# 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): September 13, 2021**

# SANA BIOTECHNOLOGY, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39941** | **83-1381173** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(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 present an updated corporate presentation (the "Corporate Presentation") at the Morgan Stanley 19th Annual Global Healthcare Conference on September 13, 2021. 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 (the "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*

| Exhibit No. | Description |
|---|---|
| 99.1 | Corporate Presentation dated September 13, 2021 |
| 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: September 13, 2021

By: /s/ James J. MacDonald

**James J. MacDonald**
**Executive Vice President and General Counsel**

Exhibit 99.

# Corporate Presentation
# September 2021

# 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 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 but not limited to its Annual Report on Form 10-K dated March 24, 2021 and Quarterly Report on Form 10-Q dated August 4, 2021. 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

**We believe the ability to modify the genome and use engineered cells as medicines will be one of the most (if not the most) important advances in healthcare over the next several decades**

**Three aspirations drive us in our pursuit to deliver on the promise of cells as medicines**

- Repair and control the genes in any cell in the body
- Replace any cell in the body
- Broad access to our therapies

**We continue to advance our technologies with multiple INDs planned as early as 2022**

# Sana goal: fix cells in the body when possible or replace them when needed

## *in vivo* Cell Engineering

**Repair and control the genes of any cell in the body**

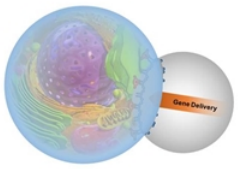
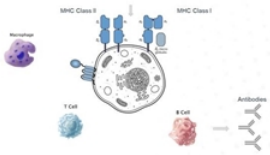
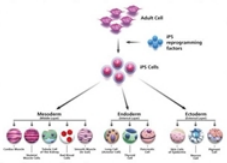
- **Deliver any payload** (DNA, RNA, protein, organelle, integrating vs non-integrating)…
- **To any cell** (unlimited volume of distribution) **in a…**
- **Specific** (e.g., just T cell),…
- **And repeatable way** (limit immunogenicity)

## *ex vivo* Cell Engineering

**Replace any cell in the body**

- **Manufacture any cell at scale**…
- **That engrafts** (the right cell in the right environment)…
- **Functions** (understand exact phenotype desired)…
- **And persists** (overcome immune rejection and cellular signaling, such as apoptotic signaling)

# Assembling an experienced team across capabilities

| Delivery of Genetic Material | Modification of Genome | Immunology | Biology | | | Manufacturing |
|---|---|---|---|---|---|---|
| | | | Cell Biology | Stem Cell Biology | Disease Biology | |
|  |  |  |  | | |  |
| Richard Mulligan, PhD<br>Jagesh Shah, PhD | Ed Rebar, PhD<br>Christina Chaivorapol, PhD | Sonja Schrepfer, MD, PhD<br>Terry Fry, MD | Sunil Agarwal, MD<br>Terry Fry, MD<br>Chuck Murry, MD, PhD<br>Steve Goldman, MD, PhD<br>Donna Dambach, VMD, PhD<br>Ke Liu, MD, PhD | | | Stacey Ma, PhD<br>Craig Lichtenstein<br>Mike Laska, PhD<br>Oscar Salas, PhD |

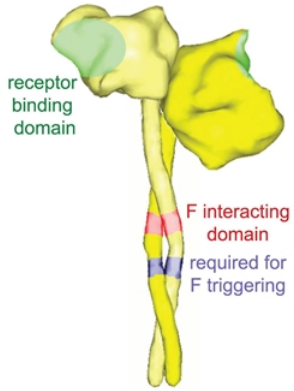
# Sana's platforms, technology and programs

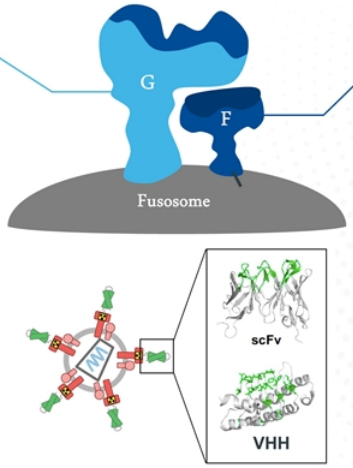
| PLATFORM | TECHNOLOGY | PROGRAMS (CELL TYPES) | THERAPEUTIC AREA | PRODUCT CANDIDATE | POTENTIAL INDICATIONS | POTENTIAL IND SUBMISSION |
|---|---|---|---|---|---|---|
| *in vivo* cell engineering | Fusogen | T cells | Oncology | **SG295 (CD8/CD19)** | NHL/ALL/CLL | As early as 2022 |
| | | | | **SG239 (CD8/BCMA)** | Multiple myeloma | As early as 2022 |
| | | | | **SG242 (CD4/CD19)** | NHL/ALL/CLL | As early as 2023 |
| | | | | **SG221 (CD4/BCMA)** | Multiple myeloma | As early as 2023 |
| | | Hepatocytes | Liver-related genetic disorders | **SG328** | OTC[1] | As early as 2023 |
| | | Hematopoietic stem cells | Hemoglobinopathies | **SG418** | Sickle cell disease | As early as 2023 |
| | | | | | Beta-thalassemia | As early as 2023 |
| *ex vivo* cell engineering | Hypoimmune donor-derived | T cells | Oncology | **SC291 (CD19)** | NHL/ALL/CLL | As early as 2022 |
| | | | | **SC255 (BCMA)** | Multiple myeloma | As early as 2022 |
| | Hypoimmune stem cell-derived | Beta cells | Diabetes | **SC451** | Type 1 diabetes | As early as 2023 |
| | Stem cell-derived (to migrate to hypoimmune) | Glial progenitor cells | Central nervous system (CNS) | **SC379** | Huntington's disease | As early as 2023 |
| | | | | | Pelizaeus-Merzbacher disease | As early as 2023 |
| | | | | | Secondary progressive multiple sclerosis | As early as 2023 |
| | | Cardiomyocytes | Cardiovascular | **SC187** | Heart failure | As early as 2023 |

[1]Ornithine transcarbamylase deficiency

# Sana's fusosome technology makes use of a viral fusogen to enable the targeting of specific cells and the delivery of different therapeutic payloads

**G protein dictates binding to a target receptor**

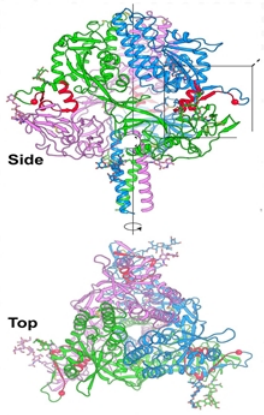




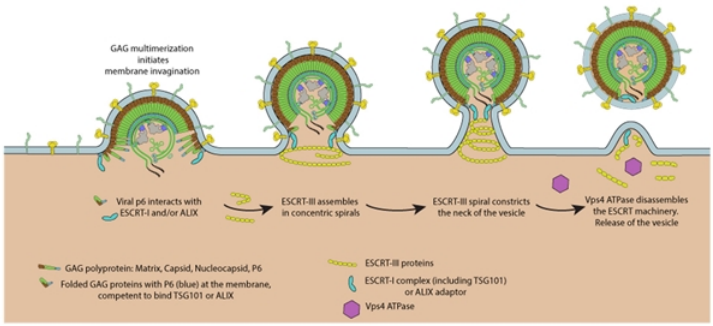


**F protein drives fusion**

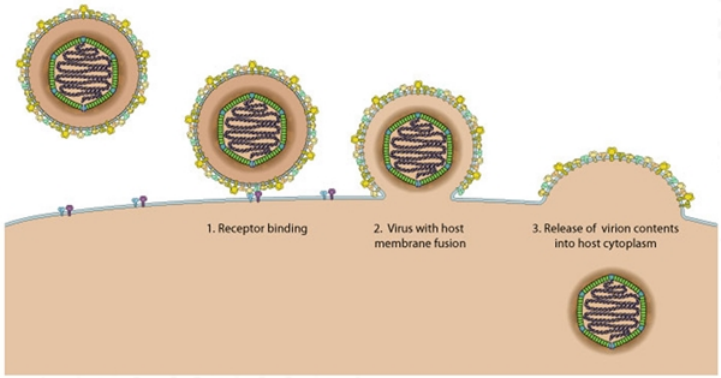


# Development of cell-specific *in vivo* delivery platform

## Fusogen Technology




Enveloped viruses incorporate viral and cellular proteins **(fusogens)** expressed on the infected cell membrane upon release from infected cells

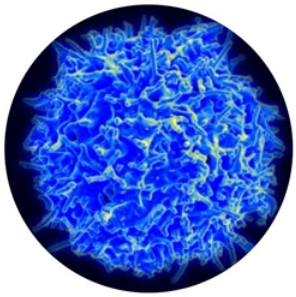



Fusogens on surface of the resulting virus particles **(fusosomes)** mediate virus entry via direct fusion of virus and cell membranes

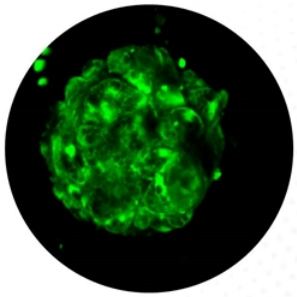
ViralZone 2011. Swiss Institute of Bioinformatics

# *in vivo* cell engineering – creating targeted medicines across a diverse set of cell types

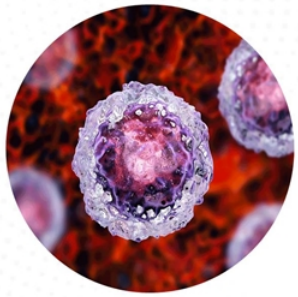
*in vivo* cell engineering strategy focused on developing therapies with transformative **fusogen platform delivery based on cell specificity and payload diversity**



**T cells**



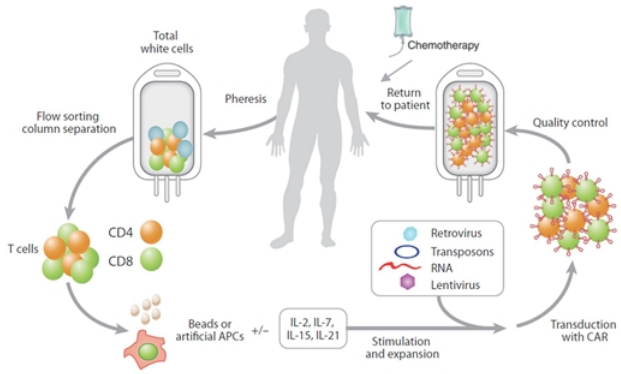
**Hepatocytes**



**Hematopoietic stem cells**

# Blood cancers remain high unmet need; despite success, current CAR T solutions have limitations

## Current *ex vivo* approaches have limitations

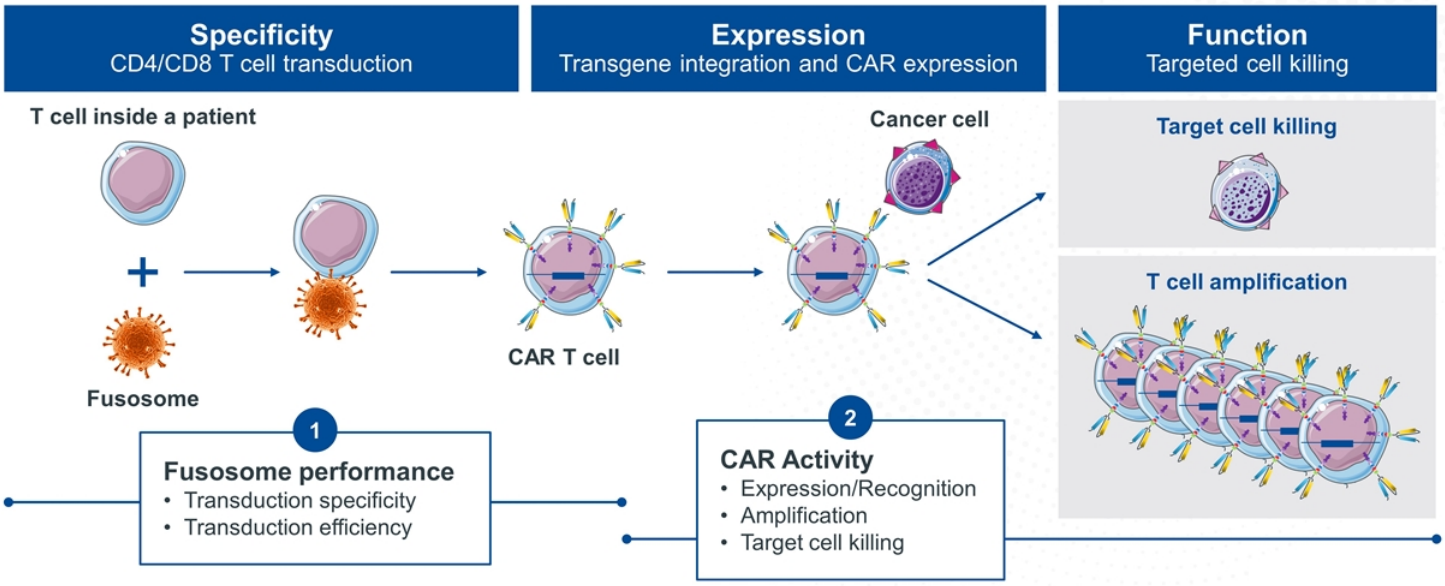



**Current manufacturing limits access**

## Fusogen platform offers potential to overcome these limitations

**T cell fusosome carrying CAR construct infused into patient; the patient is the bioreactor that creates CAR T**

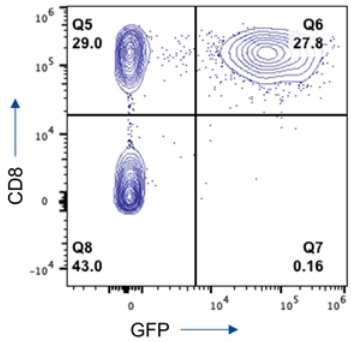
# Using a T cell-targeted fusosome to make CAR T cells *in vivo*



# Targeting of different T cell types by viral fusosomes

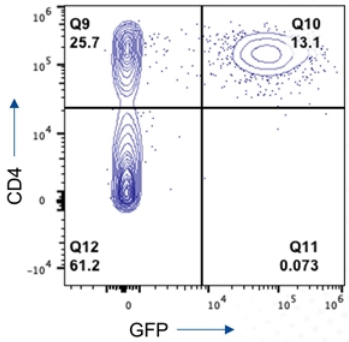
**Sana has generated fusosomes that specifically target and transduce CD8, CD4 and CD3 T cells**

CD8-targeted



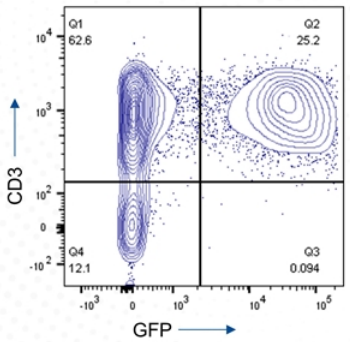

CD8-targeted fusosome
*in vitro* primary T cells

CD4-targeted




CD4-targeted fusosome
*in vitro* primary T cells

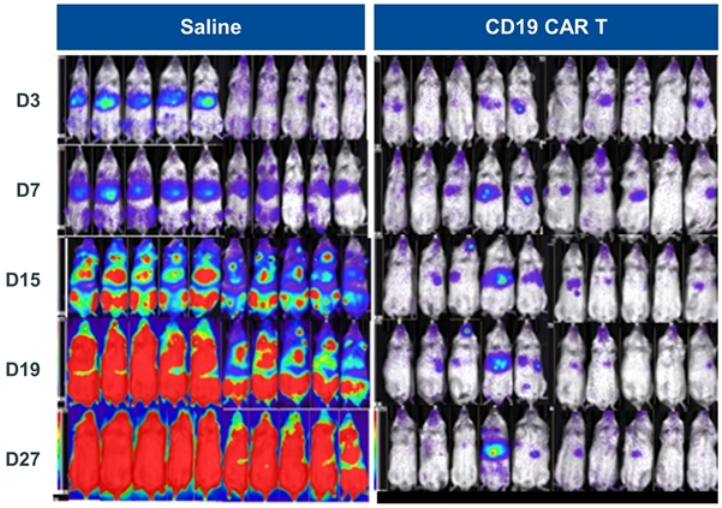
CD3-targeted



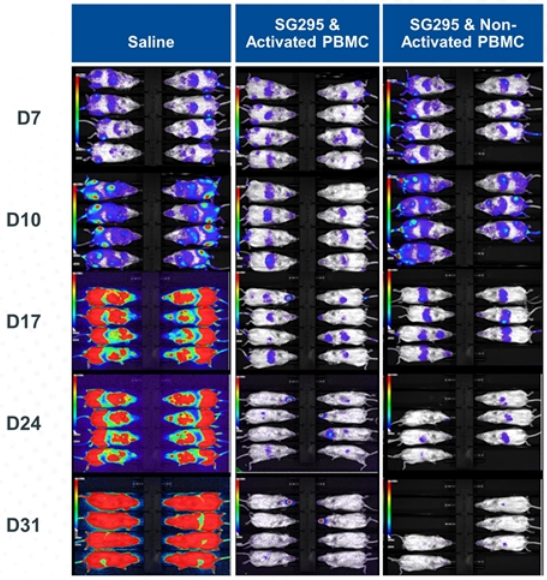

CD3-targeted fusosome
*in vitro* primary PBMCs

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

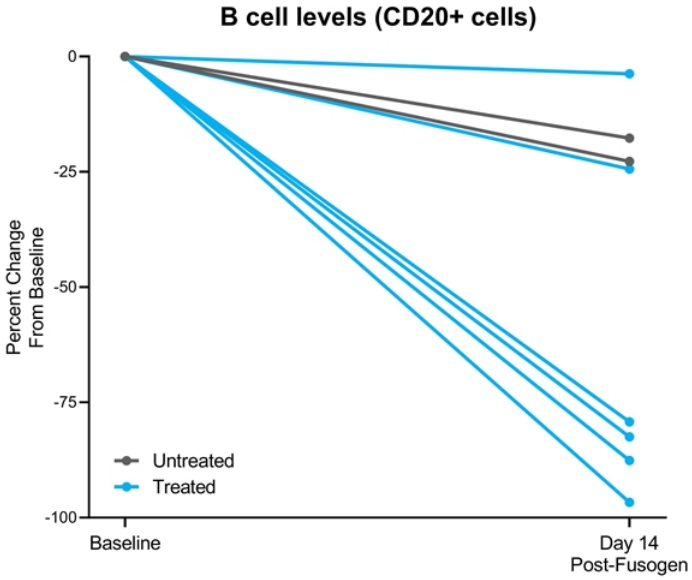
**CD19 CAR: *ex vivo***




**CD19 CAR delivered by fusogen: *in vivo***



# CD8 fusogen delivering a CD20 CAR causes B cell depletion in NHPs




- Dosing well tolerated in all animals treated with CD20 CAR T delivered by CD8 fusogen, no infusion-related toxicity or evidence of CAR-associated toxicity
- Substantial B cell depletion observed in 4/6 treated animals

# Potential first-in-class fusogen T cell programs – potential to target large markets with a single IV administration

**Next Steps SG295 and SG239**

- IND-enabling studies and scale GMP manufacturing
- Finalize development plan – expect initial indications in NHL for CD19 and multiple myeloma for BCMA

**Future Development**

- Build CD8 and CD4 fusogen programs
- CD19 indications beyond NHL
- Targets beyond CD19 and BCMA

# Protecting cells from immune destruction is key to unlocking potential of *ex vivo* cell engineering

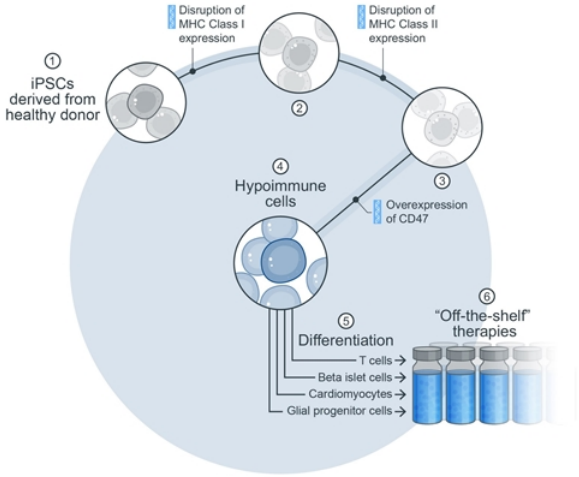
**Fetomaternal tolerance during pregnancy**

"Allogeneic" fetus:

- Half of fetal proteins are from the father, not the mother.
- However, the fetus is not rejected by the mother.

*How can we protect our engineered cells from getting attacked from the recipient's immune system?*

**Sana approach:**
**creating hypoimmune cells from human iPSCs**

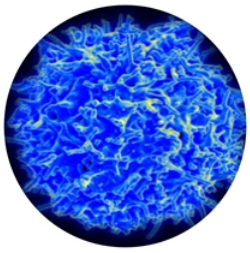


# Sana is pursuing a broad *ex vivo* cell engineering strategy

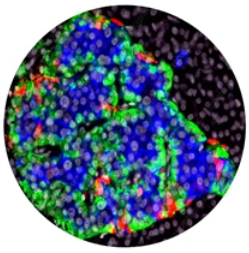
**Transforming *ex vivo* cell engineering through development of hypoimmune cell platform**

**Differentiate pluripotent stem cells with hypoimmune edits**

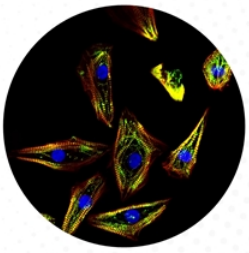
**Programs that benefit from, but do not require hypoimmune**



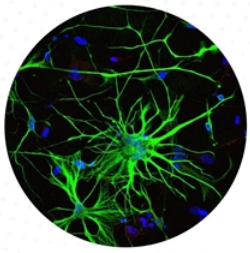
T cells



Pancreatic islets



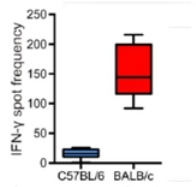
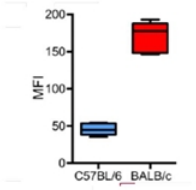
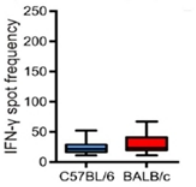
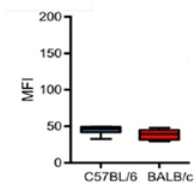
Cardiomyocytes



Glial progenitor cells

# Hypoimmune cells evade rejection from the adaptive **and** innate immune system in a mouse

## Evade the adaptive immune system

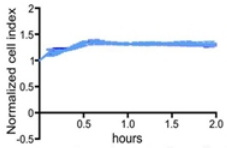
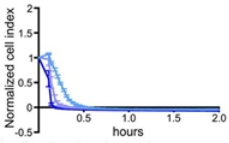
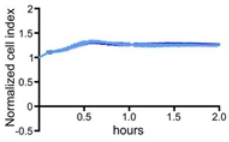
| | T Cell Activation (ELISPOT) | IgM Binding (FACS) |
|---|---|---|
| | *No systemic T cell activation with HIP cell transplantation* | *No binding of donor specific antibodies against HIP cells* |
| Unmodified iPSC |  |  |
| HIP |  |  |



## Evade the innate immune system

NK Cell Killing

*No NK cell killing with HIP*

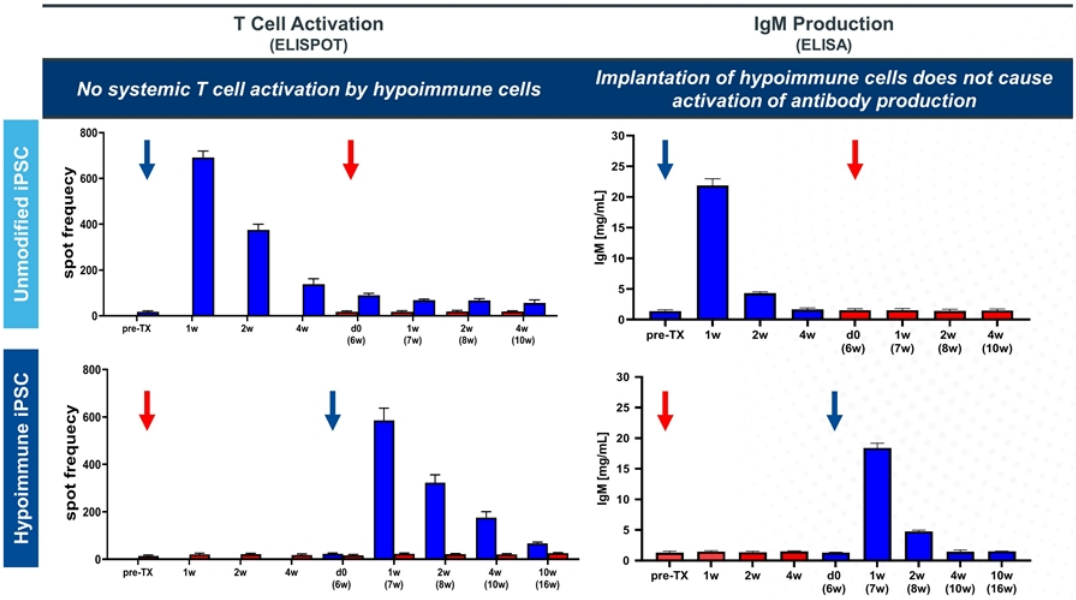
| *Wildtype Unmodified Cells* | *MHC Class I/II Disruption* | *MHC Class I/II Disruption & CD47 Overexpression* |
|---|---|---|
|  |  |  |
| No killing of unmodified cells by NK cells | Killing of partially edited iPSC; HLA I/II knockout by NK cells | No killing of HIP cells by NK cells |



Deuse T, …, Schrepfer S. *Nat Biotechnology*. 2019; 37:252-258

# Hypoimmune cells in NHP: no systemic adaptive immune activation after transplantation of hypoimmune iPSCs into naïve and sensitized NHPs

*Transplantation of NHP iPSCs into allogeneic NHPs: immune evasion is achieved even after prior sensitization*

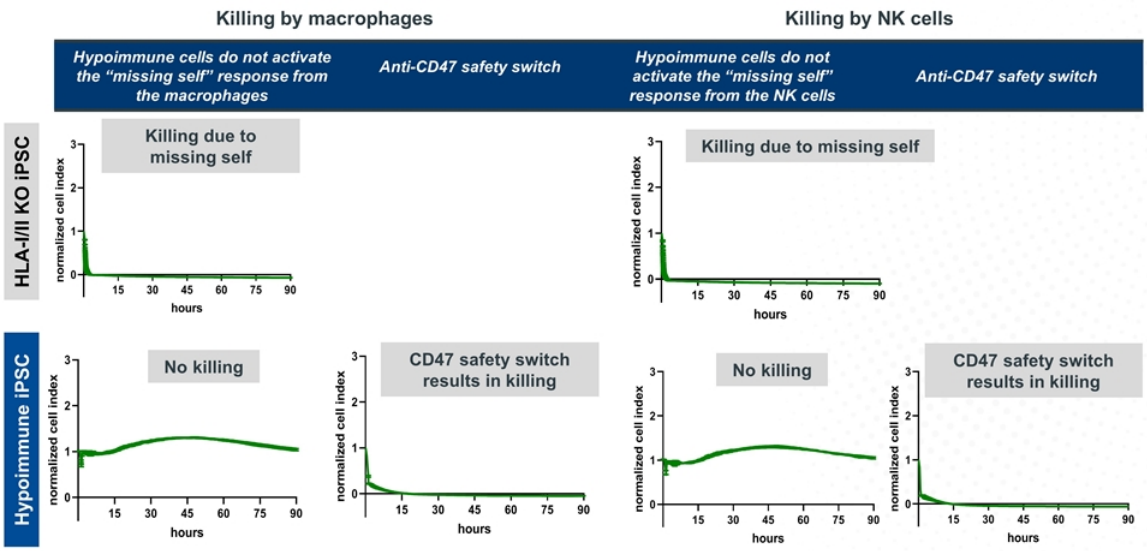



- HIP cells did not activate the systemic adaptive immune system (T cells and B cells)
- HIP cells evaded immune responses in a crossover experiment in NHP with pre-existing immunity
- Data suggest the potential to treat autoimmune disorders such as type 1 diabetes

WT HIP

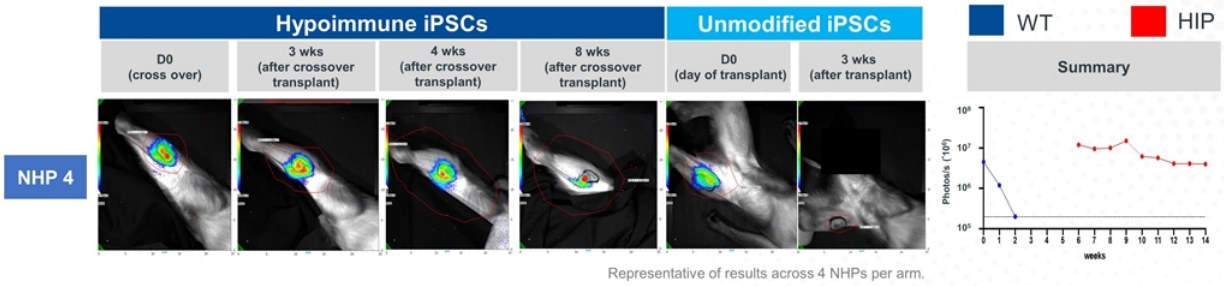
# Hypoimmune cells do not elicit an innate immune response in allogeneic NHP recipients

*Transplantation of NHP iPSCs into allogeneic NHPs (n=4/group)*




- HIP cells do not activate the "missing self" response from macrophages and NK cells
- "Safety switch": CD47 blockade results in killing by innate cells, providing a possible "safety switch"

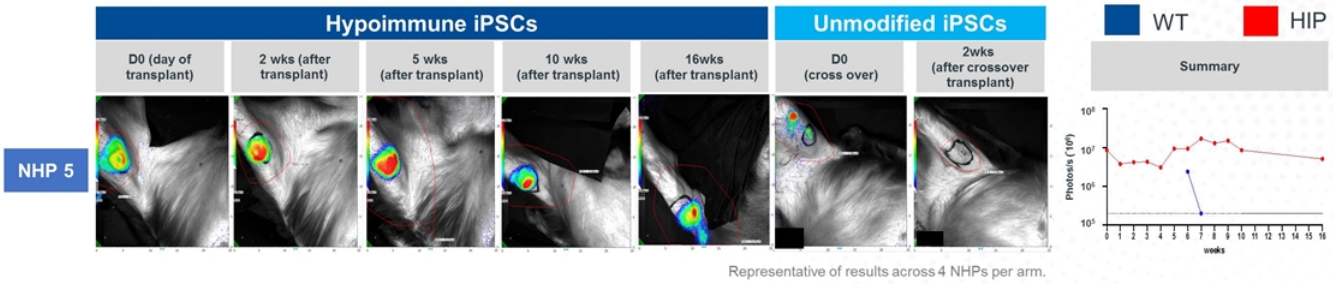
# Hypoimmune cells survive and proliferate in allogeneic sensitized NHPs without immunosuppression




Representative of results across 4 NHPs per arm.

- Unmodified cells were rejected within 3 weeks
- Hypoimmune cells survive in a crossover experiment in NHPs with pre-existing immunity
- Data suggest the potential to treat autoimmune disorders such as type 1 diabetes

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



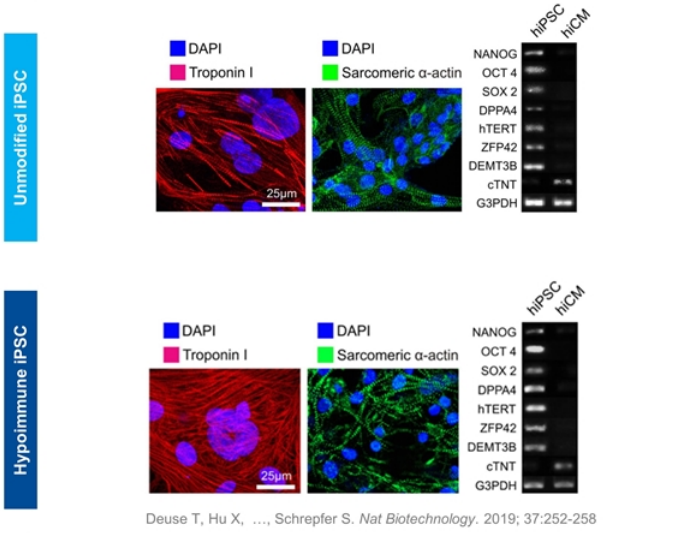

Representative of results across 4 NHPs per arm.

- Hypoimmune cells survive in allogeneic NHPs
- Unmodified cells get rejected while hypoimmune cells continue to survive

# Human hypoimmune cells differentiate into various cell types

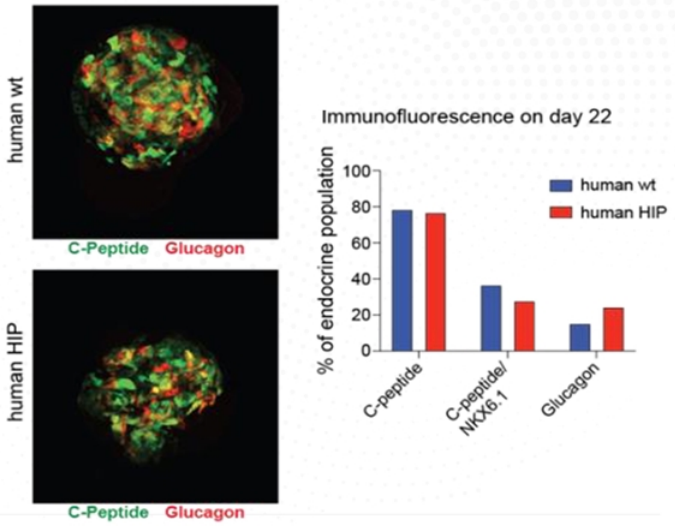
Hypoimmune edits (HLA-I knockout, HLA-II knockout, CD47tg) do not affect differentiation capacity nor intrinsic cell function.

## Cardiac cell differentiation




Deuse T, Hu X, …, Schrepfer S. *Nat Biotechnology*. 2019; 37:252-258

## Islet cell differentiation

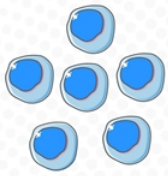


# Sana's hypoimmune allo T: potential best-in-class opportunity

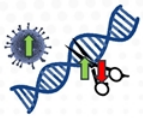
| IMMUNE CHALLENGES | CURRENT ALLO T | SANA'S HYPOIMMUNE ALLO T |
|---|---|---|
| **GvHD** | | |
| **HvGD: Adaptive Immune System** | | |
| **HvGD: Innate Immune System** | | |

**We believe we are better positioned to overcome immune challenges versus existing allo T therapies**

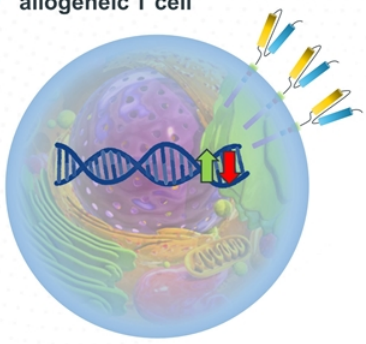
1 **Donor or iPSC T cells**



2 **Cell engineering**

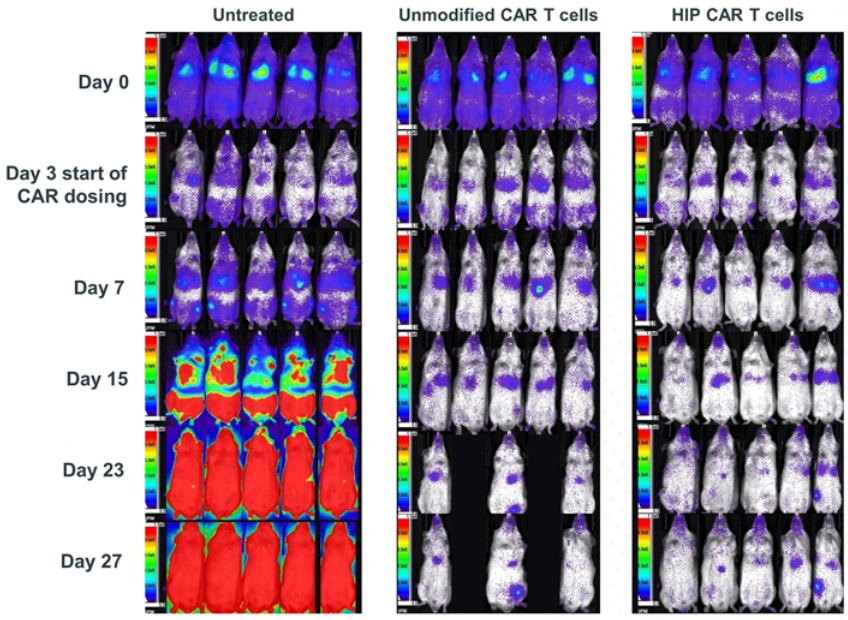


3 **CD19 targeted allogeneic T cell**



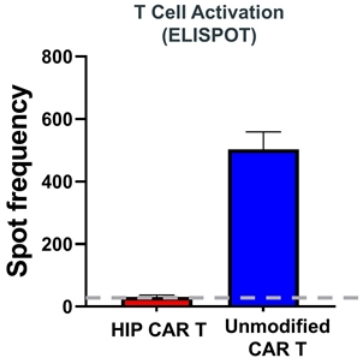
Note:
GvHD: Graft versus Host Disease
HvGD: Host versus Graft Disease

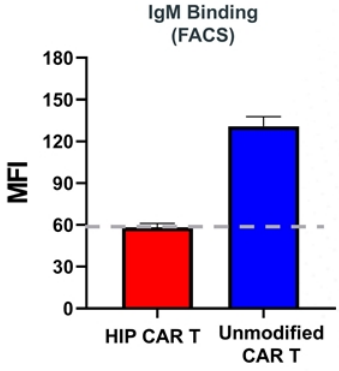
# CD19 HIP CAR T cells clear tumor *in vivo*

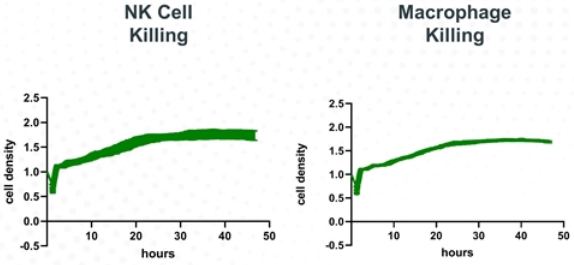


# CD19 HIP CAR T cells do not activate adaptive or innate immune responses

| T cells are not activated by HIP CAR T cells | HIP CAR T cells do not incite an antibody response | HIP CAR T cells evade innate cell “missing self” response |
|---|---|---|



# Allogeneic CAR T cells: potential best-in-class CAR T platform for off-the-shelf therapies

**Next Steps for SC291**

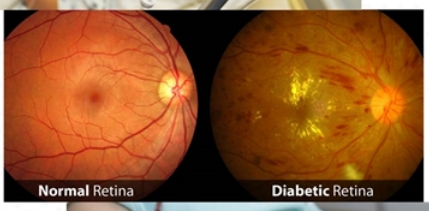
- Develop GMP gene editing and manufacturing processes
- Finalize development plan – expect initial indication in NHL

**Future Development**

- SC291 for other B cell malignancies
- SC255 for multiple myeloma
- Targets beyond CD19 and BCMA

# Type 1 diabetes represents a large unmet need with a loss of approximately 15 years of life

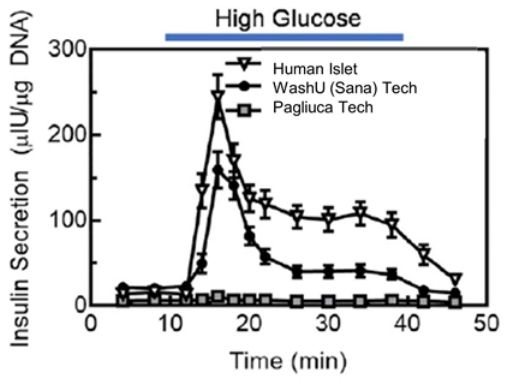
- Autoimmune disease where destruction of insulin-producing beta cells results in inability to control glucose
- 1.6 million patients with type 1 diabetes in the US and 2.4 million in Europe; 51k new patients/year combined
- Approximately 15-year shorter life expectancy*
- Long term complications: end-organ damage, including heart attack, stroke, peripheral vascular disease, retinopathy, nephropathy
- Our goal is to produce hypoimmune beta cells that evade the immune system and normalize glucose



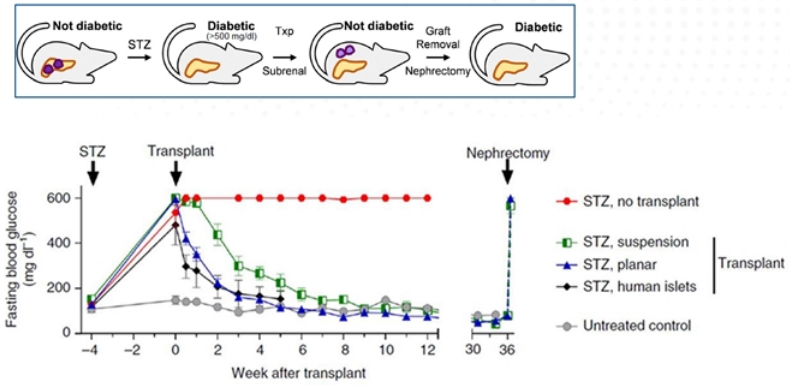

*Rawshani *et al*, Lancet 2018

# SC451: combining HIP edits with leading beta cells protocol offers transformative potential for type 1 diabetes patients

## Superior insulin secretion and faster kinetics *in vitro*




## Robust rescue of type 1 diabetes mouse model



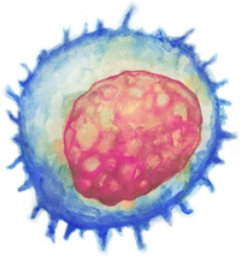
# Beta cells: potential to transform global diabetes pandemic with curative treatment

**Next Steps for SC451**

- GMP hypoimmune iPSC cell line
- Develop scalable GMP manufacturing process
- IND-enabling studies

# Sana aspiration: engineered cells as medicines

**The challenge:**



Almost all diseases result from damage to or dysfunction in a cell

**Sana: engineered cells to treat a broad set of diseases**

**Address obstacles to using engineered cells as medicines**

**Validate platforms and create important medicines**

- Fusosome for CD19 CAR T *in vivo*
- Fusosome for BMCA CAR T *in vivo*
- Hypoimmune allo CD19 CAR T
- Hypoimmune allo BCMA CAR T

**Unlock the potential of engineered cells as medicines in multiple diseases**

- Hypoimmune cells for:
  - Type 1 diabetes
  - Heart disease
  - CNS disorders
- Fusosomes delivering payloads for other diseases

# Thank You

Sana Biotechnology
www.sana.com