



Sernova (SVA.TO) & Seraxis Merge to Form;



Integrating Science.
Working with Passion.
Developing a Functional Cure for T1D.*

Non-Con Q3 2026

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MERGER AIMS TO CREATE A DIFFERENTIATED APPROACH TO T1D CELL THERAPY



OUR MISSION:

Working toward a potential functional cure for Type 1 Diabetes by uniting:

1. Stem Cell–Derived Islets

- SR-02, allogeneic insulin producing cells (IND cleared April 2026)
- SR-03, gene-edited, immune-evading insulin producing cells (IND-enabling studies; preclinical)

2. An Implantable & Retrievable Medical Device Studied in Phase 1/2

- Cell Pouch™, investigational device, Phase 1/2 completed (Open IND)
- Primary and secondary endpoints met

3. Advanced Immune Management:

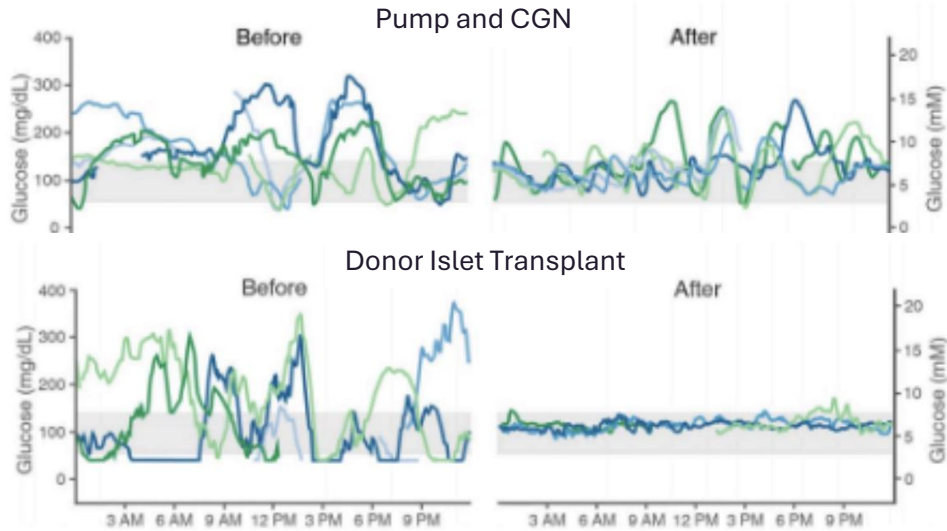
- Co-stimulatory blockers as part of immune tailoring strategy and including standard of care

UPCOMING MILESTONES

- Merger agreement executed
- Closing in November
- Patient recruitment Q4
- Phase 1/2 SR-02 study (NCT07581197): Q1 2027 dosing
- H1-2027 data readout
- SR-03 advance to IND approval in H2 2027
- Nasdaq readiness by year-end IPO Q1 2027

WHAT IS THE PROBLEM?

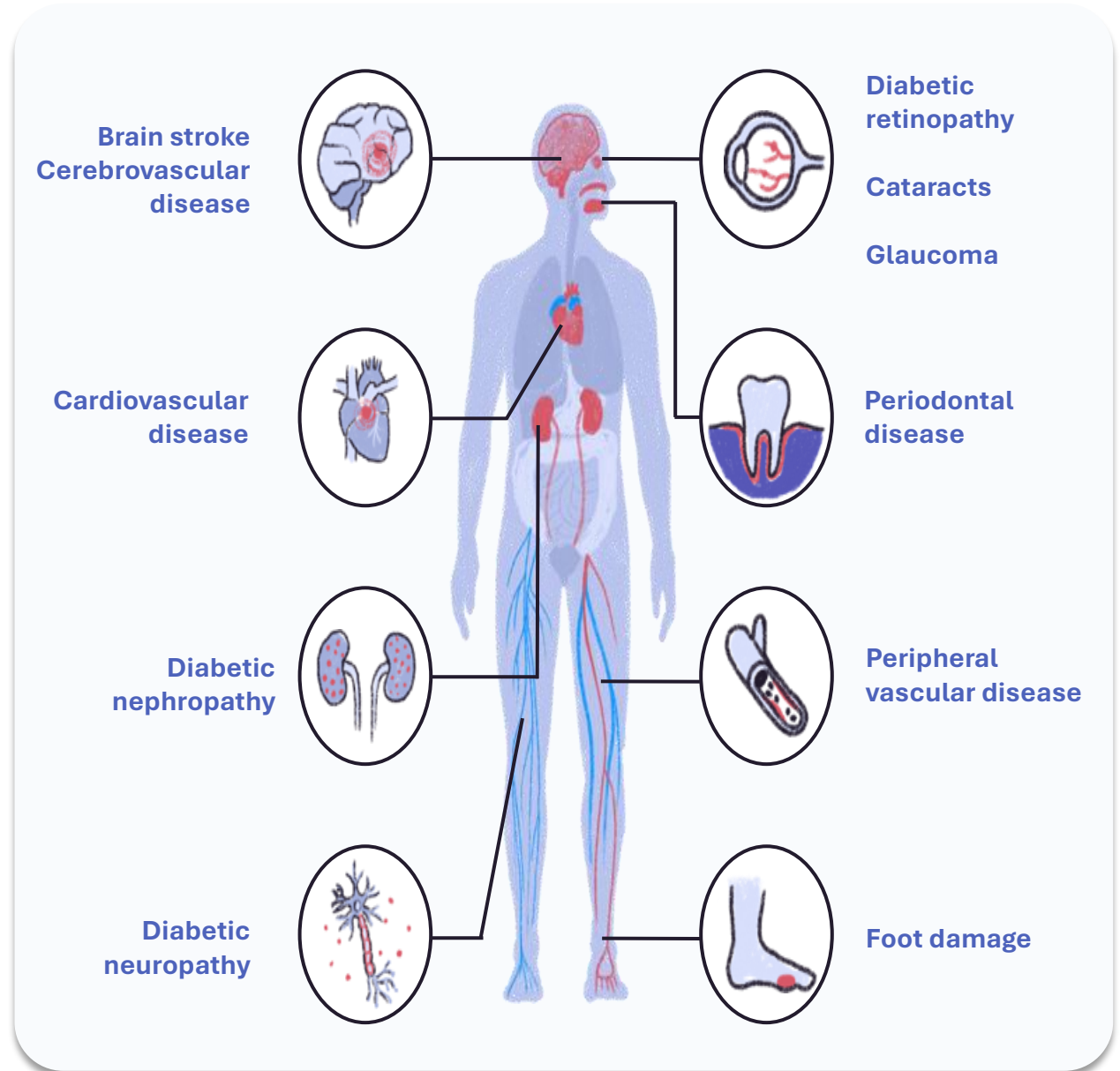
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Published research indicates roughly 1 in 10 people with T1D die of severe hypoglycemia¹

**8-13
YEARS**

Reduced Life Expectancy²



1. <https://pmc.ncbi.nlm.nih.gov/articles/PMC3425013/>

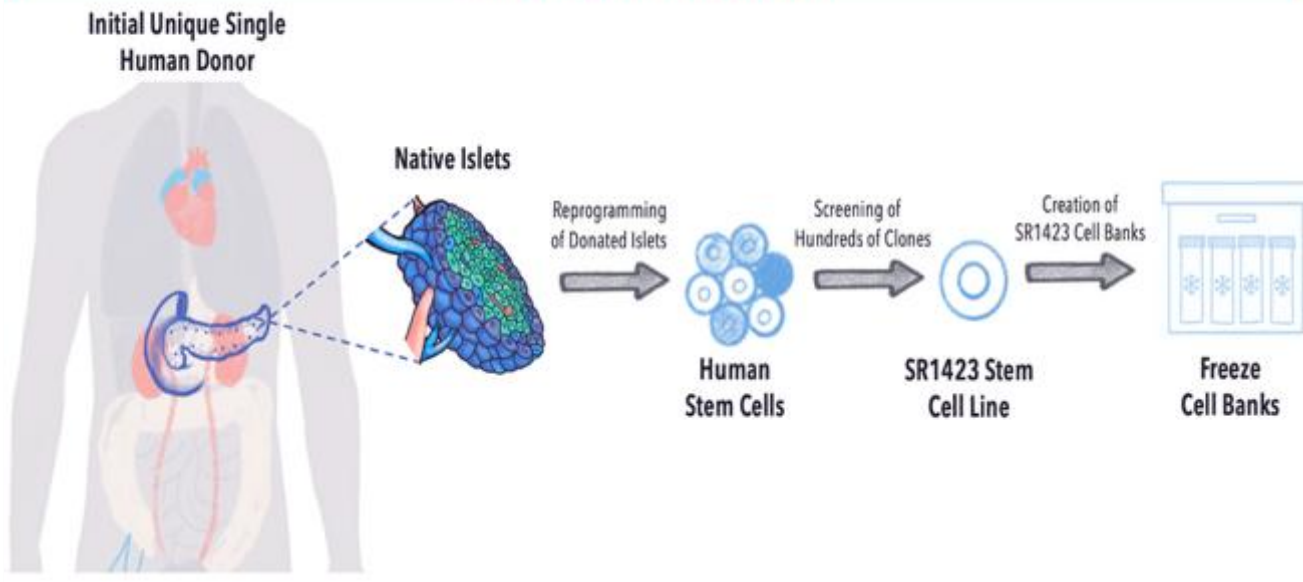
2. <https://www.healthline.com/health/type-1-diabetes-life-expectancy>

3. AACE conference April 2026

ADVANTAGES OF BETANOVA SR-02 & SR-03 STEM CELLS

A HUMAN PANCREAS-DERIVED CELL LINE FOR ISLET MANUFACTURING

INITIAL CREATION OF SR1423 CELL LINE



**SR1423 CELL LINE HAS PANCREATIC IDENTITY
BIAS, UNLIKE iPSC OR ESC**

Potent Islet Cells

- In vitro tests show high insulin secretion and glucose responsiveness

Developed For Organ Transplant Compatibility

- Blood type O, Rh negative, common HLA profile

Streamlined Manufacturing

- No sorting or selection during manufacturing process
- Demonstrated genomic stability during extended culture

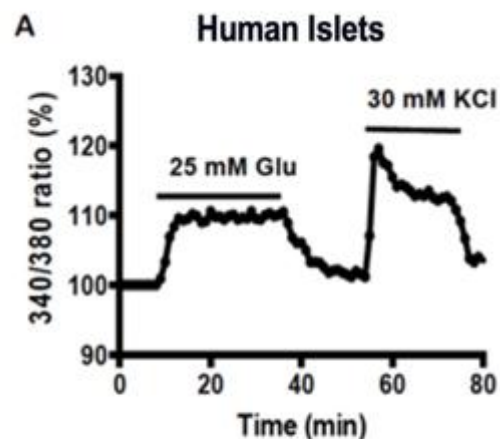
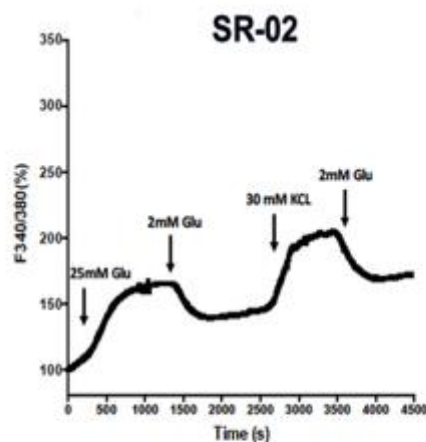
Proprietary Platform-product simplifies distribution

- 145 granted patents, >45 pending

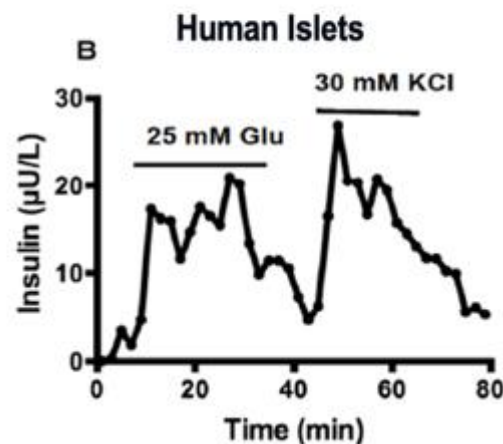
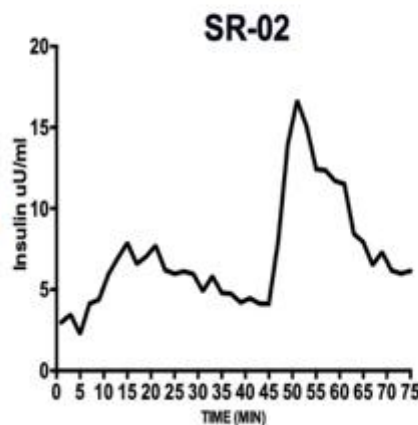
BETANOVA SR-02

THIRD PARTY ASSESSMENT OF GLUCOSE RESPONSIVENESS (Data on File)

Calcium Influx



Insulin Secretion



- Stimulation of SR-02 beta cells with glucose induced biphasic influx of calcium that correlated with insulin secretion
- Independent testing showed glucose-linked calcium influx & insulin secretion.
- Potency similar to human donor islets

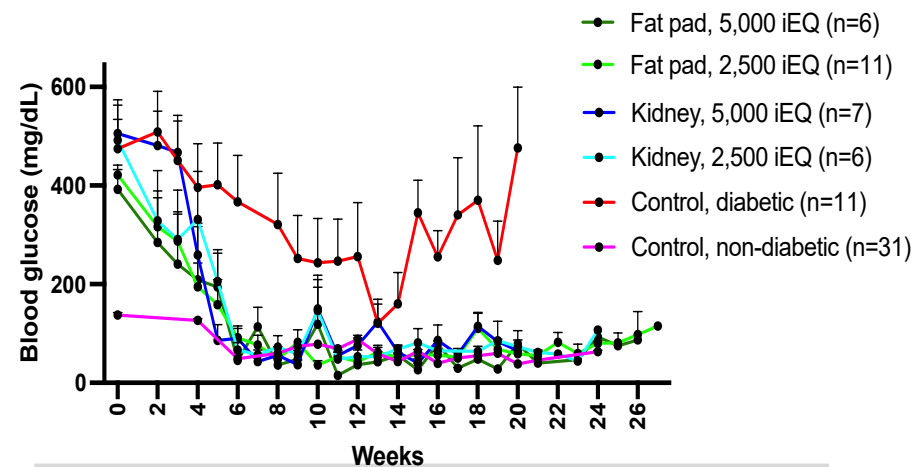
Data on file - Seraxis

SR-02 PRE-CLINICAL CELL VALIDATION

PRECLINICAL ANIMAL DATA

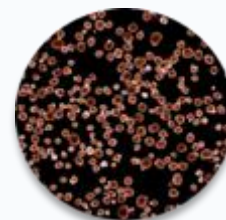
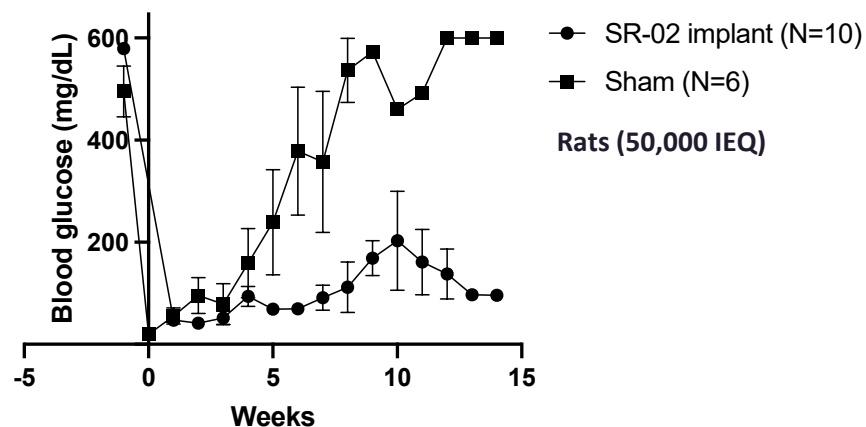
Nonfasting Blood Glucose By Site and Dose

Immunocompromised Mice



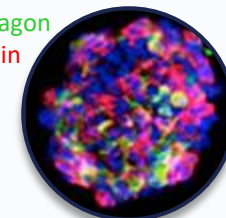
Nonfasting Blood Glucose, Omental Implant

Immunocompromised rats (n=9)



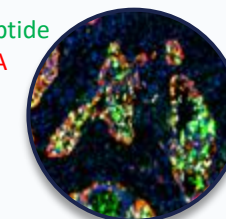
Manufactured Islets
Low Magnification

Glucagon
Insulin
DNA



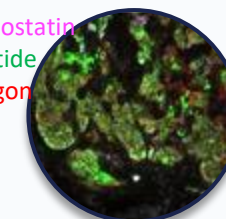
Single Islet Stained For Pancreas
Hormones
High Magnification

C-Peptide
CHGA
Pdx1
DNA



Graft at Explant, Mouse Fat Pad

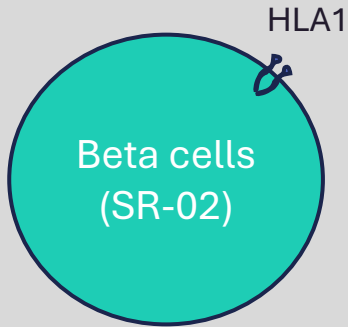
Somatostatin
C-peptide
Glucagon



Graft at Explant, Rat Omentum

REDUCING IMMUNE SUPPRESSION (Investigational)

Strategy #1 (IND cleared by FDA to begin study)



- Use modern immune-suppression to minimize burden, promote maximum tolerance
 - Co-stimulatory blockers or others
- Wean immune suppression therapy to low levels



Rationale

- Strong clinical evidence in Co-stimulatory blockers and other related trials

Strategy #2 (IND-enabling studies)



- Gene edited to avoid rejection
- Unique gene editing strategy



Rationale

- Preclinical data to date

SR-03 IMMUNE EVADING CELLS

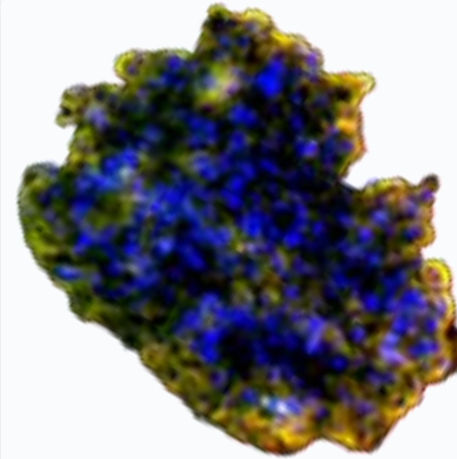
SR-03 IS GENE-EDITED TO AVOID IMMUNE TARGETING

- Loss-of-function strategy eliminates determinants of organ rejection while maintaining long-term durability

NO DETECTABLE ANTIBODIES OBSERVED

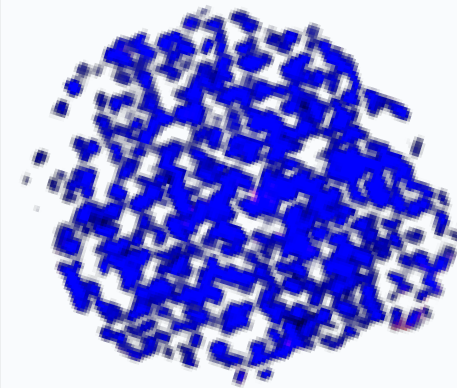
- Rodents with humanized immune systems implanted with SR-02 formed antibodies against the graft.
- Rodents implanted with SR-03 did not form antibodies.

In pre-clinical development



SR-02

- IgG IgM Nucleus
- Antibodies formed against cells



SR-03

- GENE-EDITED FROM SR-02
- No antibodies against cells
- Graft invisible to immune system

MANUFACTURING: SR-02 & SR-03 ALLOGENEIC STEM CELL LINE

HIGH-PURITY, HIGH-POTENCY ISLETS (Preclinical)

MANUFACTURING

- No sorting or selection required to achieve high purity
- Hundreds of manufacturing runs completed
- Designed to be stable and quality-controlled for shipment to point of care (commercial-scale shipping logistics not yet validated)
- High-compatibility, single-donor source
- Type O, Rh- with common HLA profile
- Established cGMP master cell bank

Manufacturing Process



❄ Frozen
Cell Banks



Step 01
Thawing of
One Cryotube



Step 02
Cell expansion
of SR1423
Stem Cells



Step 03
Differentiation
of SR1423
Stem Cells



Step 04
QC
Testing



Step 05
Package/Final Fill
of Drug
Substance For
Multiple Patients

SR1423 Cell Culture

SR1423
Drug Substance

SR-02
Drug Product

PANCREATIC DIFFERENTIATION BIAS

- Produced cell clusters with native distribution of pancreatic hormones

COMPLETED - PHASE 1 / 2 CELL POUCH CADAVERIC CELL CLINICAL TRIAL

Overall Objectives

- Demonstrate safety & tolerability of Cell Pouch/Human Donor Islet transplantation
- Define islet release criteria predictive of clinical outcomes
- Establish optimal islet dose & concentration ranges

Primary Endpoint

- Safety assessment following:
 - Cell Pouch implantation
 - Islet transplantation
 - Long-term follow-up through 1 year
 - Adverse events (AEs)/Cell Pouch/procedure-related safety

Secondary Endpoints

- Histologic evidence of islet survival/engraftment
- Reduction in:
 - Severe hypoglycemic events
 - HbA1c (>1% improvement)

✓ **PRIMARY AND SECONDARY
ENDPOINTS MET (SEE NCT03513939)**

*Compared to historical cadaveric-islet
literature—
not head-to-head; see ref.¹*

Detailed supporting data presented herein

30 YEARS

CUMULATIVE PATIENT SAFETY DATA

[]

BETANOVA CELL POUCH™ BIO-HYBRID ORGAN

Phase 1/2 Findings on Safety and Function

Phase 1/ 2 clinical trial for Type 1 Diabetes complete

Vascularized Tissue Environment

Designed to remodel the implant site into a vascularized tissue environment for islet engraftment and function

Cell Containment and Retrievability

Designed for long-term safety monitoring, with the ability to remove the device if necessary

Thin, Flexible Implant

Made from biocompatible medical- grade surgical mesh designed to integrate naturally with body tissue

CELL POUCH PRE-IMPLANT



BIO – HYBRID ORGAN POST REMOVAL



IMPLANTATION PROCESS

1

IMPLANT

2

VASCULARIZE

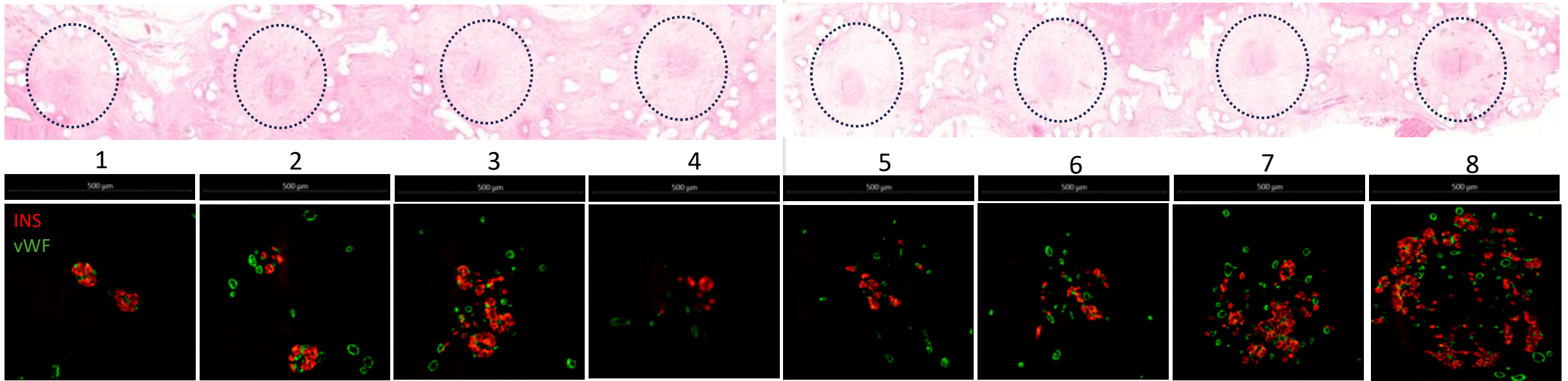
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LOAD CELLS

4 – 6 WEEKS

PHASE 1/ 2 TRIAL - ABUNDANT, VASCULARIZED, INSULIN-PRODUCING BETA CELLS THROUGHOUT CELL POUCH™ AFTER 5-YEARS

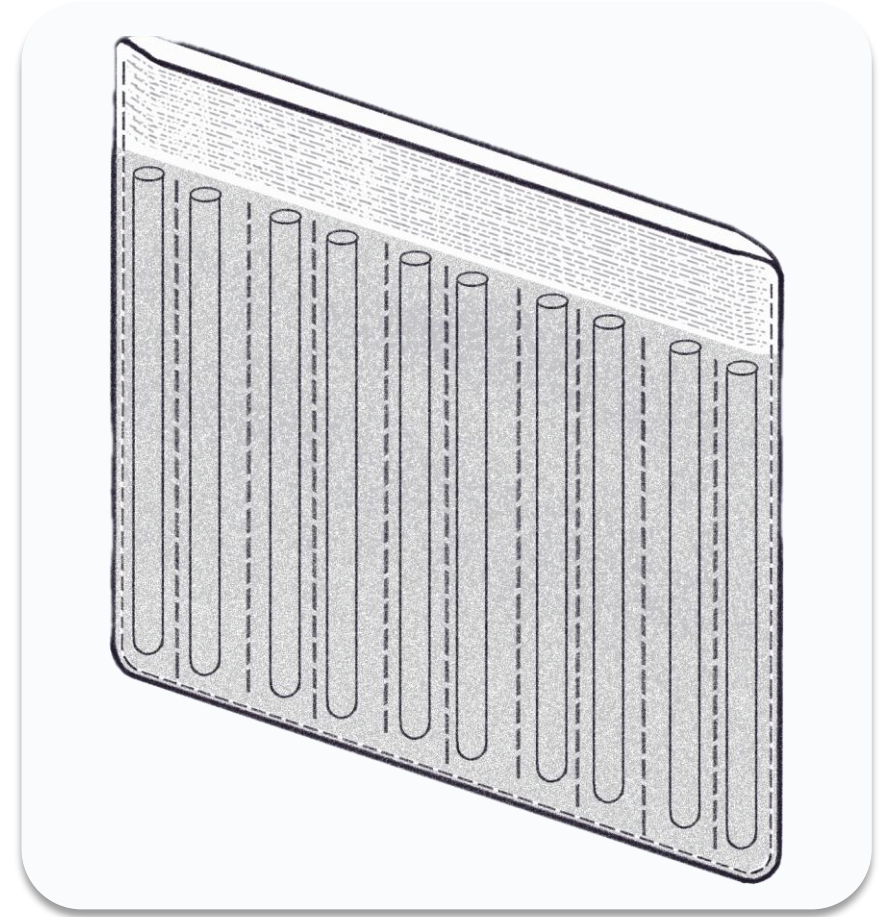
8 CHANNEL CELL POUCH TISSUE CHAMBERS:



- Positive immunofluorescent staining for **Insulin**, and **Von Willebrand Factor** (blood vessels), **Glucagon & Somatostatin**
- **Rich vascularization of abundant insulin-producing cells and no evidence of detrimental fibrotic tissue**

FDA POSITION ON RETRIEVABILITY AND CONTAINMENT FOR STEM CELL- DERIVED ISLET THERAPY

- FDA guidance ; a retrieval mechanism is preferable for stem cell-derived islet therapies^{1,2,4}
 - Company believes a retrievable device is more likely to be required as a safety requirement
 - Stem cell-derived and genetically modified cells are considered by the agency to incur heightened risk of genetic instability over time
- The Cell Pouch™ is a retrievable, biocompatible cell containment device that, in the Company's Phase 1/2 study, supported islet survival and function.³ Comparison to other device platforms has not been independently verified.



1. <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies#:~:text=These%20regenerative%20medicine%20products%20have,such%20as%20hepatitis%20and%20HIV.>

2. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10642112/#:~:text=Moreover%2C%20encapsulation%20devices%20offer%20the%20benefit%20of,for%20necessary%20adjustments%20or%20modifications%20as%20required.>

3. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11286215/#S15>

4. https://www.breakthrough1d.org/?jdrf_topic=cell-therapies#:~:text=Autologous%20cells%20are%20those%20removed,are%20expected%20to%20be%20required.&text=Allogenic%20cells%20are%20those%20that,be%20generated%20at%20large%20scale.

PATIENT WILLINGNESS TO ADOPT CELL-BASED THERAPIES FOR T1D IS OVERWHELMING

2017

Survey across North America, Europe, and Asia found **72%** interested in participating in clinical trials for bio-artificial pancreas systems, (*Diabetes Technology & Therapeutics*, 2017).

2019

Study found **~75%** expressed interest in an artificial pancreas or cell-based therapy as a future treatment option (*Journal of Diabetes Science and Technology*, 2019).

2020

Study **70%** reported they would consider islet transplantation or the Sernova Cell Pouch to improve glycemic control (*Diabetes Care*, 2020).

2021

Study **~60%** stated they would be interested in stem cell-based treatments like the Sernova Cell Pouch (*Diabetes Therapy*, 2021).

2023

Study reported **97%** would be willing to receive an islet delivery device (IDD), such as the Sernova Cell Pouch. (*Transplant International*, 2023).

2025

Qualitative study on perceptions of benefits and risks of novel therapies, **100%** would adopt replacement cell therapy if available (*Diabetes Therapy* 2025).



Thank You

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