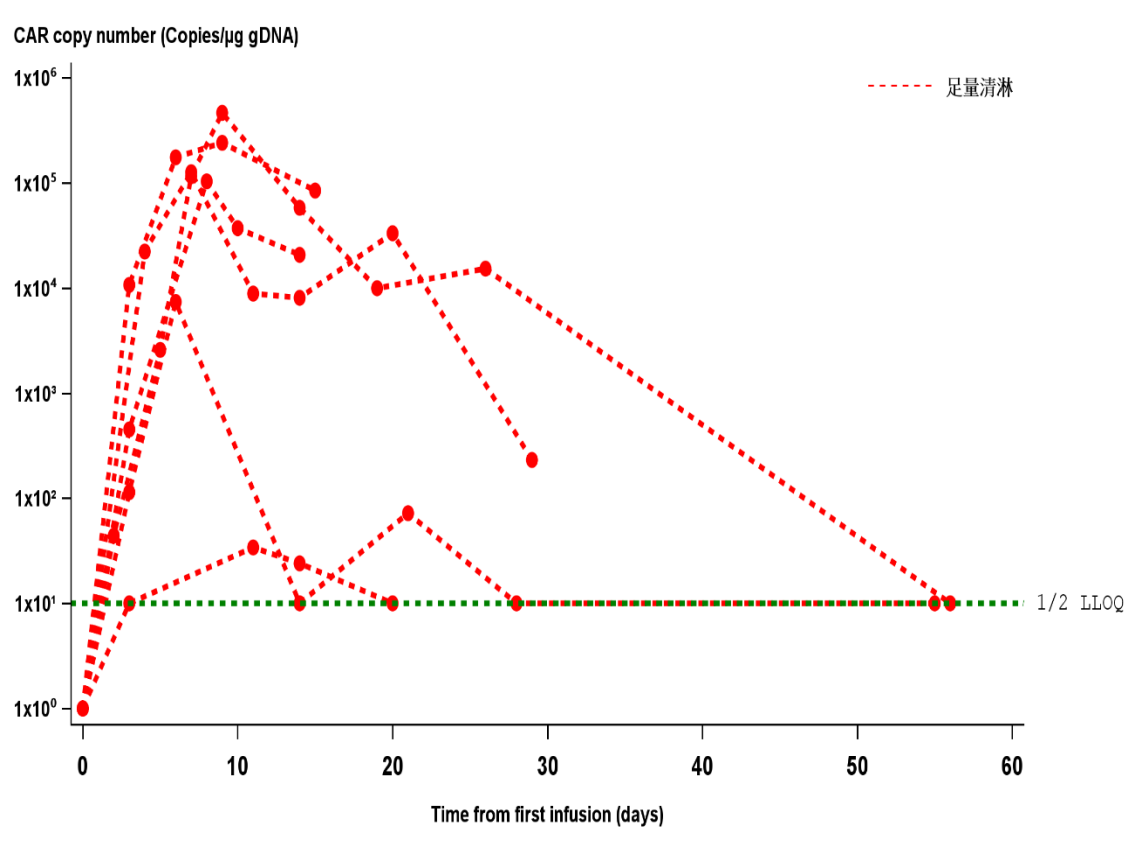
- All three FL patients achieved CR, resulting in an ORR of 100% and a CRR of 100%. One FL patient had failed immunochemotherapy, a PI3K inhibitor, chemotherapy + autologous HSCT, and CD3/CD20 bispecific antibody therapy. Another FL patient had failed immunochemotherapy + autologous HSCT and CD19 CAR-T therapy. The peak expansion copy number reached 10^3-10^4 copies/μg gDNA.

➢ Lymphodepletion Regimen: Fludarabine 30 mg/m² × 3 days + Cyclophosphamide 1000 mg/m² × 2 days

- 8 patients were enrolled under this regimen, including 2 MCL patients (cell dose: 6×10^8) and 6 DLBCL patients (cell doses: 3×10^8: 1 patient; 4.5×10^8: 1 patient; 6×10^8: 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 6×10^8 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 10^5 copies/μg gDNA.
  - ✓ In the 6×10^8 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 × 10^8), involving 6 patients (4 DLBCL, 2 MCL), the median Cmax of CT1190B reached 10^5 copies/μg gDNA. This significantly exceeds the levels observed with currently approved autologous CAR-T products (typically 10^3-10^4) and other investigational allogeneic CAR-T products (around 10^3).

Registration and Development Plan for CT0596 and CT1190B

Based on the strong clinical data from CT0596 and CT1190B—particularly their robust expansion and favorable benefit-risk profiles across multiple indications—we are accelerating their registration-enabling clinical studies. Our strategy focuses on indications with straightforward regulatory pathways and potential for priority review, allowing us to expedite the delivery of allogeneic CAR-T therapies to patients.

- **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.**

Scalability of CARsgen's Technology Platform

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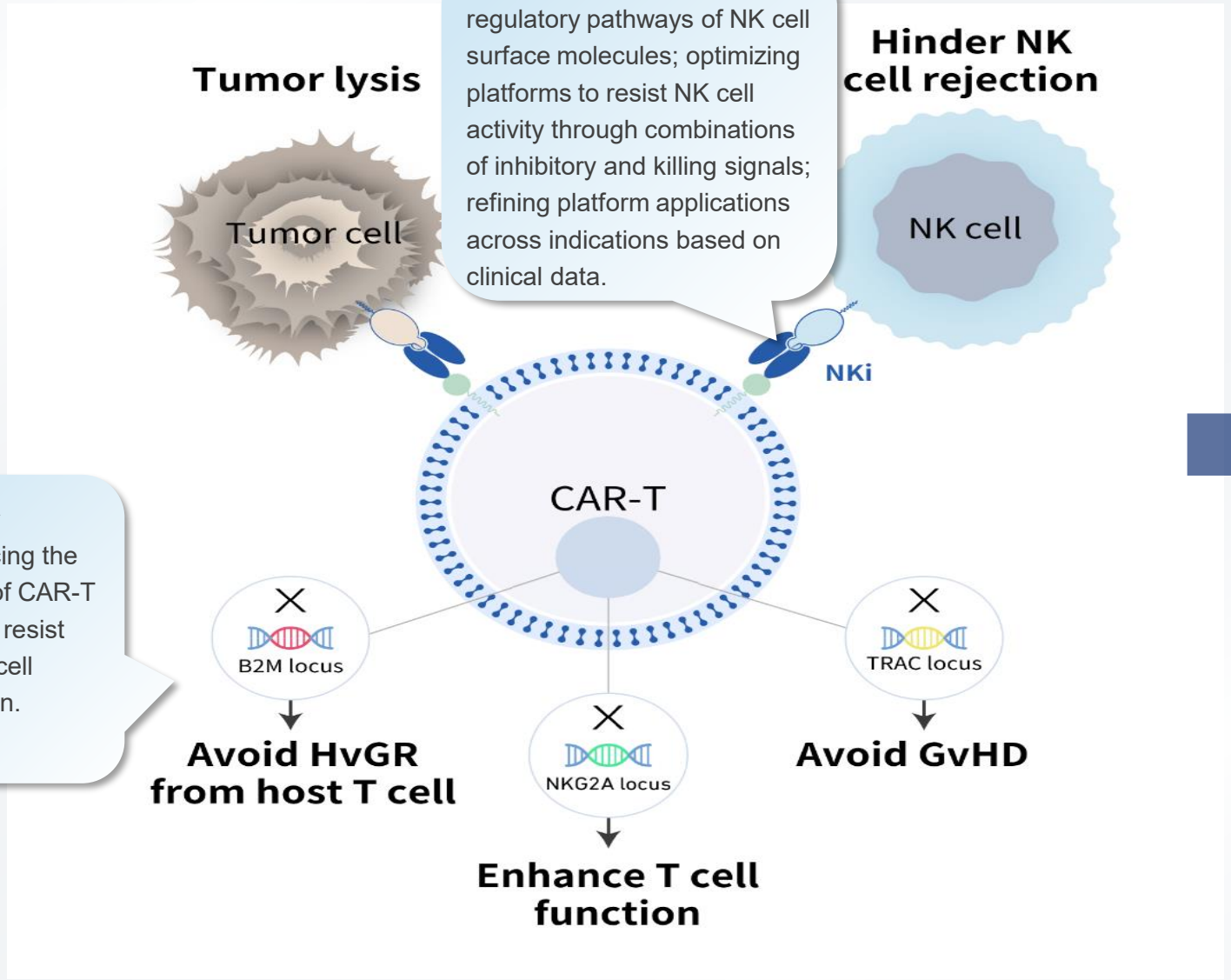
CARsgen's Allogeneic CAR-T Platform Demonstrates High Scalability



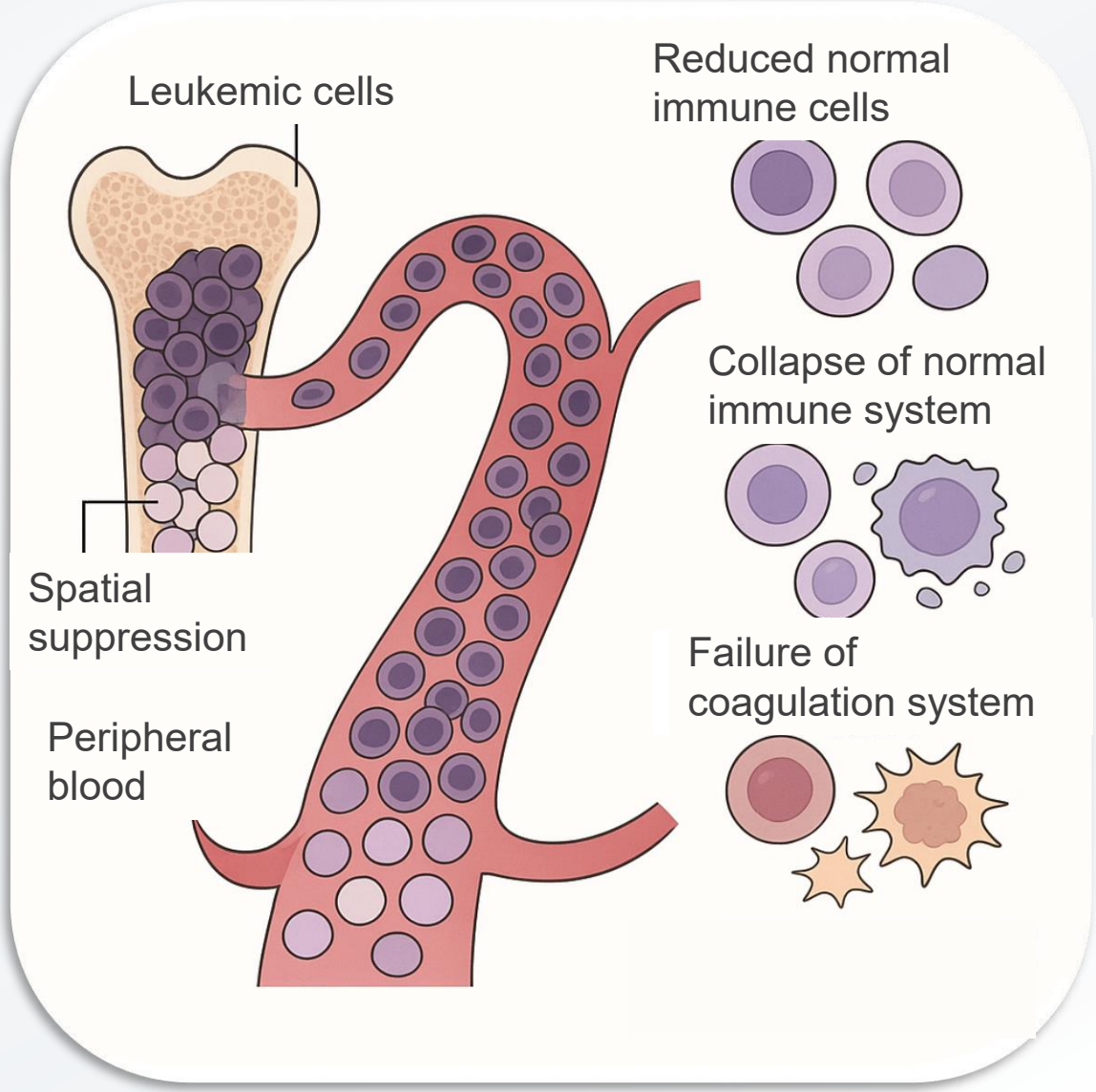
Addressing heterogeneity in NK cell activity across broader populations to support development in multiple disease areas:

Hematological malignancies

Solid tumors

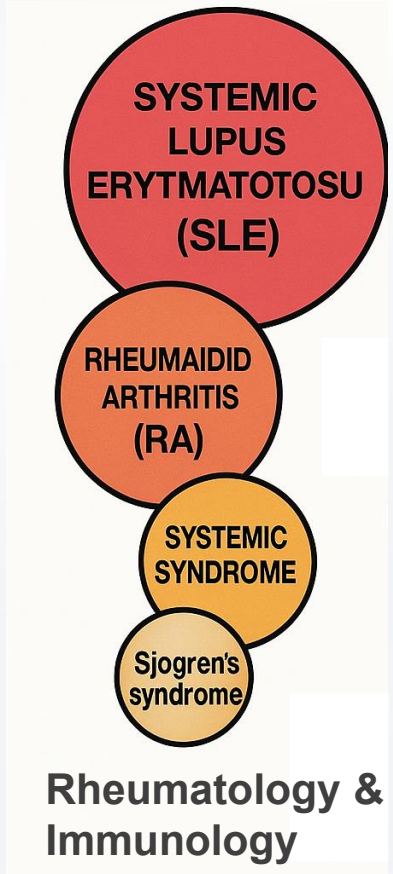
Autoimmune diseases…

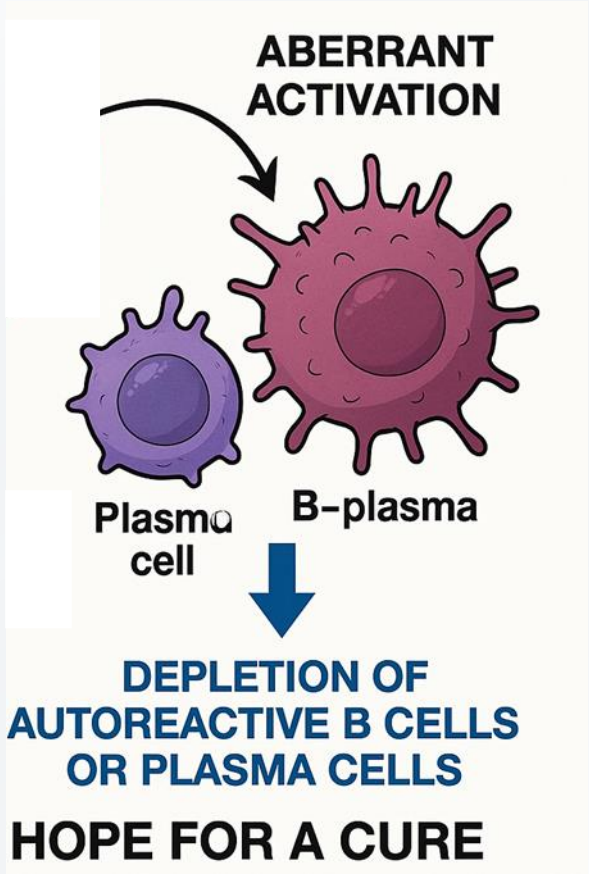
Deepening Our Presence in Hematologic Malignancies: Advancing into Acute Myeloid Leukemia

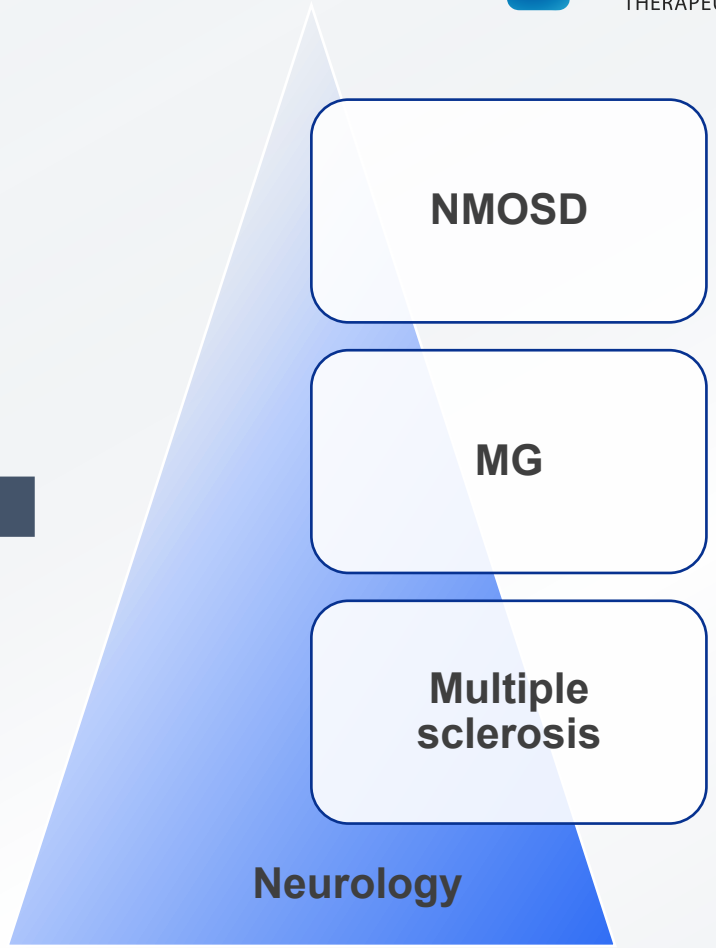


- ✓ Acute Myeloid Leukemia Disease Characteristics: Rapid progression; patients in advanced stages exhibit an immunosuppressed state due to bone marrow occupation by leukemic cells; immunotherapies relying on autologous immune cells (e.g., autologous CAR-T, bispecific antibodies) have shown limited progress in this area; current overall survival for relapsed/refractory AML patients is approximately 6 months, creating an urgent need for novel treatments.
- ✓ Allogeneic off-the-shelf CAR-T cells derived from healthy donor T cells will bring the promise of immunotherapy to these patients.
- ✓ Multiple CARsgen platform-based products targeting different antigens are planned for exploration in AML, aiming to tackle this tough challenge in immunotherapy
  - KJ-C2320: CD38 target, currently **in progress**
  - KJ-C2526: NKG2DL target, planned **H1 2026 IIT**
  - CLL1-targeted program will initiate clinical exploration in 2026

Expanding into Autoimmune Diseases: Leveraging Platform Advantages to Build Differentiation





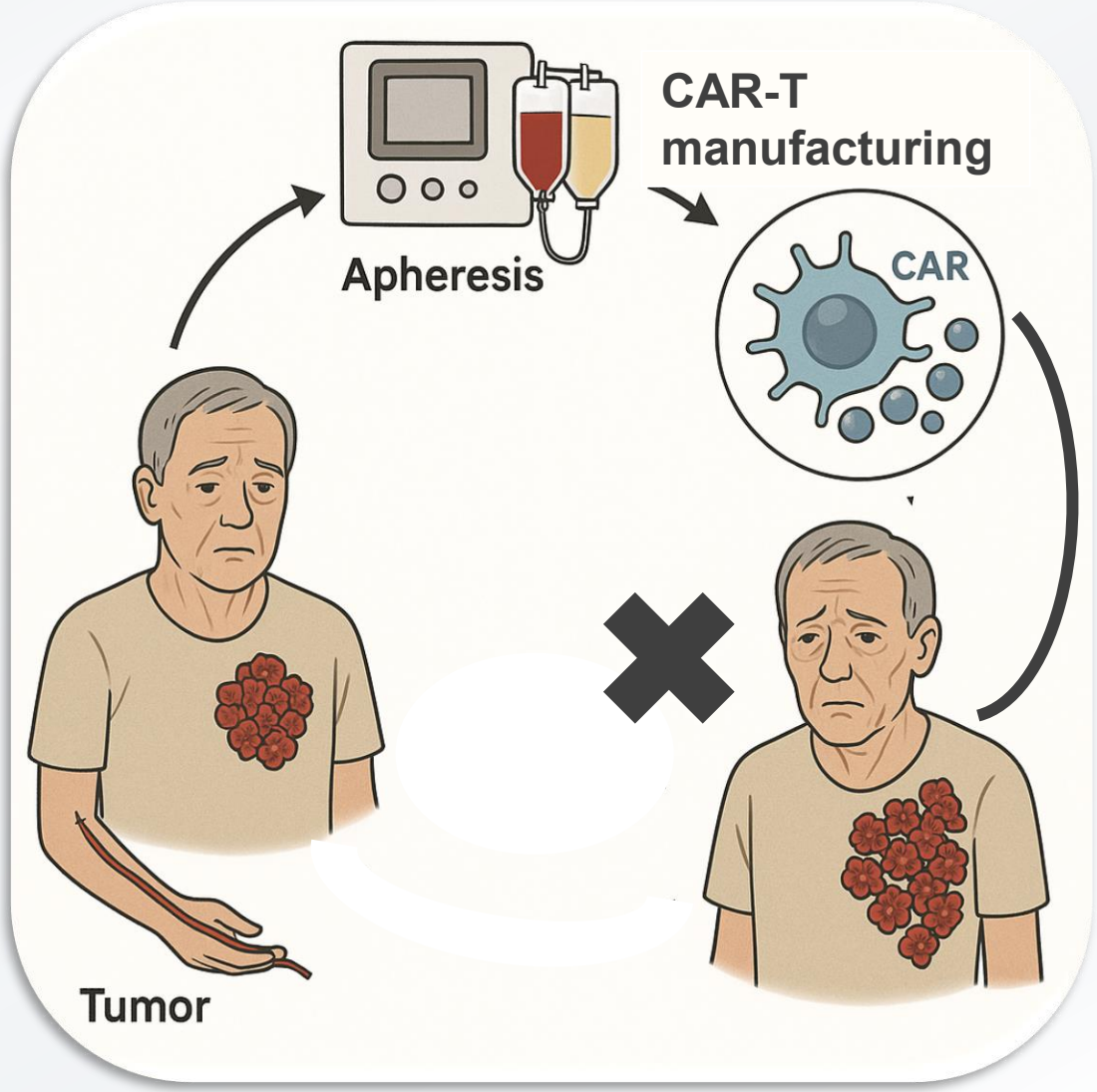


- CT1190B: Currently in progress
- Additional novel target programs in clinical planning, including a dual-target BCMA product

- Varying contributions of B cells and plasma cells across disease types
- Heterogeneity in NK cell activity among different diseases
- Selecting platforms and targets to deepen differentiation

- **CT059X, a dual-target BCMA allogeneic CAR-T, plans to initiate exploration in this field in 2026**

Expanding into Solid Tumors: Improving Accessibility and Efficacy for Late-Line Patients



- Late-line solid tumor patients often present with poor baseline conditions and rapid disease progression. A subset of patients experience disease progression during cell manufacturing, losing the opportunity for cell therapy.
- CARsgen's enhanced allogeneic CAR-T platform for solid tumors aims to provide more accessible, convenient, and efficacious treatment options for late-line patients.
  - ✓ An IIT for a Claudin18.2-targeted allogeneic CAR-T product is planned for 2026.
  - ✓ Selecting the appropriate technology platform for solid tumor patients

Expanding into Solid Tumors: Broader Early-Line Applications

CARsgen's Claudin18.2 IHC test kit with high sensitivity

Gastric Cancer	Pancreatic Cancer	Bile Duct Cancer
		
Moderate / high positivity (≥2+, ≥40%)	Moderate / high positivity (≥2+, ≥40%)	Moderate / high positivity (≥2+, ≥40%)
68%	55%	25%

- Claudin18.2 demonstrates broad expression profiles in gastrointestinal cancers.
- Early data from CT041 early-line exploratory studies (first-line sequential therapy in gastric cancer and adjuvant therapy in pancreatic cancer) indicate that incorporating CAR-T therapy in early-line solid tumor treatment can provide patients with prolonged disease-free survival and progression-free survival, while improving quality of life.
- Using our allogeneic platform, we will advance the most potent tumor-eliminating products identified in late-line settings to early-line applications.
- The high convenience and flexible dosing features of allogeneic CAR-T will better integrate with existing first-line treatments and standard adjuvant therapies in solid tumors, precisely targeting optimal therapeutic windows to enhance convenience, deepen responses, and maintain disease-free status.

Summary

- As a living drug, CAR-T plays a critical role in the deep clearance of tumors through its expansion and the formation of an optimal effector-to-target ratio.
- The greatest challenge faced by allogeneic CAR-T in clinical application is HVGR. Existing technologies require effective integration with lymphodepletion to achieve a favorable effector-to-target ratio within the treatment time window.
- By integrating CAR-directed killing of NK cells with the suppression of NK cell signaling, CARsgen's platform for overcoming HVGR sets it apart as both proprietary and cutting-edge.
- CARsgen's platform for overcoming HVGR has shown expected efficacy in multiple myeloma, plasma cell leukemia, and various types of non-Hodgkin lymphoma. At the recommended lymphodepletion dose, combined with a specific cell infusion dose, it can achieve peak expansion levels comparable to those of autologous CAR-T cells, forming an optimal effector-to-target ratio and creating conditions for deep tumor cell clearance.
- CARsgen will fully advance the registrational clinical studies of CT0596 and CT1190B under the current TAHNK-u Plus™ platform. With a clear preferred registration pathway and indications eligible for priority review, the company aims to rapidly bring allogeneic CAR-T products to market.
- CARsgen's platform for overcoming HVGR exhibits strong extensibility. Depending on the varying activity of NK cells in different disease contexts, the platform will employ tailored strategies for resistance and elimination, providing systematic allogeneic CAR-T solutions for a wide range of diseases and application scenarios.

Making Cancer Curable

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THERAPEUTICS