

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2023

**SANA BIOTECHNOLOGY, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39941**  
(Commission  
File Number)

**83-1381173**  
(IRS Employer  
Identification Number)

**188 East Blaine Street, Suite 400  
Seattle, Washington 98102**  
(Address of principal executive offices, including Zip Code)

**Registrant's telephone number, including area code: (206) 701-7914**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SANA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

Sana Biotechnology, Inc. (the “Company”) intends to discuss an updated corporate presentation (the “Corporate Presentation”) at the 41st Annual J.P. Morgan Healthcare Conference on January 10, 2023. A copy of the Corporate Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this “Current Report”) and is incorporated by reference herein.

By furnishing the information in this Item 7.01 of this Current Report, including Exhibit 99.1, the Company makes no admission as to the materiality of such information. The information contained herein is intended to be considered in the context of the Company’s filings with the U.S. Securities and Exchange Commission (the “SEC”) and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in the Corporate Presentation, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

In accordance with General Instruction B.2 of Form 8-K, the information furnished with this Current Report, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

See the Exhibit Index below, which is incorporated by reference herein.

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Corporate Presentation dated January 10, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**Sana Biotechnology, Inc.**

Date: January 10, 2023

By: \_\_\_\_\_ /s/ Bernard J. Cassidy  
**Bernard J. Cassidy**  
**Executive Vice President and General Counsel**

**Corporate Presentation**  
January 2023



# Cautionary Note Regarding Forward-Looking Statements

**This presentation contains forward-looking statements about Sana Biotechnology, Inc.** (the “Company,” “we,” “us,” or “our”) within the meaning of the federal securities laws. All statements other than statements of historical facts contained in this presentation, including, among others, statements regarding the Company’s strategy, expectations, cash runway and future financial condition, future operations, and prospects, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results to vary materially, including, among others, the risks inherent in drug development such as those associated with the initiation, cost, timing, progress and results of the Company’s current and future research and development programs, preclinical studies, and clinical trials.

For a detailed discussion of the risk factors that could affect the Company’s actual results, please refer to the risk factors identified in the Company’s SEC reports, including its Quarterly Report on Form 10-Q dated November 2, 2022. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.



# Sana Biotechnology

## Engineered Cells as Medicines

### **Sana's ambition is to repair or replace any cell in the body. Technologies address fundamental barriers:**

- **Hypoimmune (HIP) technology:** Overcoming immune rejection of allogeneic cells
- **Fusogen technology:** *In vivo* delivery of genomic modification reagents in a cell-specific manner

### **Overcoming immune rejection of allogeneic cells has potential to change cell therapy:**

- Allogeneic CAR T cells that perform clinically like autologous CAR T cells can transform treatment of hematological malignancies
- Key to unlocking the potential of stem cell-derived therapies such as pancreatic islet cells for the treatment of type 1 diabetes

### **Two opportunities in 2023 for clear clinical proof of concept:**

- SC291: Cell persistence and clinical efficacy
- HIP primary islets in patients with type 1 diabetes
- Results will provide insights in CAR T cell and stem-cell based platforms – ability to overcome allogeneic and autoimmune cell rejection

### **Pipeline poised to deliver multiple clinical data readouts over next several years:**

- **Hypoimmune allogeneic CAR T cells:** SC291 (CD19), SC262 (CD22), SC255 (BCMA), and beyond
- **Regenerative medicine:** SC451 (type 1 diabetes) and SC379 (CNS disorders)
- ***In vivo* fusogen platform:** SG295

### **Balance sheet allows potential for multiple data readouts**



# Sana's platforms, technology, and programs

Pipeline poised to deliver multiple clinical data readouts over next several years

Product Candidates	Mechanism	Potential Indications	Expected Clinical Milestones	
			2023	2024
SC291 (HIP)	CD19-targeted allo CAR T	NHL/ALL/CLL	●	●
HIP primary islet cells <sup>1</sup>		Type 1 Diabetes	● ●	●
SG295 (Fusogen)	<i>In vivo</i> CAR T (CD8/CD19)	NHL/ALL/CLL	●	●
SC262 (HIP)	CD22-targeted allo CAR T	NHL/ALL/CLL	●	●
SC451 (HIP)	Stem-cell derived pancreatic islet cells	Type 1 Diabetes		● ●
SC255 (HIP)	BCMA-targeted allo CAR T	Multiple Myeloma		●
SC379	Glial progenitor cells	PMD, HD, SPMS		●
SG239 (Fusogen)	<i>In vivo</i> CAR T (CD8/BCMA)	Multiple Myeloma		
SG242 (Fusogen)	<i>In vivo</i> CAR T (CD4/CD19)	NHL/ALL/CLL		
SG221 (Fusogen)	<i>In vivo</i> CAR T (CD4/BCMA)	Multiple Myeloma		
SG233 (Fusogen)	<i>In vivo</i> CAR T (CD8/CD22)	NHL/ALL/CLL		
SC418 (Fusogen)	<i>In vivo</i> hematopoietic stem cells	SCD, Beta-Thalassemia		

● IND filing  
● Clinical data

<sup>1</sup>IST, investigator sponsored trial.

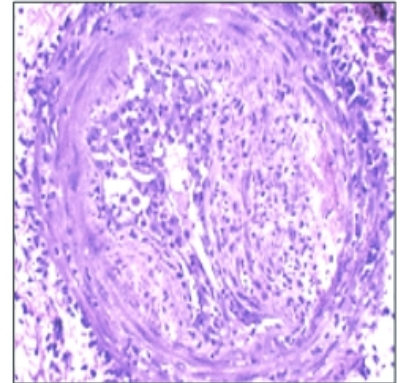
Abbreviations: ALL, acute lymphoblastic leukemia; CLL, chronic lymphocytic leukemia; HD, Huntington's disease; IND, investigational new drug; NHL, non-Hodgkin's lymphoma; PMD, Pelizaeus-Merzbacher Disease; SCD, sickle cell disease; SPMS, Secondary Progressive Multiple Sclerosis.



# Overcoming allogeneic immune rejection has been key limitation in transplant and cellular medicine

- ~75 years of organ and bone marrow transplants – immune rejection remains the largest problem
- Cell-based medicines face similar immune rejection challenges
- Significant immunosuppression is current standard
- Genome modification efforts to date have generally been incomplete
- Autologous therapies have limited scalability and are only available for a small number of cell types
- Red blood cell transfusions are the only example of successful, broadly available transplanted allogeneic cells
- Overcoming immune rejection of foreign cells has potential to unlock entire field of cellular medicine

**Biopsy of acute rejection of a pancreas transplant**



Drachenberg et al. *Am. J. Transplant.* 2008

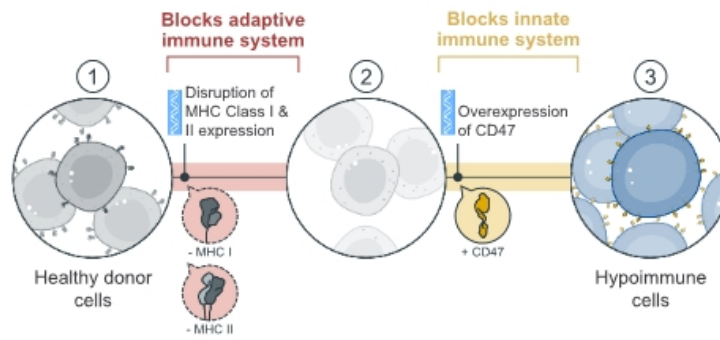


# Sana's hypoimmune solution: Leverage insights from nature

## Leverage insights from nature to create hypoimmune cells

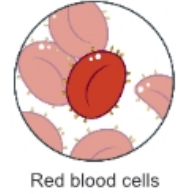


## Sana's hypoimmune approach



## Red blood cells

- Overexpress CD47
- Do not express MHC Class I and II

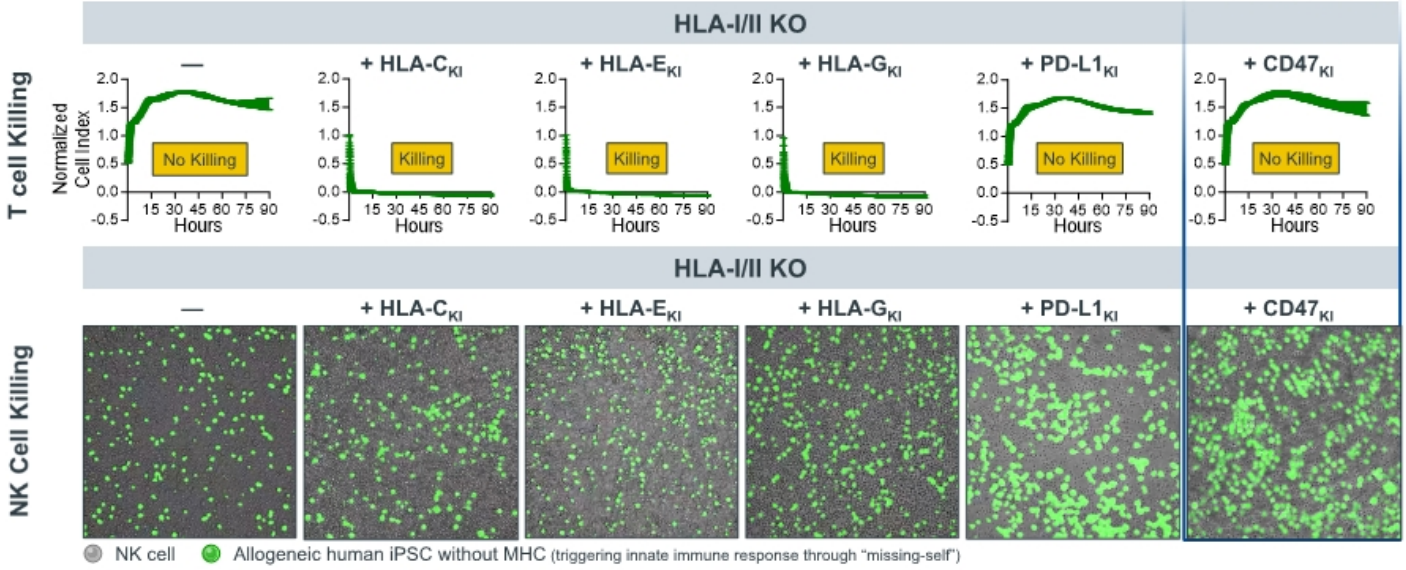


Abbreviations: MHC, major histocompatibility complex; RBC, red blood cell.  
Current clinical platform with multiple ongoing approaches in research phase.



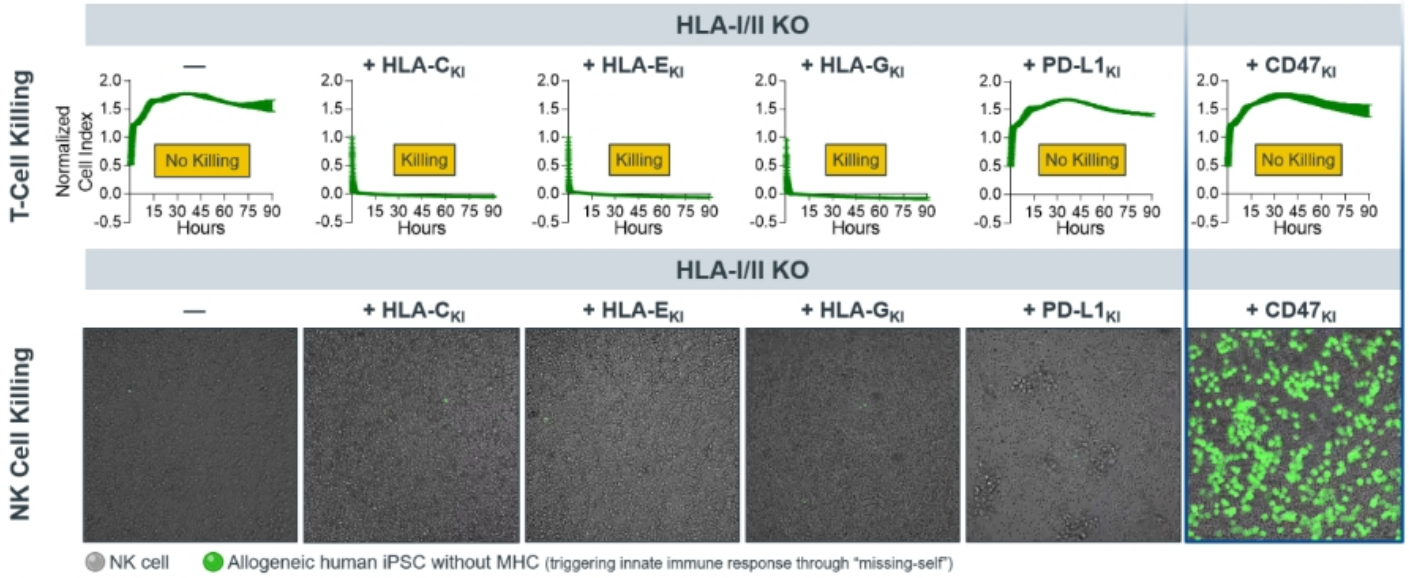
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# Sana's HIP modifications offer superior protection from innate cell killing



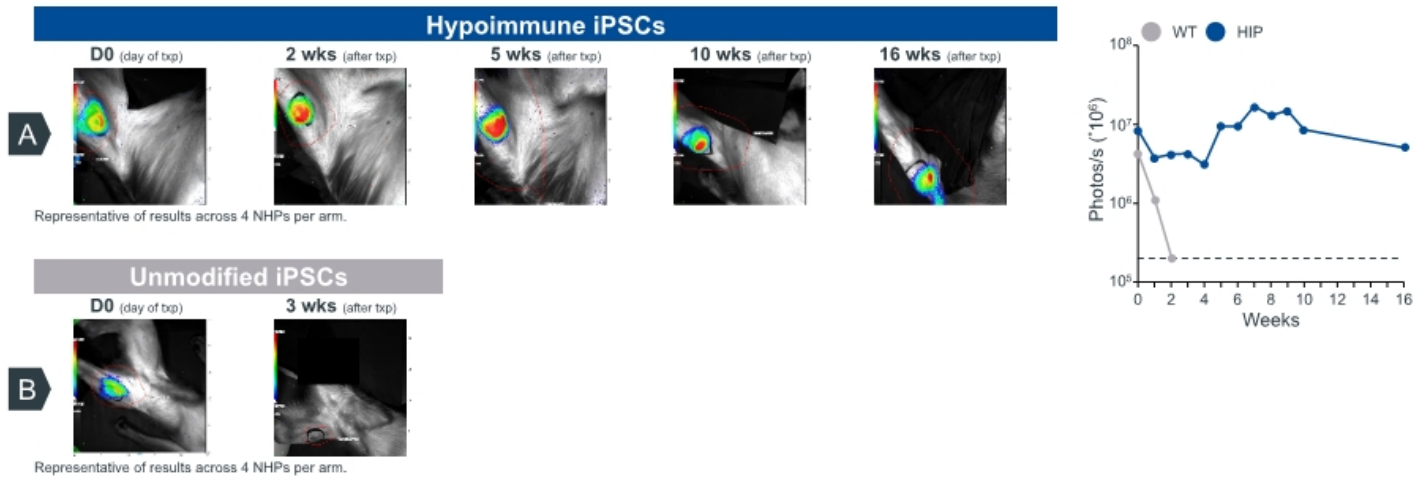
Abbreviations: HLA, human leukocyte antigen; iPSC, induced pluripotent stem cells; KI, knock-in; KO, knock-out; NK, natural killer; PD-L1, Programmed death-ligand 1.

# Sana's HIP modifications offer superior protection from innate cell killing



Abbreviations: HLA, human leukocyte antigen; iPSC, induced pluripotent stem cells; KI, knock-in; KO, knock-out; MHC, major histocompatibility complex; NK, natural killer.

# Hypoimmune cells survive *in vivo* when transplanted in NHP while unmodified iPSCs get rejected



NHP unmodified iPSCs (WT) & NHP hypoimmune iPSCs (HIP) were transplanted into eight allogeneic NHP recipients

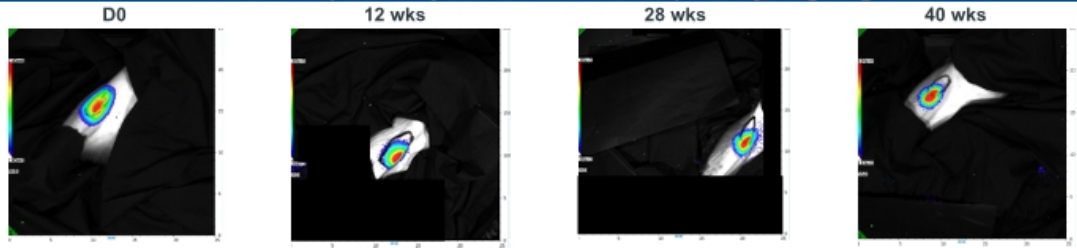
Abbreviations: NHP, non-human primate; Txp, transplant; WT, wild type.

# Survival of allogeneic hypoimmune pancreatic islet cells for 10+ months without immunosuppression

## Study design:

- NHP primary islet cells isolated and HIP-edited
- Cells injected intramuscularly into a healthy, allogeneic NHP without immunosuppression

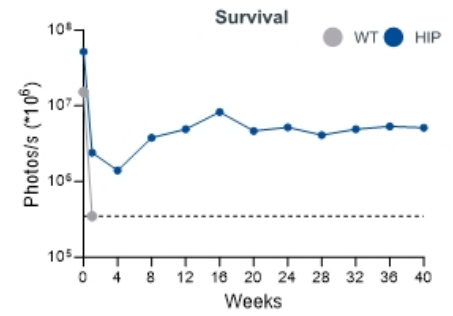
## HIP results (follow up shown: 10 months). Study ongoing.



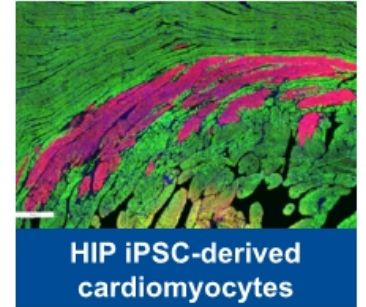
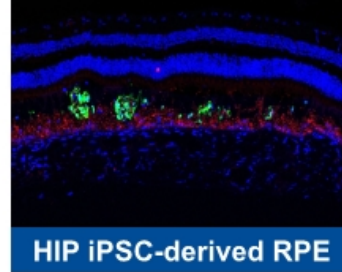
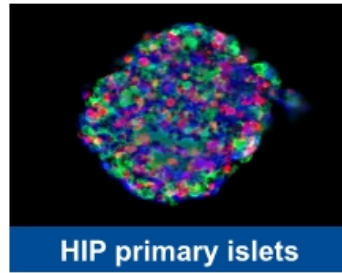
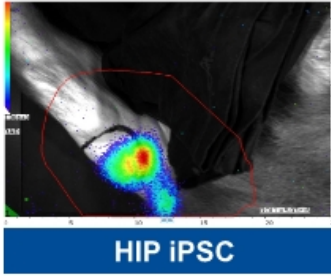
## WT results (no survival after 1 wk)



n=1 HIP primary islet cells; n=1 WT primary islet cells.



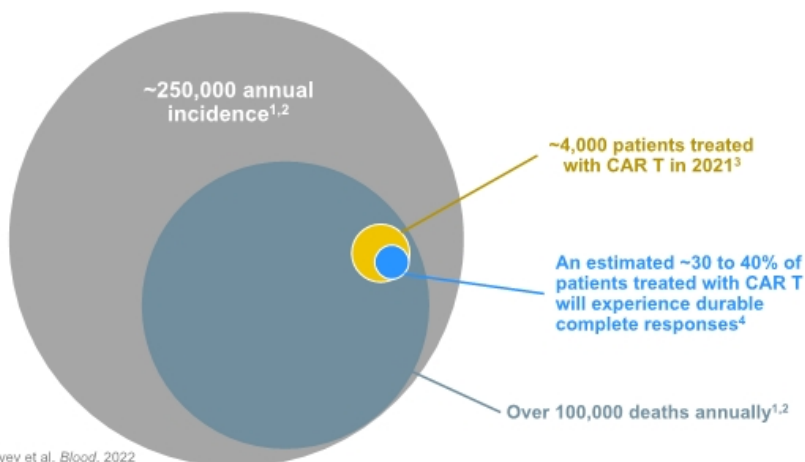
# Survival and immune evasion after transplant for different cell types in multiple NHP studies



Abbreviations: RPE, retinal pigment epithelium.

# Hematologic cancers continue to have a high unmet need

## High mortality in lymphoma and myeloma in the US and EU5



<sup>1</sup>Avezbakdyev et al. *Blood*. 2022

<sup>2</sup>Durie et al. *The Oncologist*. 2020

<sup>3</sup>Clarivate DRG NHL Market Forecast Nov 2021

<sup>4</sup>Scivida 2022 NHL Factbook

Abbreviations: EU5, France, Germany, Italy, Spain, UK

## Challenges

- Autologous CAR T cell scalability
- Many patients fail CAR T treatment
- Allogeneic CAR T cells immune rejection limits persistence and efficacy

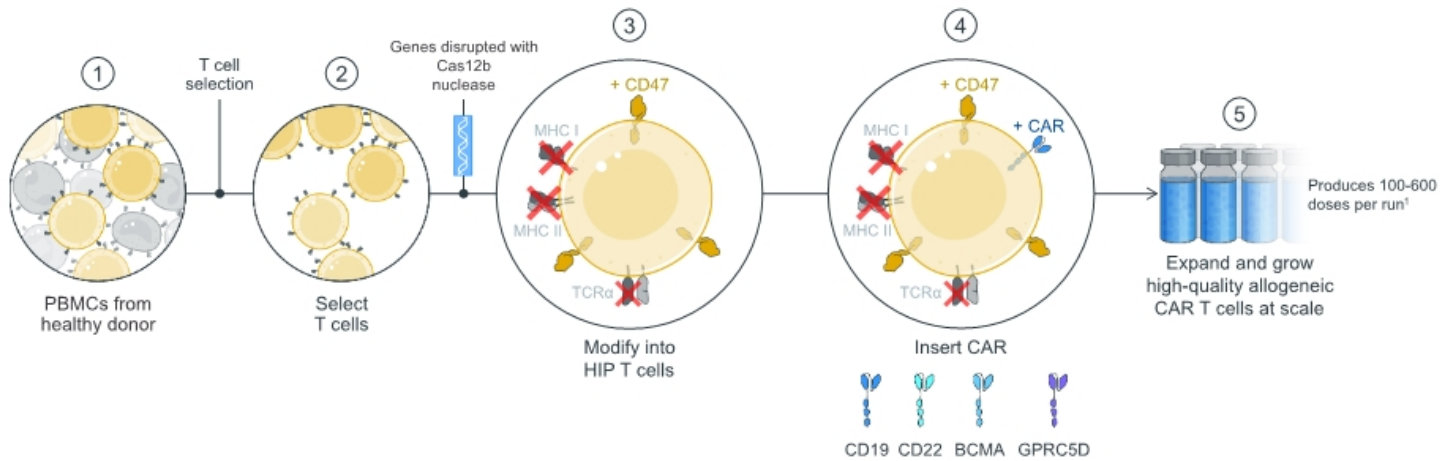
## Opportunity

- Known targets
- Known efficacy and safety bar

**Sana's HIP CAR T platform can address challenges and exploit opportunities**



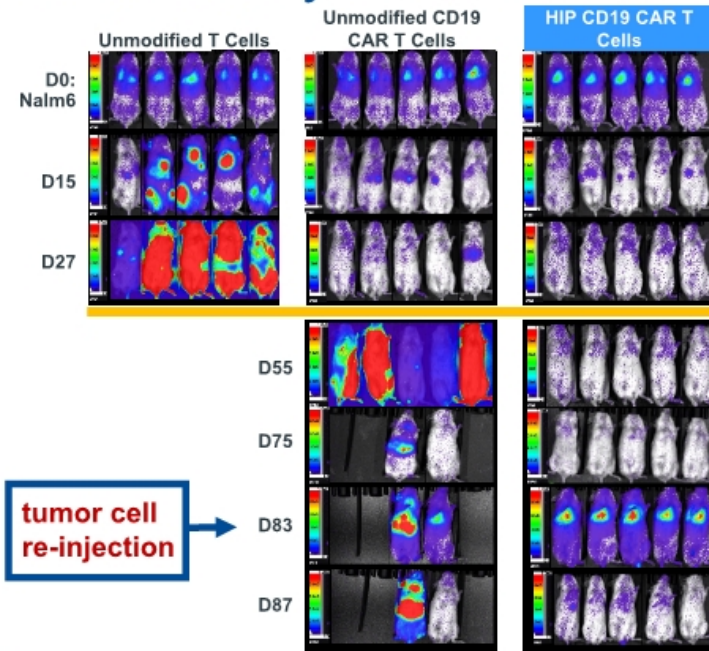
# Sana's HIP platform can create a regenerative pipeline for allogeneic CAR T therapies



<sup>1</sup>Based on current scale, assuming 50% hold back for analytical and other testing, and variability in dose in Phase 1 study.  
Abbreviations: Cas12b, CRISPR associated protein 12b; GPRC5D, G protein-coupled receptor, class C, group 5, member D; PBMC, peripheral blood mononuclear cell.



# HIP CD19 CAR T cells demonstrate persistence and continued efficacy in humanized mice model

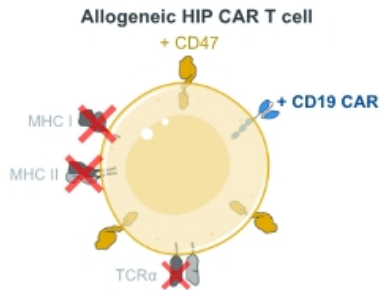


- SC291 tumor control comparable at early timepoints to standard CD19 CAR T cells
- SC291 tumor control superior at later timepoints to standard CD19 CAR T cells
- SC291 controls tumors when animals are rechallenged with tumor

# Improved persistence can lead to best-in-class allogeneic CAR T platform

## SC291: Sana's CD19 HIP allogeneic CAR T

- IND filed
- First clinical data in 2023



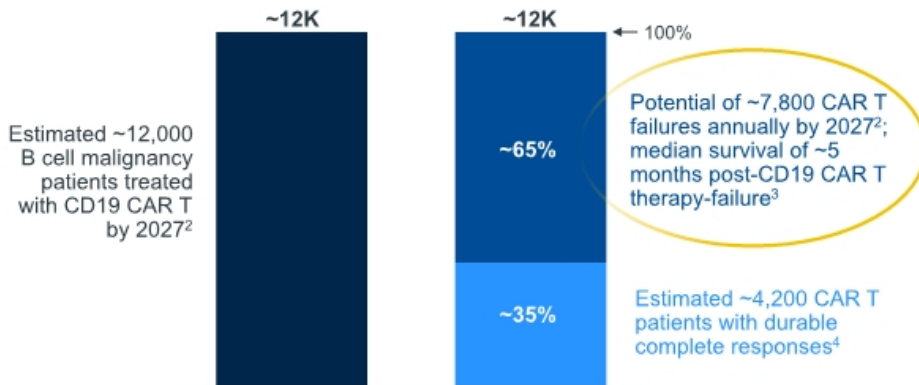
## Data show CAR T cell persistence correlates with long term complete response (CRs) rates<sup>1</sup>

CAR T Persistence		Potential Efficacy Outcome
≤ 1 month	▶▶▶	Comparable to existing Allo CAR T
2 to 3 months	▶▶▶	Best-in-class Allo CAR T
3 to 6 months	▶▶▶	Comparable to Auto CAR T
≥ 6 months	▶▶▶	Better than Auto CAR T

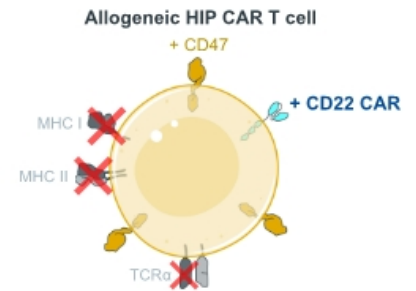
<sup>1</sup>Porter et al. *Science Translational Medicine*, 2015

# SC262: Targeting growing population of patients with inadequate response to CD19 therapy

## CD19 CAR T relapsed patients represent large and growing unmet need<sup>1</sup>



## SC262 utilizes a clinically-validated CD22 CAR



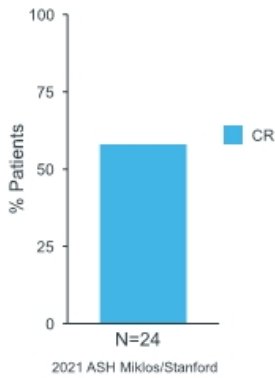
<sup>1</sup>US, EU5, and Japan.

<sup>2</sup>Clarivate DRG NHL Market Forecast Nov 2021; 2027 Forecast is 2L+ LBCL patients.

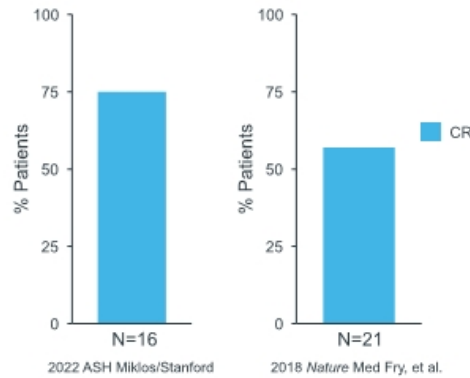
<sup>3</sup>Di Biasi et al. *Blood*.2022; DESCAR-T registry.

# SC262: Licensed CD22 CAR produced strong clinical data in CD19 failures when part of autologous CAR T

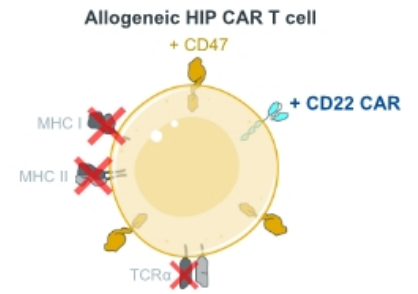
>50% 6-month CR rate in CD19 CAR failure DLBCL patients



High rate of CRs in CD19 failure ALL patients  
~80% patients with prior CD19 therapy



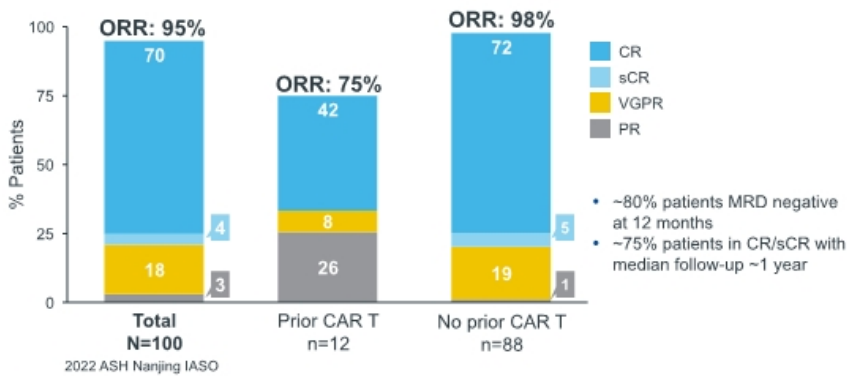
Expand our allo T platform to CD22 with Sana's SC262 candidate



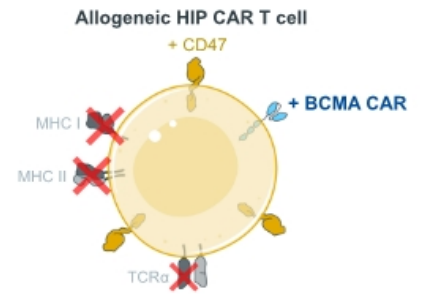
SC262 Goals: File IND this year; clinical data in 2024

# SC255: Licensed BCMA CAR produced strong clinical data in myeloma when part of autologous CAR T

## High response rate in multiple myeloma with 95% of patients MRD negative



## Expand our allo T platform to BCMA with Sana's SC255 candidate



**SC255 Goal: File IND as early as 2024**

Abbreviations: CR, complete response; ORR, objective response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

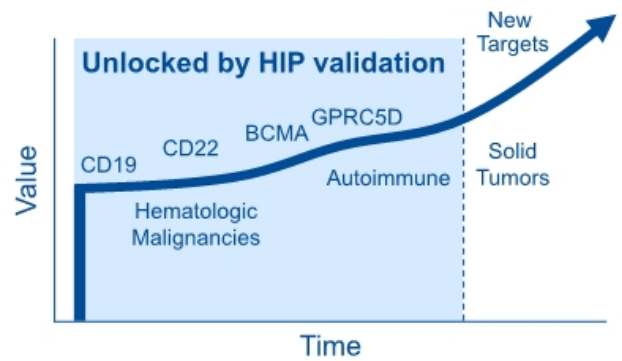
# Goal is to build a best-in-class CAR T portfolio to treat patients with a range of cancers and beyond

## Known

- Validated targets
- Validated CAR constructs
- >100,000 potential cancer patients worldwide<sup>1,2</sup>
- HIP platform understood in preclinical models

## Future State

- Potential for SLE and other autoimmune disorders
- Solid Tumors
- HIP platform understood in humans



## Unlocking the potential of our allogeneic CAR T franchise across multiple patient populations

<sup>1</sup>Avezbakiyev et al. *Blood*, 2022.

<sup>2</sup>Durie et al. *The Oncologist*, 2020.

Abbreviations: SLE, systemic lupus erythematosus.

# Type 1 diabetes represents a large unmet need with a loss of ~15 years of life<sup>1</sup>

- Disease caused by autoimmune destruction of insulin-producing beta cells in the pancreas; results in inability to control blood glucose
- Type 1 diabetes is a large unmet need with 1.6M patients in the U.S. and 2.4M in Europe<sup>2</sup>
- Long-term complications: end-organ damage, including heart attack, stroke, blindness, and kidney failure
- SC451 goal is euglycemia without exogenous insulin or immunosuppression



<sup>1</sup>Rawshani et al. *Lancet*. 2018

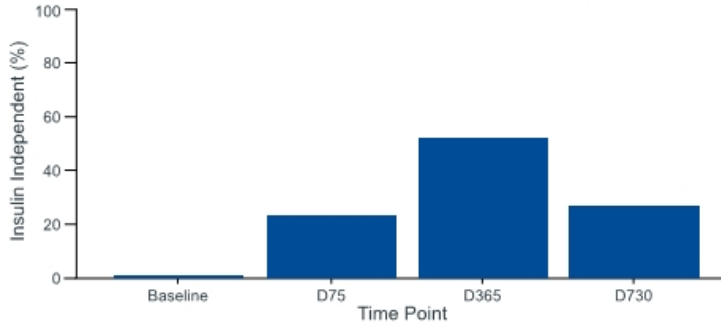
<sup>2</sup>Centers for Disease Control and Prevention, *Diabetes Report*, 2017-2018.



# Islet cell transplantation has been shown to work in type 1 diabetes

## Islet cell transplants result in insulin independence in type 1 diabetics

- Phase 3 trial of primary islets showed 52% & 42% of patients become insulin independent at 1 & 2 years, respectively
- Utilization limited by need for lifelong immunosuppression



Hering et al, *Diabetes Care*, 2016.

N= 48 adults; demonstrated efficacy of islet transplant with 87.5%/71% achieving primary endpoint (HbA1c <7% and no serious hypoglycemia) at 1 and 2 years.

## Sana's solution: Hypoimmune islet cells for type 1 diabetes (SC451)

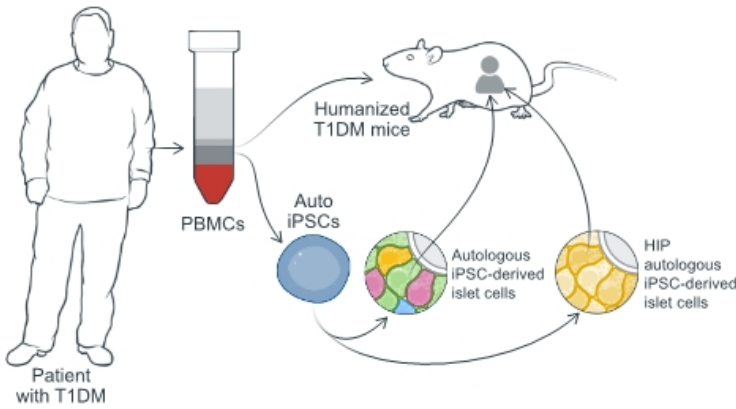
- PSCs can provide scale and product consistency
- HIP has potential to eliminate immunosuppression, protecting against both allogeneic and autoimmune rejection





# Sana's immunology, gene modification, & stem cell capabilities create proprietary type 1 diabetes model

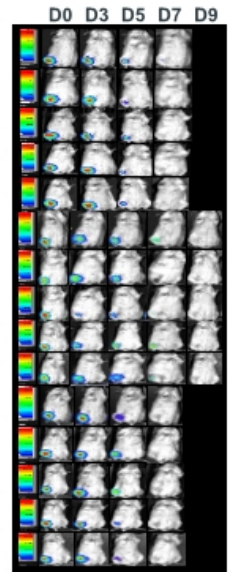
**Type 1 diabetic PBMCs used to generate stem cell-derived islet cells and to humanize immune system in mice**



**Unmodified patient stem cell-derived islet cells do not survive**



**Patient T cells eliminate islet cells due to autoimmunity**

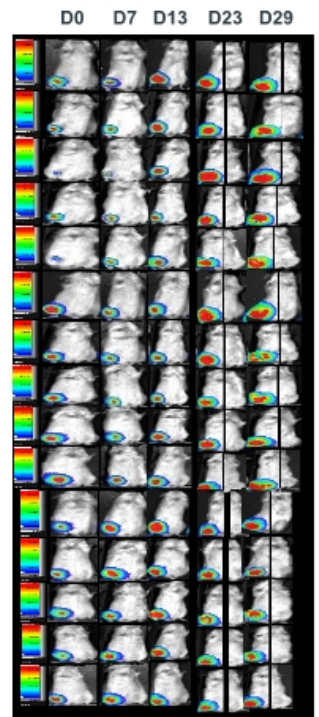
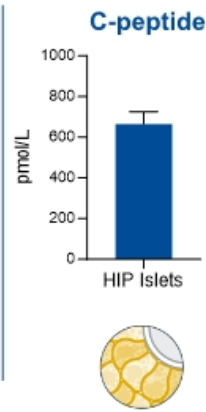
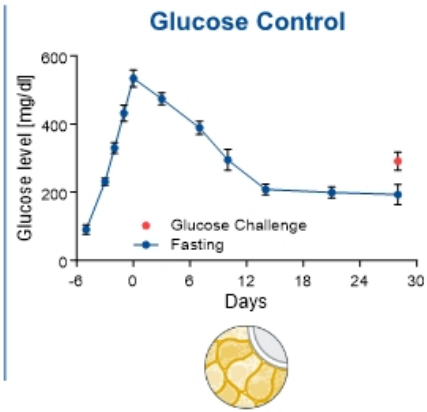
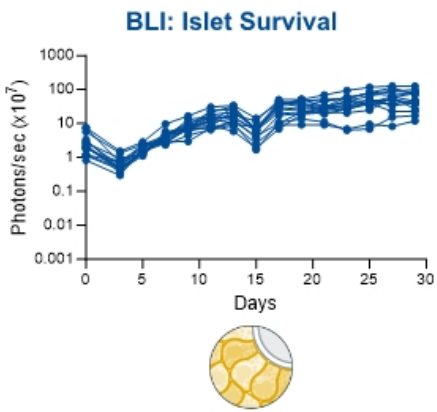


Abbreviations: T1DM, type 1 diabetes mellitus.



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# HIP iPSC-derived pancreatic islet cells from T1DM patient evade autoimmune killing and control glucose



**SC451 Goal: File IND and share clinical data in 2024**

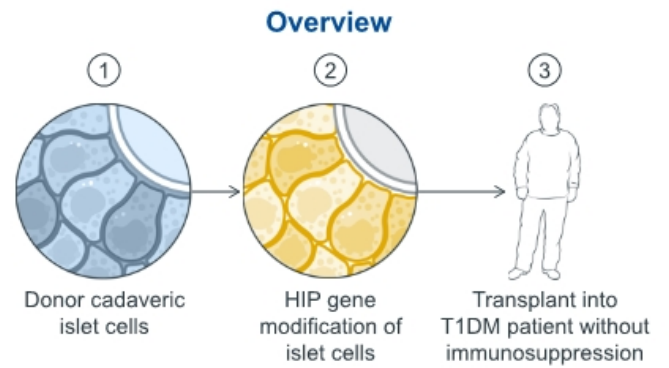
Abbreviations: BLI, bioluminescence imaging.



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# Path to potential clinical validation of hypoimmune islet cells in T1DM patients in 2023

- Investigator sponsored trial
- Primary human HIP islet cells transplantation in type 1 diabetes patients
- Goal: Cell survival with no immunosuppression
- Goal: Data in 2023
- Insight for SC451

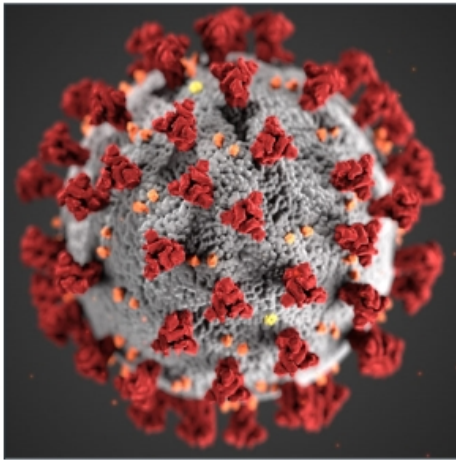


## Key Measured Outcomes

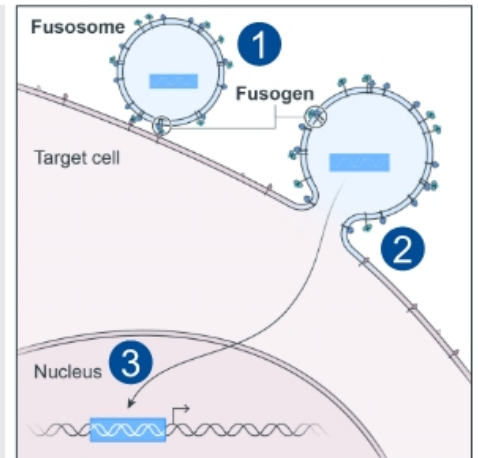
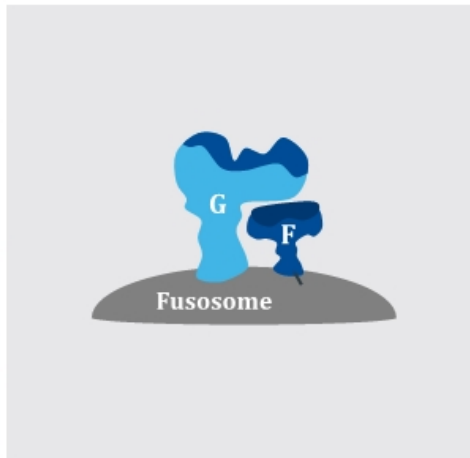
Cell survival & immune evasion  
C-peptide  
Glycemic control

# Fusosome technology: Development of cell-specific *in vivo* delivery platform

Sana approach: Leverage insights from nature to deliver various payloads to specific cells



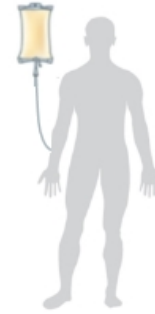
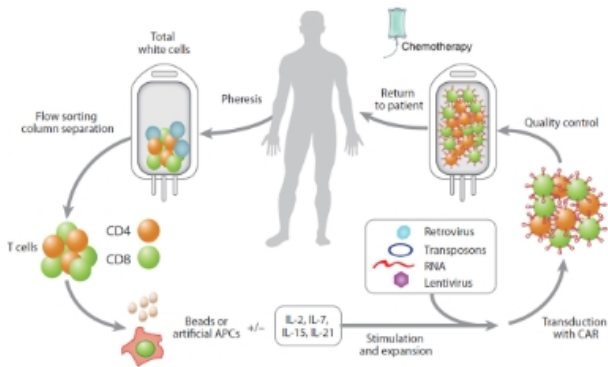
Source: CDC website



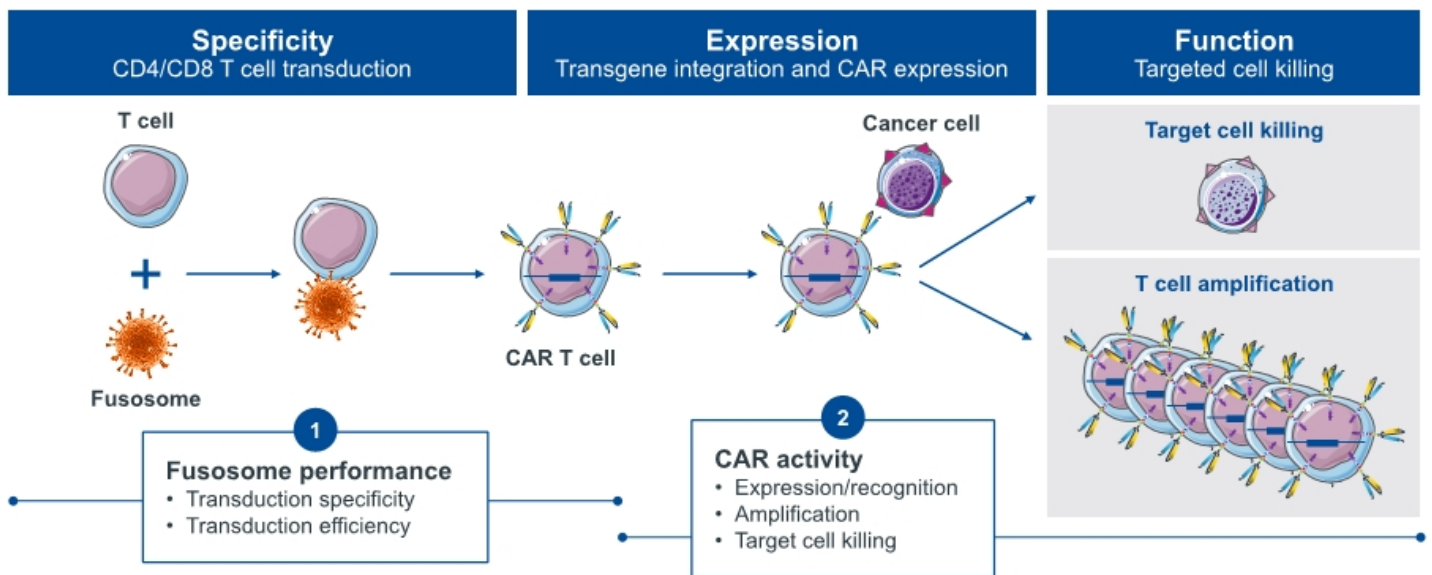
# Fusogen technology has potential to eliminate conditioning chemotherapy and *ex vivo* manufacturing

Current *ex vivo* approaches have limitations

Fusogen platform offers potential to overcome these limitations

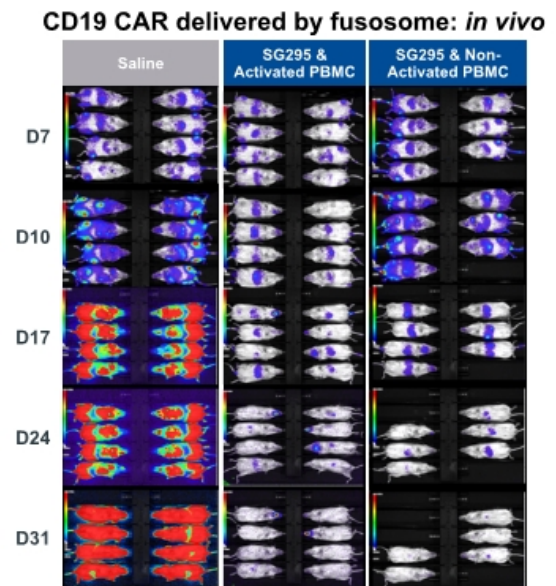
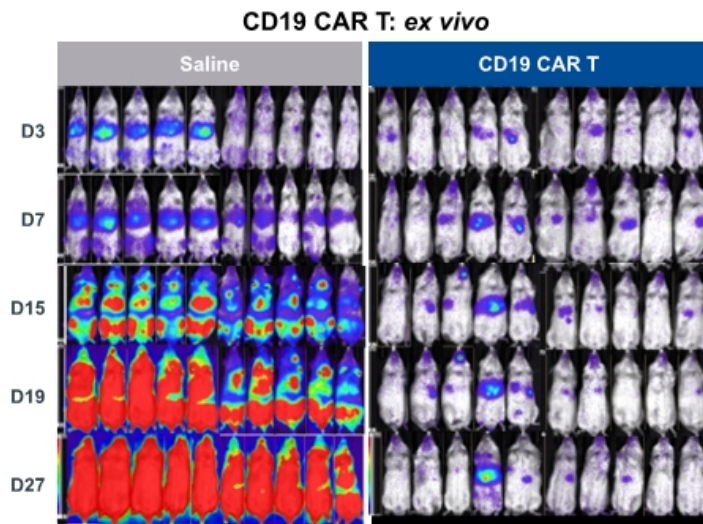


# T cell fusosome delivers CAR construct directly to T cells *in vivo*



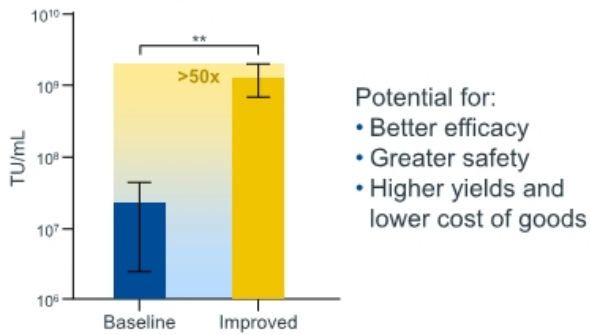


# IV administration of CD19 CAR delivered by fusosome can clear B cell tumors in humanized mice comparably to *ex vivo* CD19 CAR T

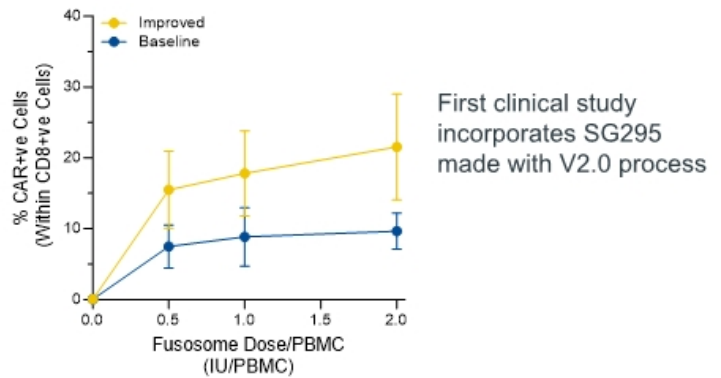


# Significant improvements in manufacturing process may lead to a better therapy

## SG295 made with V2.0 process results in >50X potency improvement



## SG295 made with V2.0 process transduces more T cells at the same dose



**SC295 Goals: File IND in 2023; clinical data in 2024**

Abbreviations: TU, transduction units.



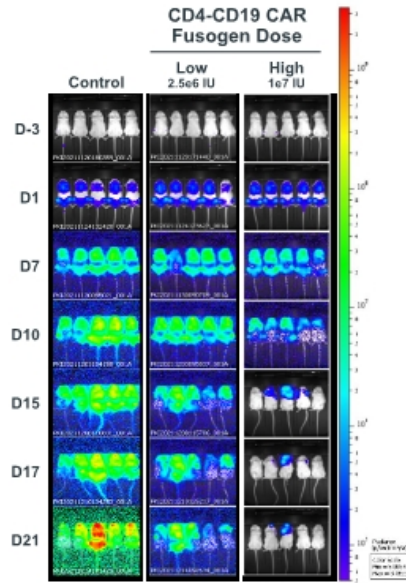
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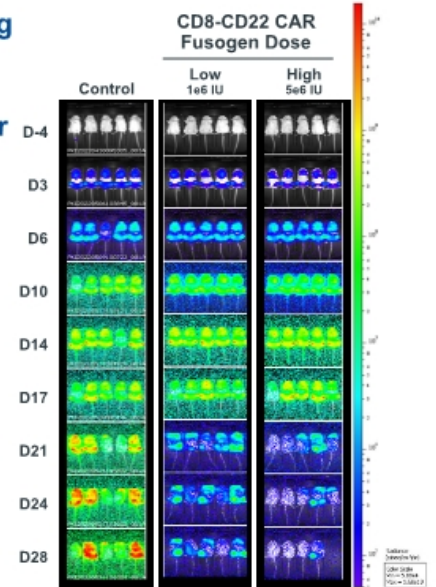


# Tumor control achieved with fusosomes targeting other cell types and alternate tumor antigens

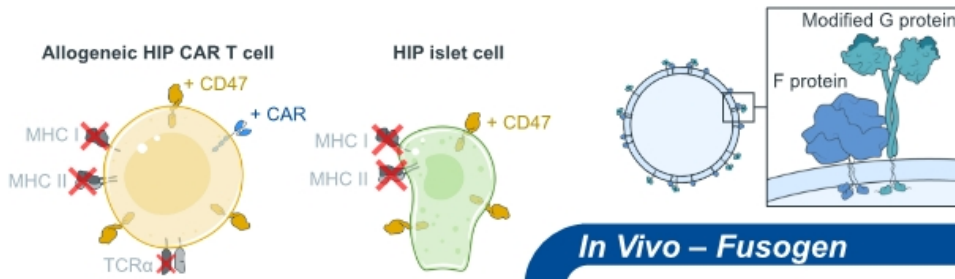
**CD4 T cell targeting fusosomes delivering CD19 CAR achieve tumor control in mice**



**CD8 T cell targeting fusosomes delivering CD22 CAR achieve tumor control in mice**



# Sana aspiration: Engineered cells as medicines



Engineered cells into new therapeutic areas

## Ex Vivo – Hypoimmune

### Allogeneic CAR T Franchise

- Oncology: SC291, SC262, SC255
- Autoimmune

### Stem Cell-Derived

- Type 1 Diabetes: SC451
- CNS: SC379<sup>1</sup>

2023

<sup>1</sup>Does not incorporate hypoimmune genomic modifications



## In Vivo – Fusogen

- *In vivo* CAR T: SG295
- Cell-specific *in vivo* HSC editing: SG418
- Cell-specific delivery of genomic modification material

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# Thank You

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