

**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 9, 2024

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 42nd Annual J.P. Morgan Healthcare Conference on January 9, 2024. 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate Presentation dated January 9, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Corporate Presentation

January 2024



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 8, 2023. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.



Sana Biotechnology

Changing the Possible for Patients

Sana's hypoimmune technology goal is to overcome allogeneic rejection

- HIP technology provides foundation for potential multiple drugs across many therapeutic areas

Begin 2024 with four clinical programs treating seven diseases

- SC291 oncology – NHL and CLL
- SC291 B-cell mediated autoimmune – lupus nephritis, extrarenal lupus, and ANCA-associated vasculitis
- SC262 oncology – r/r NHL, initially in CD19 CAR T failures
- HIP primary islet cells in patients with type 1 diabetes

Pipeline positioned to deliver additional clinical data over time

- Regenerative medicine: SC379 (CNS disorders) and SC451 (type 1 diabetes)
- Hypoimmune allogeneic CAR T cells: SC255 (BCMA) and beyond

Balance sheet allows potential for multiple data readouts



Sana pipeline positioned to deliver meaningful clinical data

PRODUCT CANDIDATE	MECHANISM	INDICATIONS	PRECLINICAL IND-ENABLING	PHASE 1	PHASE 2/3	SANA'S RIGHTS
Oncology						
SC291	CD19-directed allo CAR T	NHL	ARDENT			WW
SC291	CD19-directed allo CAR T	CLL	ARDENT			WW
SC262	CD22-directed allo CAR T	NHL (CD19 failures)	VIVID			WW
SC255	BCMA-directed allo CAR T	MM				WW
B-cell Mediated Autoimmune Diseases						
SC291	CD19-directed allo CAR T	LN	GLEAM			WW
SC291	CD19-directed allo CAR T	ERL	GLEAM			WW
SC291	CD19-directed allo CAR T	AAV	GLEAM			WW
SC291	CD19-directed allo CAR T	Other indications				WW
Regenerative Medicine						
UP421	HIP primary islet cells ¹	T1D				WW
SC451	Stem-cell derived pancreatic islet cells	T1D				WW
SC379	Glial progenitor cells	HD, PMD, SPMS				WW

¹Investigator sponsored trial.

Abbreviations: AAV, ANCA-associated vasculitis; CLL, chronic lymphocytic leukemia; ERL, extrarenal systemic lupus erythematosus; HD, Huntington's disease; LN, lupus nephritis; MM, multiple myeloma; NHL, non-Hodgkin lymphoma; PMD, Pelizaeus-Merzbacher Disease; SPMS, secondary progressive multiple sclerosis; T1D, type 1 diabetes; WW, worldwide.

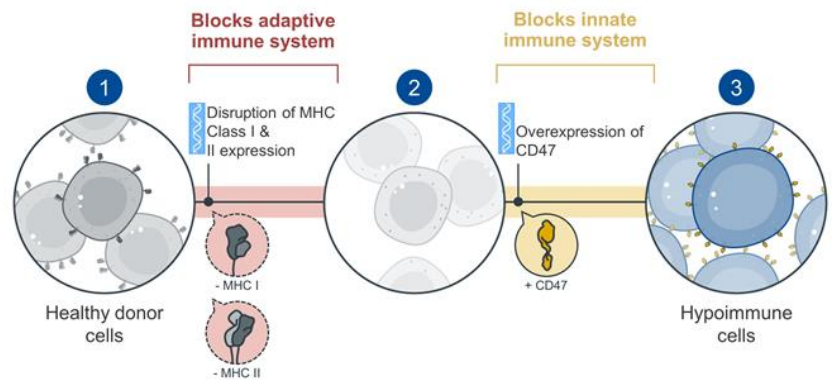


Overcoming allogeneic immune rejection has been key limitation in transplant and cellular medicine

Allogeneic cell rejection

- ~75 years of transplants – immune rejection remains the largest problem
- Lifelong 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

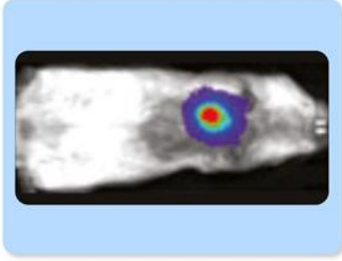
Sana's hypoimmune approach



Current clinical platform with multiple ongoing approaches in research phase.

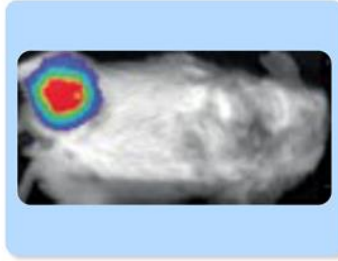


HIP-modified cells successfully transplanted in allogeneic models across various species and cells types



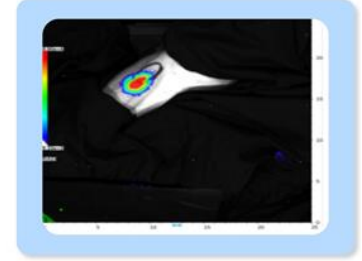
Mice

- Mouse iPSCs
- Mouse iPSC-derived endothelial cells
- Mouse iPSC-derived smooth muscle cells
- Mouse iPSC-derived cardiomyocytes



Humanized mice

- Human iPSCs
- Human iPSC-derived endothelial cells
- Human iPSC-derived smooth muscle cells
- Human iPSC-derived cardiomyocytes
- Human iPSC-derived pancreatic islet cells
- Human donor-derived islet cells
- Human donor-derived CAR T cells

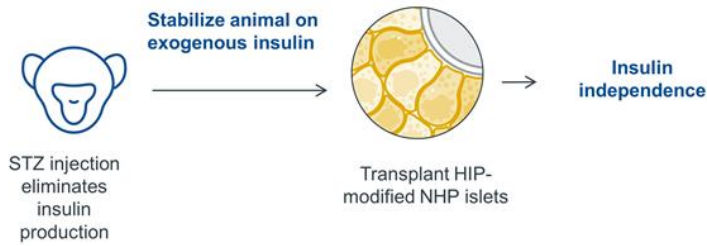


NHPs

- NHP iPSCs (16 weeks follow-up)
- NHP donor-derived islets (40 weeks follow-up)
- NHP iPSC-derived cardiomyocytes
- NHP iPSC-derived retinal pigment epithelium (RPE) cells

HIP-modified allogeneic islet cells to control glucose in a type 1 diabetic NHP model

Type 1 diabetes is a disease of missing pancreatic beta cells



Study Design (N=1)

- NHP treated with STZ
- Glucose stabilized with exogenous insulin
- Allogeneic NHP primary islet cells isolated and HIP-modified
- Cells injected intramuscularly without immunosuppression

Key goals of study

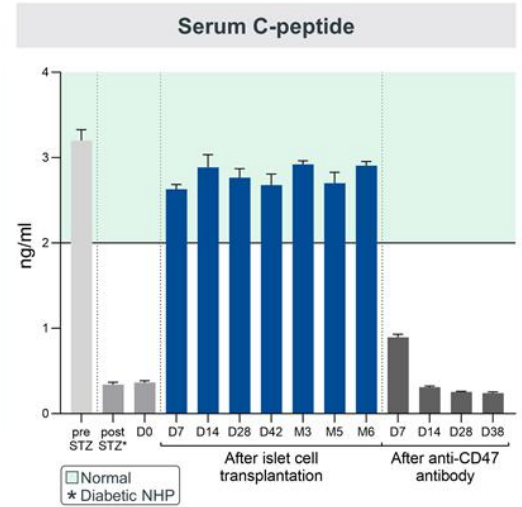
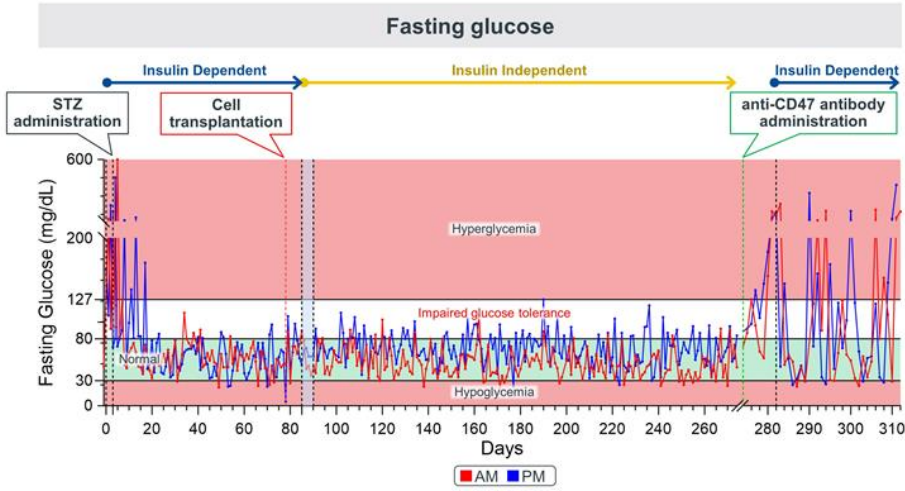
- Demonstrate survival and function of HIP-modified allogeneic islet cells in diabetic NHP without immunosuppression
- Demonstrate long-term glucose normalization in diabetic NHP without exogenous insulin or immunosuppression
- Demonstrate the principle of graft ablation/safety switch with anti-CD47 antibody

Abbreviations: NHP, non-human primate; STZ, Streptozotocin.

Survival and function of allogeneic hypoimmune pancreatic islet cells in diabetic NHP 6 months without immunosuppression

Study Design (N=1)

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



Near-term opportunities to apply HIP modifications to validated mechanisms with unmet need

Blood cancers:
>100,000 patients/year^{1,2}



B-cell mediated autoimmune diseases:
>5 million patients³



Type 1 diabetes:
>8 million patients⁴



¹Avezbakiyev et al. *Blood*. 2022

²Durie et al. *The Oncologist*. 2020

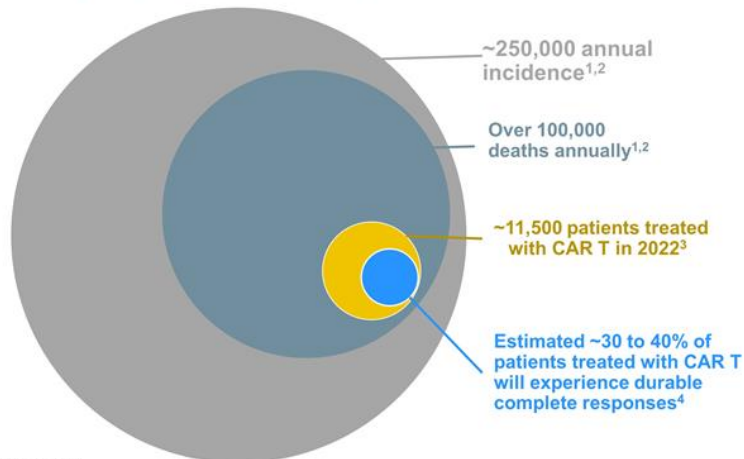
³NIH Autoimmune Diseases Coordinating Committee: Autoimmune Diseases Research Plan, October 2017, U.S.

⁴t1dindex.org



Hematologic cancers continue to have a high unmet need

High mortality in lymphoma and myeloma in the US and EU5



¹Avezbakiyev et al. *Blood*. 2022

²Durie et al. *The Oncologist*. 2020

³Clarivate DRG NHL and MM Market Forecast Nov 2022; internal analysis of secondary EPI data.

⁴Scivida 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 cell 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

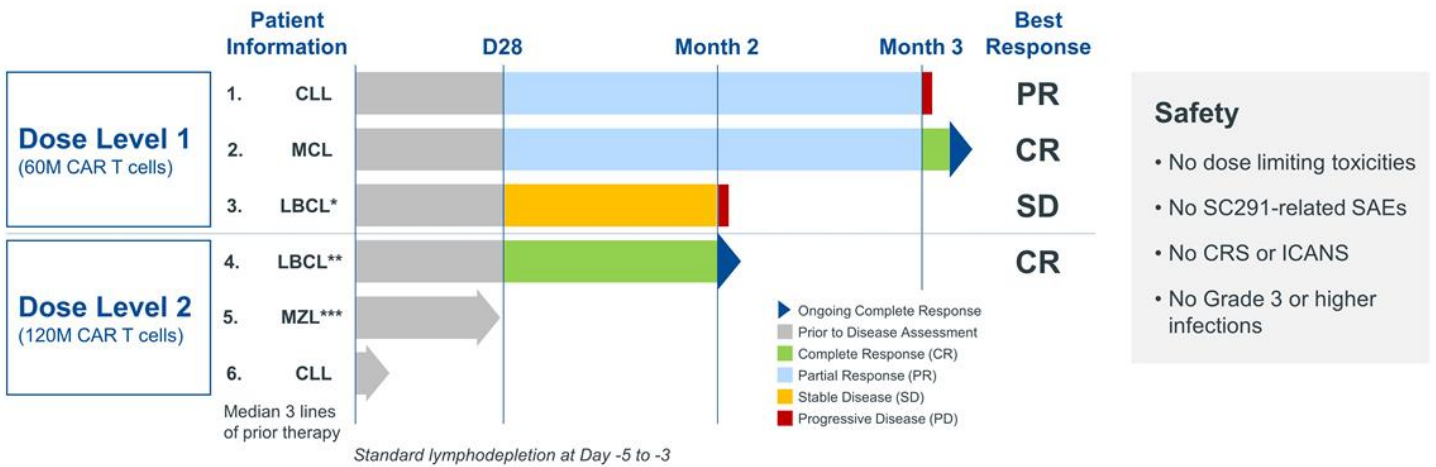
Defining success for SC291 in oncology

Understanding levels of evidence as data mature



ARDENT: 3 of 4 evaluable patients had at least a partial response, with 2 ongoing complete responses

6 patients treated to date; dose escalation ongoing

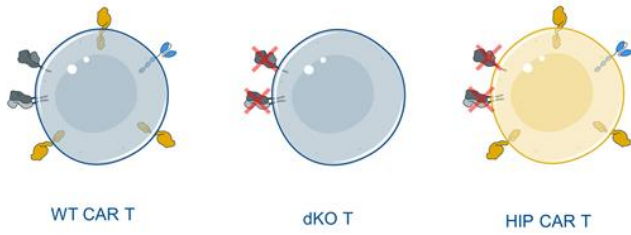


Clinical data as of: January 5, 2023
 evaluable defined as patients treated with SC291 and had at least one disease assessment
 Transformed DLBCL from FL. *Assessment ongoing as of January 5, 2023.

Immune response data provide important early insights

Translating preclinical data to people

1 SC291 is a mixture of HIP and non-HIP CAR T cells



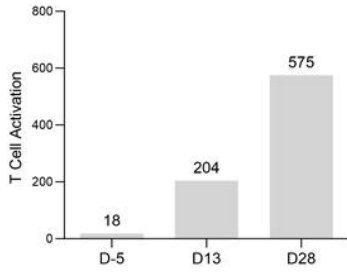
T Cell Population	Genetic Modifications
WT CAR T	CD47-CD19 CAR
dKO T	HLA I/II deficient
HIP CAR T	CD47-CD19 CAR; HLA I/II deficient

2 Test the patient's immune system against SC291

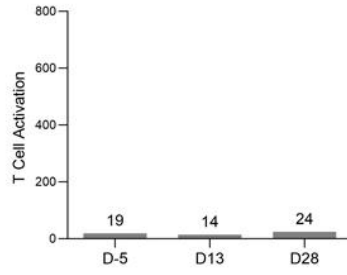
Cell	Day 28			
	T cell	Ab	NK cell	Blood
WT CAR T	Red	Red	Green	Red
dKO T	Green	Green	Red	Red
HIP CAR T	Green	Green	Green	Green

Patient T cells kill WT CAR T cells but do not kill dKO T cells or HIP CAR T cells

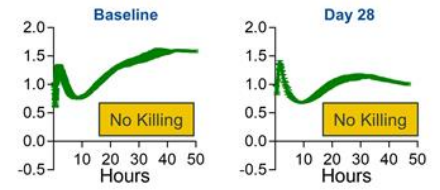
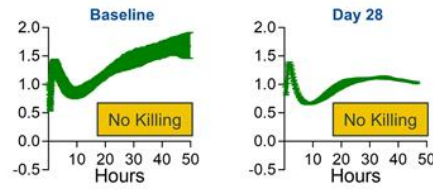
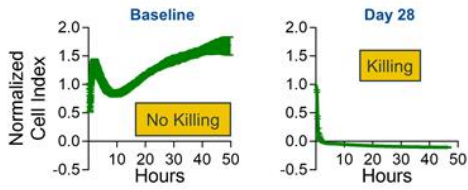
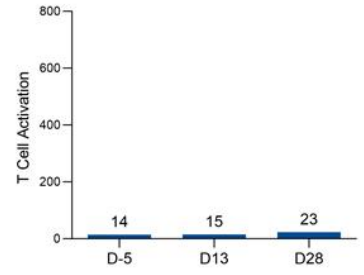
Patient T cells kill WT CAR T cells



Patient T cells do not kill dKO T cells



Patient T cells do not kill HIP CAR T cells

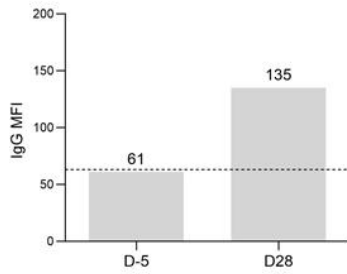


From Patient #1 in the ongoing ARDENT trial.

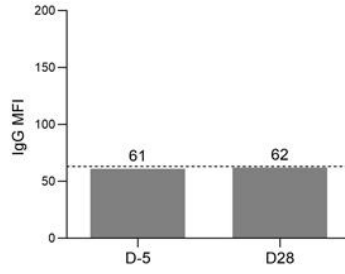


Patient generates antibodies against WT CAR T cells but not dKO T cells or HIP CAR T cells

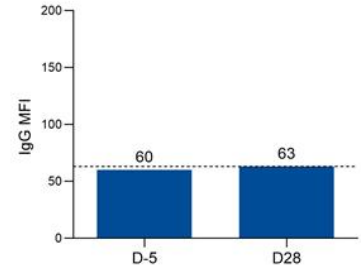
WT CAR T cells induce an antibody response



dKO T cells do not induce an antibody response



HIP CAR T cells do not induce an antibody response



From Patient #1 in the ongoing ARDENT trial.



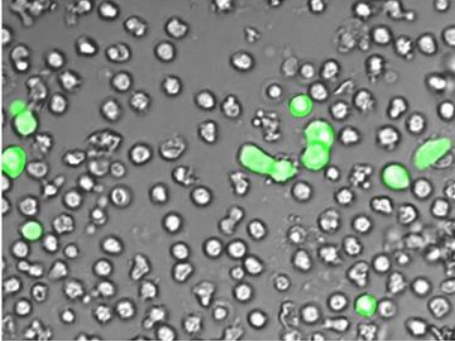
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Only HIP CAR T cells avoid NK cell killing

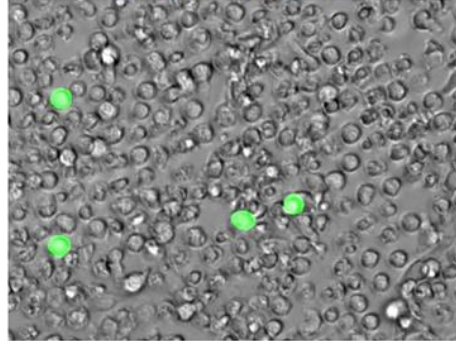
NK cells taken from patient's blood

Patient's NK cells from day 13 after SC291 dosing

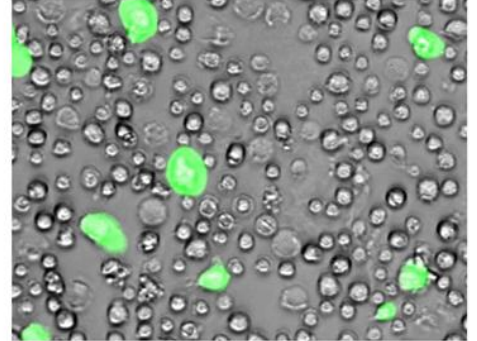
NK cells kill dKO T cells



NK cells kill dKO T cells with HLA-E overexpression



NK cells do NOT kill HIP CAR T cells



Actual assay time = 4 hours.

 T cell with editing profile in column title  NK cells

From Patient #1 in the ongoing ARDENT trial.

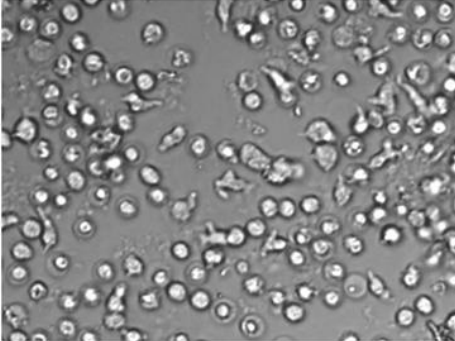


Only HIP CAR T cells avoid NK cell killing

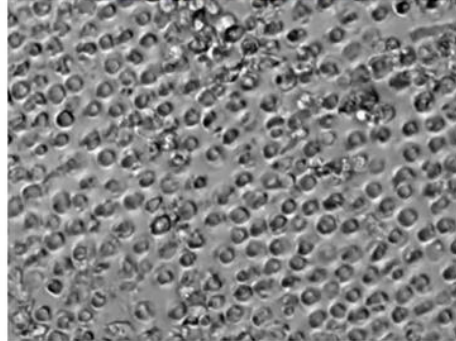
NK cells taken from patient's blood

Patient's NK cells from day 13 after SC291 dosing

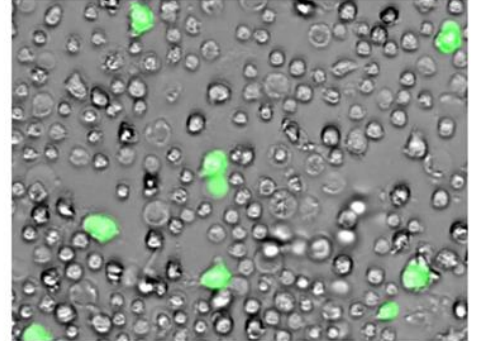
NK cells kill dKO T cells



NK cells kill dKO T cells with HLA-E overexpression



NK cells do NOT kill HIP CAR T cells



Actual assay time = 4 hours.

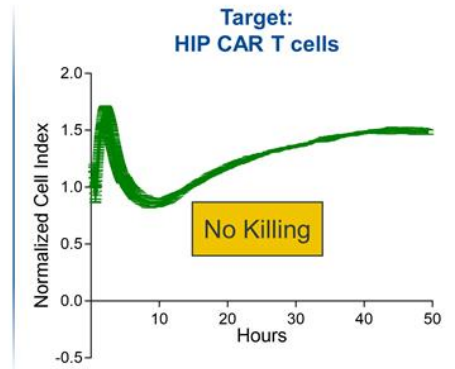
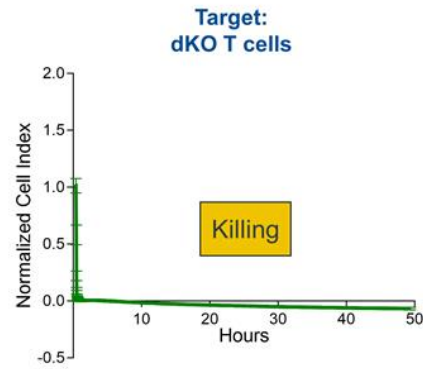
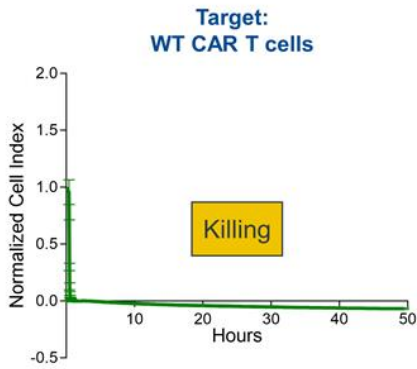
 T cell with editing profile in column title  NK cells

From Patient #1 in the ongoing ARDENT trial.



No detectable immune response in the patient toward HIP CAR T cells

D28 blood sample



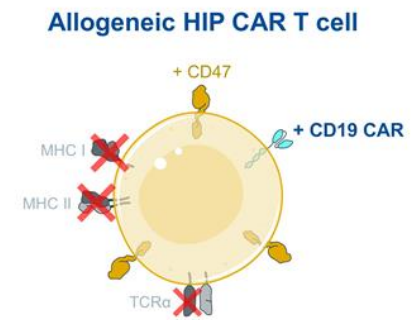
From patient #1 in the ongoing ARDENT trial.



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SC291: ARDENT trial continues enrollment with more data expected in 2024

- Early data suggest ability to dose safely, the desired immune evasion profile, and clinical efficacy
- More data to come
 - Immune evasion
 - Safety profile
 - Response rate
 - Cell persistence
 - Durability of responses



An effective allogeneic CAR T cell therapy offers potential to transform outcomes for patients

Autoimmune diseases have emerged as promising opportunity

1 B-cell targeting therapies have been efficacious across many autoimmune diseases¹

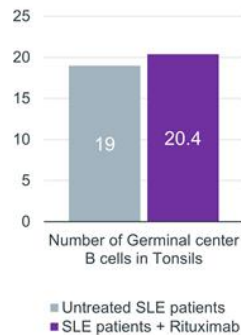
- SLE
- Vasculitis (granulomatosis with polyangiitis & microscopic polyangiitis)
- Neuromyelitis optical spectrum
- Pemphigus
- Relapsing and progressive MS
- Rheumatoid arthritis
- Lupus nephritis
- Sjogren syndrome
- NMDAR encephalitis
- Thrombocytopenic purpura
- Amyloidosis
- Scleroderma
- Autoimmune hemolytic anemia
- Chronic immune demyelinating polyradiculoneuropathy
- Immune-mediated necrotizing myopathy
- Membranous nephropathy

¹Adapted from Zhang et al. *Frontiers in Immunology*. 2023; Oh et al. *Immune Network*. 2023; Lee et al. *Nature Reviews Drug Discovery*. 2021.

²Anolik et al. *Arthritis and Rheumatism* 2007

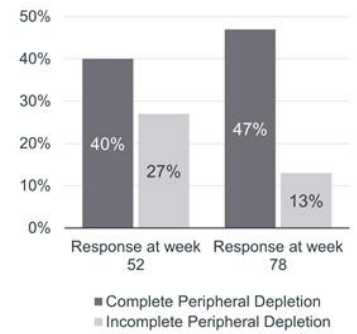
³Mendez et al. *Clinical Journal of the American Society of Nephrology* 2018

2 Germinal center B cells are unaffected by rituximab treatment²



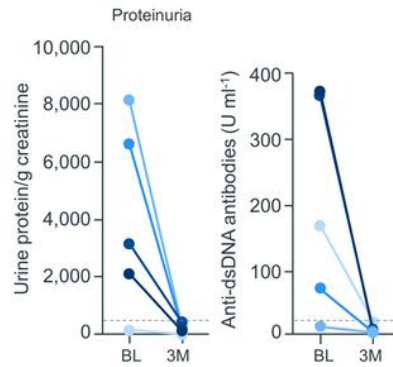
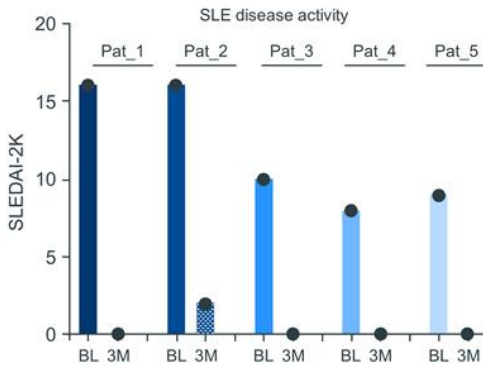
3 Depth of B cell depletion with treatment predicts efficacy in early trials³

Complete B-cell depletion resulted in greater complete responses in Lupus Nephritis patients²



Autologous CD19 CAR T therapy results in durable drug-free remission in refractory SLE patients

Improvement in signs and symptoms of SLE after CD19 CAR T treatment



- Well tolerated – mild CRS (Grade 1) and no ICANS seen
- 5/5 patients are in a durable complete remission and off all drugs
- All known disease biomarkers rapidly normalized and have remained so thus far
- 24+ months of drug-free remission seen in patients constituting a potential functional cure
- B-cell recovery and immune system reset in ~3 months with sustained SLE remission

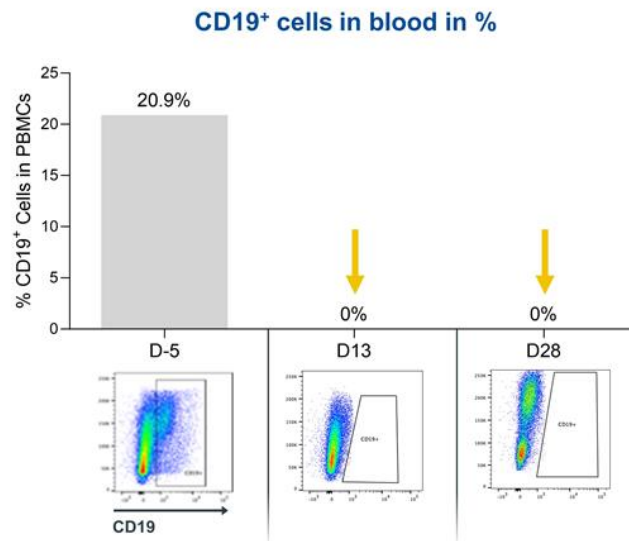
Mackensen et al. *Nature Medicine*. 2022

Abbreviations: BL, baseline; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; M, months; SLE, systemic lupus erythematosus.



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ARDENT trial: SC291 treatment leads to deep B cell depletion in oncology patient



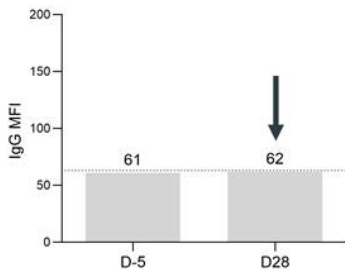
From Patient #4 in the ongoing ARDENT trial.



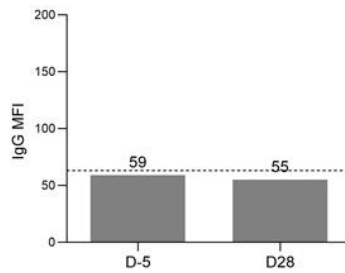
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Complete B cell depletion may be even more important in autoimmune than oncology patients

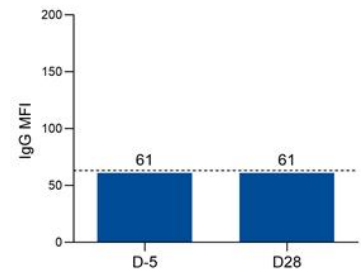
No anti-HLA antibody production against WT CAR T cells suggests complete B cell depletion



dKO T cells do not induce an antibody response



HIP CAR T cells do not induce an antibody response



From Patient #4 in the ongoing ARDENT trial.



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SC291 offers potential for transformative treatment for B-cell mediated autoimmune diseases

Targeting multiple indications

Phase 1 trial – multiple autoimmune disorders

- 1 Lupus nephritis >230K^{1,2} patients³
- 2 Extrarenal SLE >200K¹ patients³
- 3 ANCA-associated vasculitis >60K⁴ in US

SC291 benefits versus autologous therapies

- 1 No patient apheresis
- 2 Product availability
- 3 Scaled manufacturing
- 4 Consistent T cell quality

¹Lu et al. *Annals of Rheumatic Diseases*. 2023

²Guzman et al. *Arthritis Rheum*. 2013

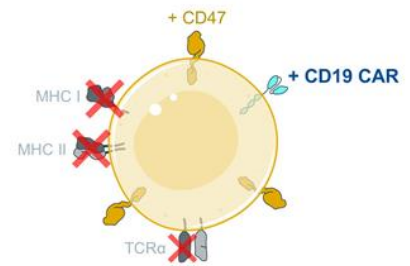
³US, EU5, and Japan

⁴Jayne et al. *ANCA-Associated Vasculitis: An Update*

SC291: GLEAM Phase 1 trial goals are to understand safety, dose, and early efficacy

- Key features of Phase 1 trial (GLEAM)
 - Patients with refractory lupus nephritis, extrarenal SLE, and AAV
 - Starting dose of 90 million CAR T cells
 - Potential to expand beyond these indications over time
- Data expected in 2024 from multiple indications
 - Safety and tolerability
 - Early response rates

Allogeneic HIP CAR T cell



An effective allogeneic CAR T offers potential to transform outcomes for patients

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

CD19 CAR T relapsed patients represent large and growing unmet need¹

Estimated ~12,000 B cell malignancy patients treated with CD19 CAR T in 2027²

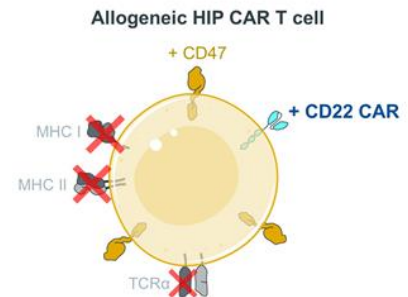


- Potential of ~7,500 CAR T failures annually in 2027²
- Median survival of ~5 months post-CD19 CAR T therapy failure³

Estimated ~35-40% of CAR T patients with durable complete responses⁴

= 1,000 people

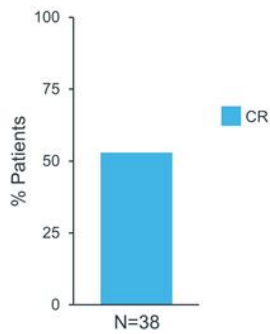
Expand our allo T platform to CD22 with Sana's SC262 candidate



¹US, EU5, and Japan. ²Clarivate DRG NHL Market Forecast Nov 2021; 2027 Forecast is 2L+ LBCL patients; internal analysis of secondary EPI data. ³Di Blasi et al. *Blood*.2022; DESCAR-T registry.

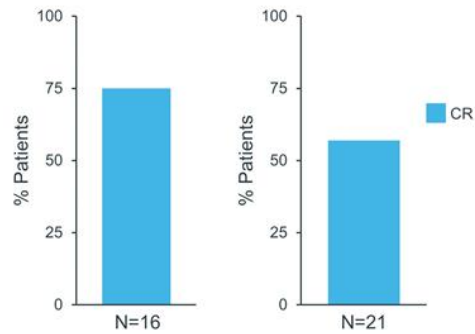
SC262: Licensed CD22 CAR produced strong clinical data in CD19 failures when part of autologous CAR T

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



2023 ASH Yi-Jiun Su

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



2022 ASH Miklos/Stanford

2018 *Nature Med* Fry, et al.

VIVID Phase 1 Trial

- CD19 CAR T exposed relapsed and/or refractory NHL
- Adult subjects
- Dose escalation study
- Cell dose: 90M, 150M, and 250M
- Standard lymphodepletion
- Primary Endpoints: Safety and tolerability
- Secondary Endpoints: Patient response

Type 1 diabetes represents a large unmet need with a loss of ~15 years of life¹

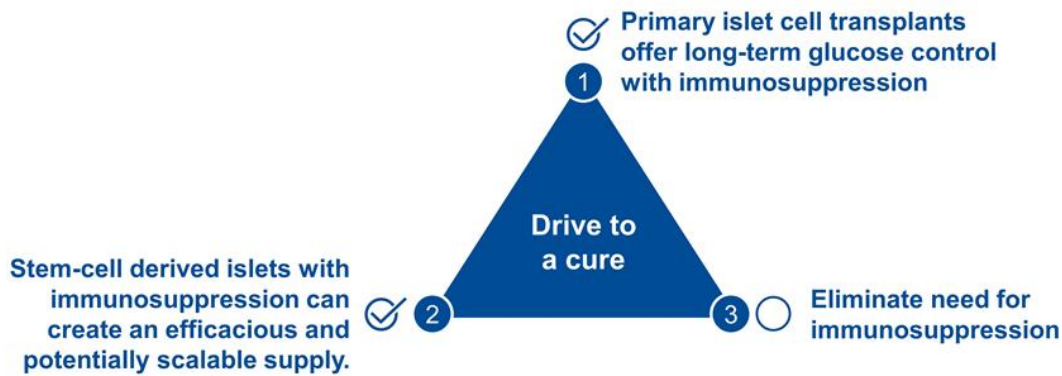
- Disease caused by autoimmune destruction of insulin-producing pancreatic beta cells, resulting in no insulin production
- Type 1 diabetes is a large unmet need with >8M WW²
- Short-term complications result from hypo- and hyperglycemia
- Long-term complications result from micro- and macrovascular disease and end-organ damage: including heart attack, stroke, blindness, and kidney failure
- SC451 goal is euglycemia without any immunosuppression or exogenous insulin



¹Rawshani et al. *Lancet*. 2018
²11dindex.org

Emerging data suggest a cure is possible

Sana – combining stem cell, gene editing, and immunology expertise

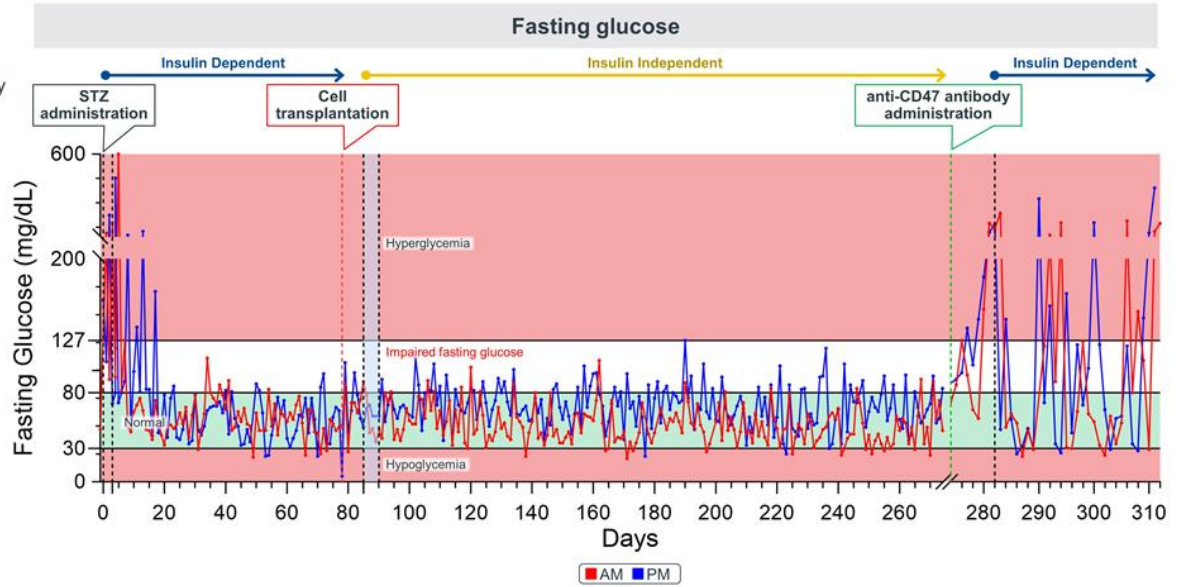


Goal – single treatment with long-term normal blood glucose without immunosuppression or insulin

Survival and function of allogeneic hypoimmune pancreatic islet cells in diabetic NHP 6 months without immunosuppression

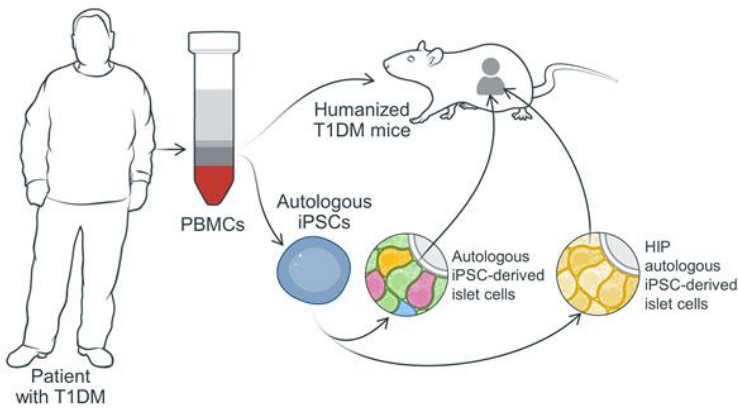
Study Design (N=1)

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



Type 1 diabetes model highlights potential to overcome autoimmune rejection of pancreatic beta cells

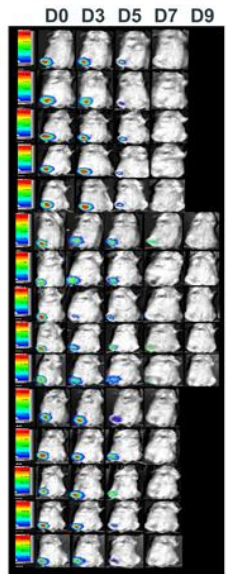
PBMCs from patient with T1DM used to generate stem cell-derived islet cells and to humanize immune system in mice



Unmodified stem cell-derived islet cells from patient with T1DM do not survive



Patient T cells eliminate islet cells due to autoimmunity

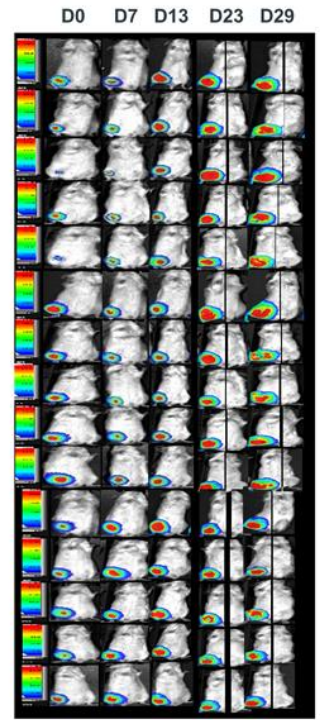
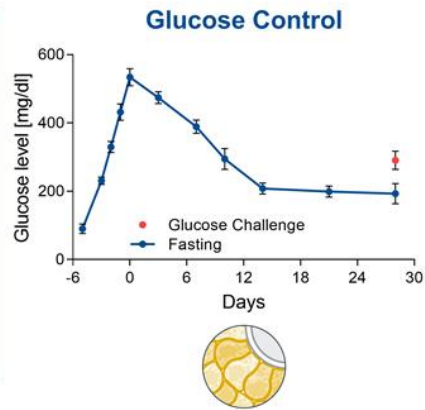
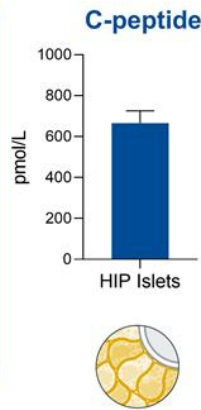
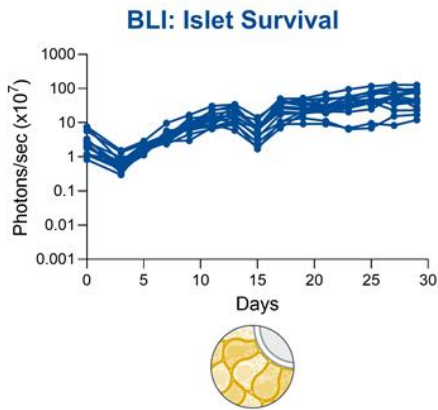


Abbreviations: T1DM, type 1 diabetes mellitus
Hu et al. *Sci Transl Med*. 2023



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



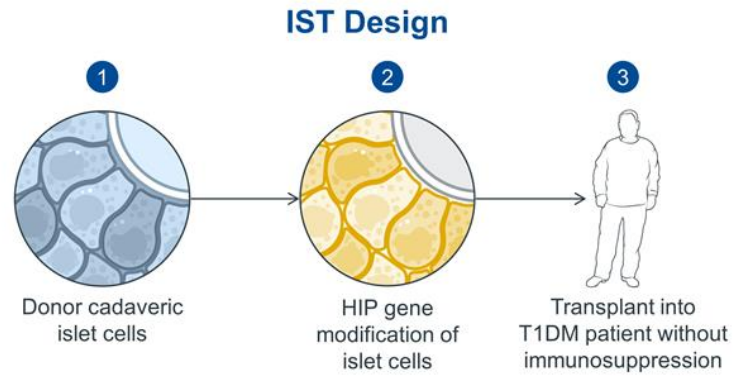
Abbreviations: BLI, bioluminescence imaging
Hu et al. *Sci Transl Med*. 2023.



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Potential clinical validation of hypoimmune islet cells in T1DM patients

- Trial authorized at Uppsala University Hospital
- Primary human HIP islet cells transplantation in type 1 diabetes patients
- Intramuscular administration in forearm
- No immunosuppression
- Insights for SC451

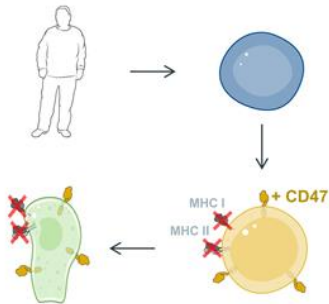


Key Measured Outcomes

Cell survival & immune evasion
C-peptide
Glycemic control

Sana's approach to treat type 1 diabetes

1 Make hypimmune islet cells from stem cells



2 Manufacture at scale

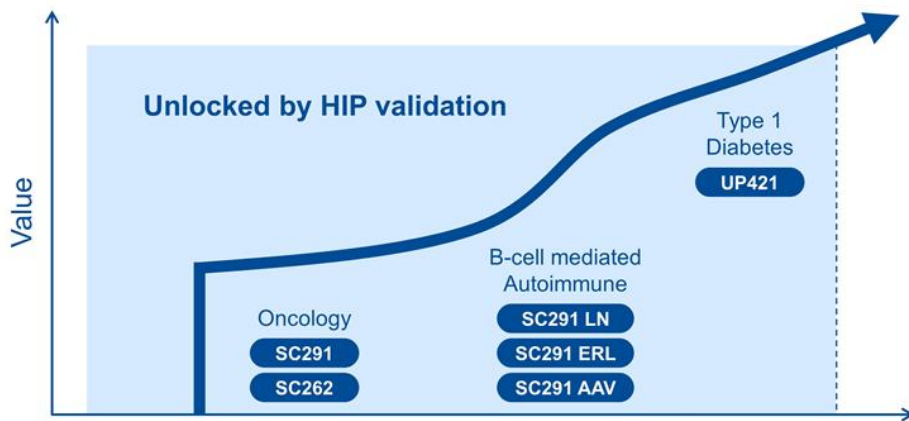


3 Deliver as a single therapy



SC451 program – HIP stem cell-derived islet cell therapy – delivered with no immunosuppression

Meaningful clinical data in multiple diseases in 2024



Unlocking the potential of our hypimmune platform across multiple patient populations

Thank You

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