



**A future where chronic conditions
are no longer insurmountable obstacles**

March 2024

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Sernova is Pioneering 'Functional Cures' for Chronic Diseases

Blazing the trail in regenerative medicine

Valuable & Expanding Portfolio

- Clinical stage company
- Lead program: insulin-dependent diabetes (T1D)
Insulin-producing cells + pre-implanted Cell Pouch™ reduces or eliminates the need for life-long insulin injections
- Additional programs in thyroid diseases and hemophilia A

Cell Pouch System™

- Proprietary technology - delivery vehicle
- A flexible, implantable device containing immuno-protected therapeutic cells
- Creates highly vascularized, organ-like environment
- Cells sustainably produce missing therapeutic proteins or hormones

Therapeutic Cell Platform

- Creating true 'functional cure' for chronic diseases
Not simply treating symptoms with burdensome, incomplete and lifelong medications
- Portfolio potential for multiple conditions in multi billion-dollar markets
- Ethically derived therapeutic cell sources

T1D Cohort 1 Patient Testimonial Speaks Volumes

Insulin Independent for ~4 Years



After completing the safety, tolerability and efficacy study of Sernova's Cell Pouch for clinical islet transplantation and as the first transplant candidate, I can easily state how absolutely wonderful life is, to be free of always thinking of how to manage my diabetes.

After having T1D for 47 years with approximately 21,535 injections of various cow/pig, synthetic insulins, 34,310 finger sticks, 1,460 urine tests, 15 years on the pump, carbohydrate counting, blood tests, low blood sugar reactions, and doctors...doctors and more doctors' visits, I have now been free of the need for injectable insulin for 15 months.*

My only wish is that it could have been done sooner.

Cohort 1, Patient 1 – June 2021



*Insulin independent for ~47+ months as of March 13 2024

Note: Above quote is from a single patient and may not be indicative of the experience of all patients now or in the future.

Executive Summary: Advancing Cell Therapeutics for Functional Cures

Pipeline of cell therapies combined with the Cell Pouch delivery vehicle for chronic diseases

The Cell Pouch System

- Forms an organ-like environment for administration of cell-based therapies
- Ensures complete containment of therapeutic payload and full retrievability
- Established clinical proof of concept in patients with **Type 1 Diabetes (T1D)**
- Preclinical proof of concept established in Post-operative **Hypothyroidism** and **Hemophilia A**

Type 1 Diabetes

- Ongoing Phase 1/2 trial with human donor islets in T1D patients
 - 5 of 6 fully transplanted patients in first cohort achieved insulin independence – longest, to date, continues ~4 years
- Next-generation T1D therapy: the Cell Pouch System with proprietary **iPSC-derived islet-like clusters**, in collaboration with Evotec
 - IND/CTA -enabling activities are being conducted across 2024
 - Positive pre-submission regulatory interactions, to date

Hemophilia-A

- Development of novel LV-corrected BOECs* for treatment of **Hemophilia A**, in collaboration with University of Eastern Piedmont
- **Orphan Drug Designation** and **Rare Pediatric Disease Designation** granted by US FDA

Hypothyroidism

- Advanced preclinical development in Post-operative **Hypothyroidism** towards **IND filing** in 2024 for Phase I/II clinical trial

New Developments at Sernova

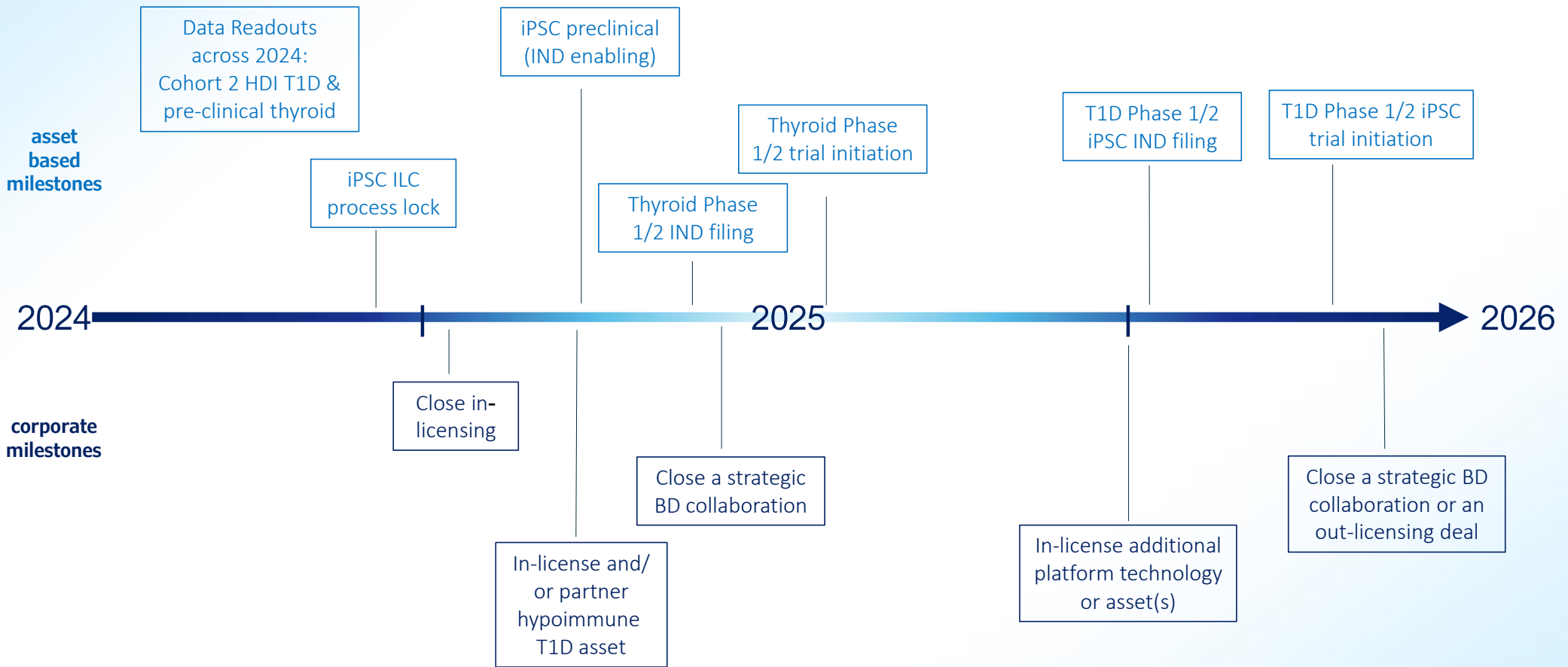
- 1Q2024: Long term **islet survival** in Cell Pouch (from P1/2 T1D clinical setting)
 - histological evidence of abundant, vascularized islets expressing insulin throughout the Cell Pouch chambers
 - Patient from cohort 2; > 1 year from transplant; patient has sustained elevated C-peptide and has achieved insulin independence
 - Believed to be a **1st** in the industry
- 1Q2024: **New research program with Astra Zeneca**
 - Expanding our work with AZ via an exciting new research collaboration
- 4Q2024: **Investigational New Drug (IND)** filing for post operative hypothyroidism
 - Based on recent positive findings in post-surgical hypothyroidism pre-clinical model
 - Moving forward with interactions with regulatory agencies in preparation for IND filing
- **Malignant cell animal study:** further proof that the cell pouch has powerful **containment** – and retrievability – capabilities
 - Malignant cells remained alive in cell pouch for 90-day duration of study with NO evidence of malignancy in animal upon pouch explantation
 - Believed to be a **1st** in the industry
- T1D Human Donor Islet Phase 1/2 Clinical Study: Cohorts 1 and 2 **learnings** to support iPSC study in 2025
 - Optimal islet dose and density
 - Continue to test various advanced immunosuppressive regimens in preparation for Phase 1/2 iPSC ILC T1D study



Sernova has largest clinical database for T1D cell therapy

Today to 2026: Potential Milestones & Value Inflection Points

Development for T1D, Thyroid Disease & Hem A Continues Across 2024-2026



fundraising activities will be conducted as appropriate

all milestones are subject to sufficient financing, positive data readouts, regulatory interactions and our partners ability to deliver



Pipeline Today – Multiple Indications

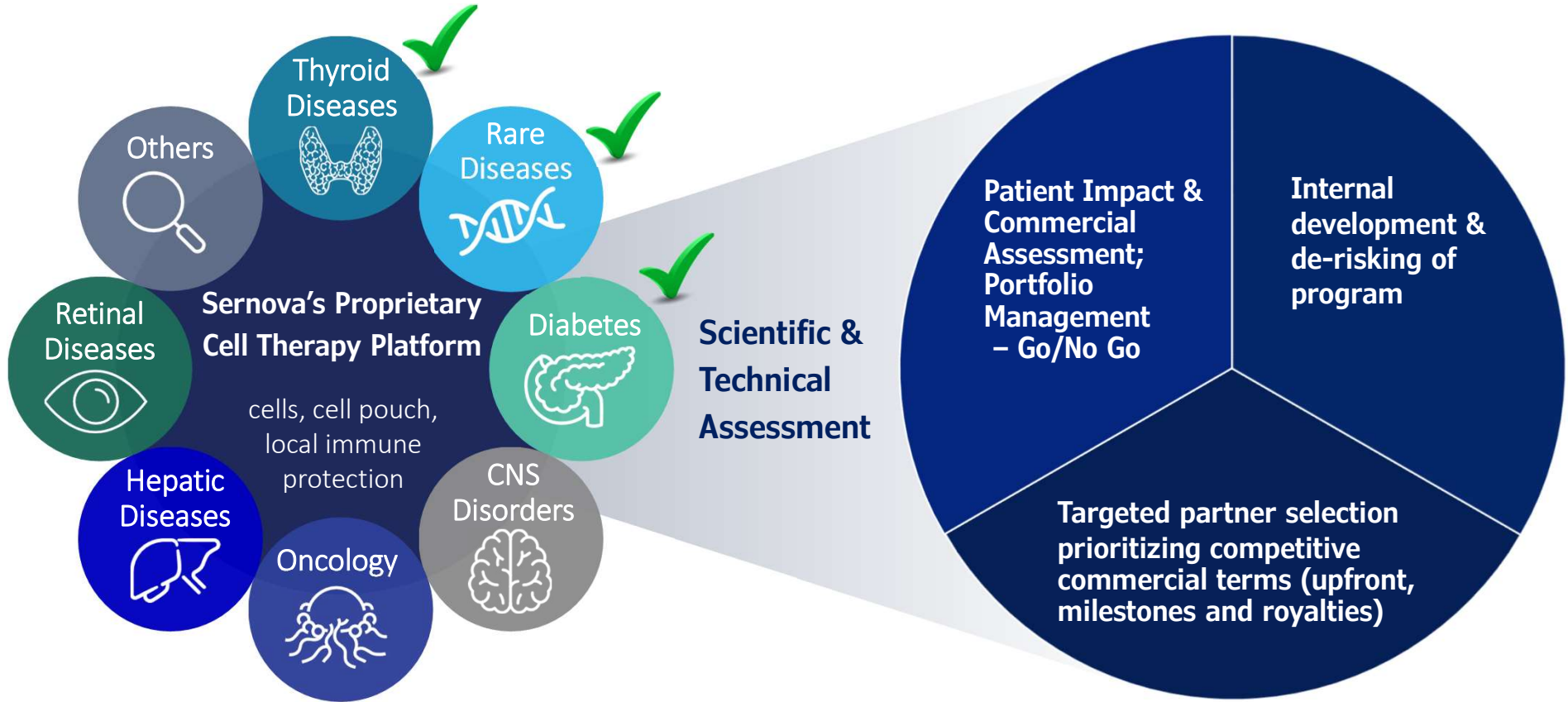
Impacting patients around the world

Indication	Therapeutic Cell Source	Discovery	Pre-Clinical	Phase 1/2	Phase 3	BLA
Insulin - dependent Diabetes	Human donor islet cells <i>serves as proof of concept for iPSC study</i>					
	iPSC islets					
Hemophilia A	Corrected patient cells Autologous					
Hemophilia A	Allograft immune protected stem cells					
Thyroid Diseases / Post Operative Hypothyroidism	Thyroid cells Autologous					
	Allograft immune protected stem cells					



Implementing a Portfolio Strategy

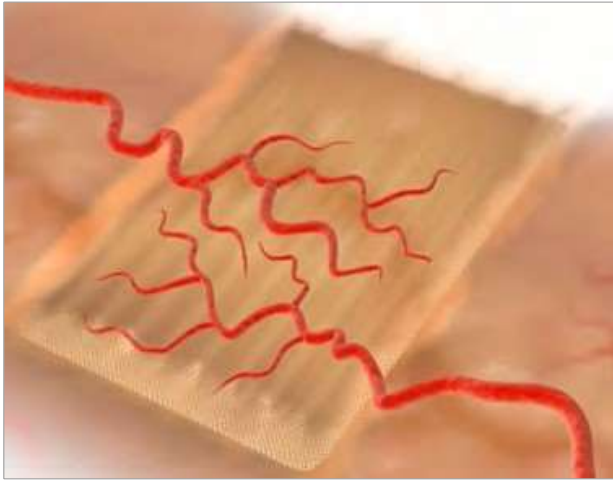
Multiple opportunities to expand our portfolio & to extend our reach to more patients



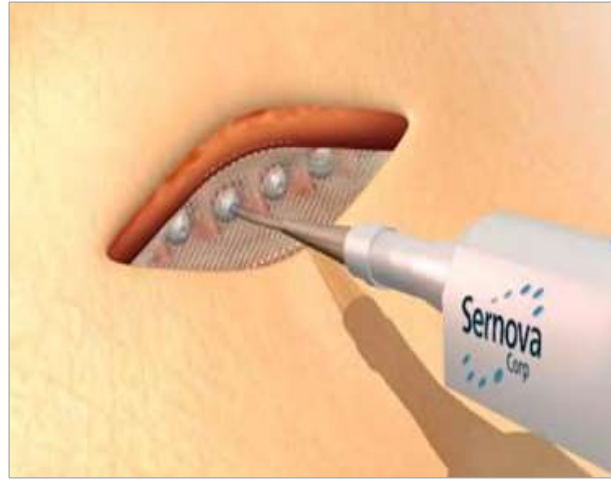
Identified additional chronic disease indications for further pipeline expansion, with a focus on endocrine disorders

Cell Pouch + Therapeutic Provides Organ-Like Environment

Creates vascularized tissue chambers to allow optimal engraftment of therapeutic cells



- Cell Pouch is placed deep under the skin in a short procedure
- Vascularized tissue chambers develop, enabling long-term survival and function of therapeutic cells



- After 3 weeks, therapeutic cells can be transplanted into the vascularized tissue chambers enabling rapid **engraftment** within tissue matrix



- Therapeutic cells are responsive to endogenous regulation and able to **correct biologic dysfunctions** by producing missing proteins or hormones



Development of tool kit enabling consistent pouch placement & therapeutic payload transplantation is underway





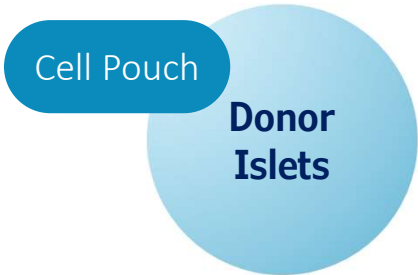
Type 1 Diabetes

**Market, Current SOC &
Sernova's Phase 1|2 T1D Study**

Product Innovation → Functional Cure for T1D

Evolution of program built to expand the treatable patient population

1 Cell Pouch + Donor Islets *Phase 1/2 Ongoing*



- Insulin-dependent T1D patients with history of hypoglycemic events
- Functional cures observed in Phase 1/2 clinical trial
- Cohort 2- ongoing, optimized dose & islet density

2 Cell Pouch + iPSC *Phase 1/2 Planning Underway*

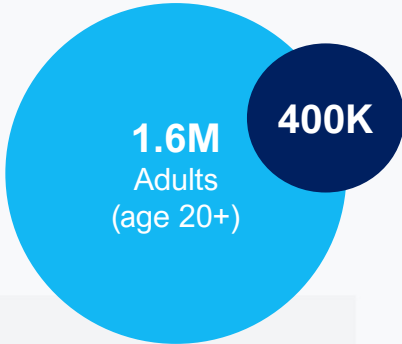


- Broad T1D population
- ILCs = unlimited supply
- Pre-clinical performance in >35 animals (donor islets ≈ ILCs)
- ILCs are cryopreserved for improved commercial logistics, providing competitive advantage

Large Addressable Market for a Functional Cure in T1D

Potential to eliminate daily insulin injections and provide tighter blood sugar control

United States
T1D Population¹



Adults with
hypoglycemia
unawareness²



of the 1.6M US adults with T1D experience “*hypoglycemia unawareness*” characterized by periodic drops in blood glucose, which can lead to loss of consciousness



Payor survey
supports potential pricing of

\$200-400K

per patient



1%

share of the hypoglycemia
unawareness patients would
translate to

\$1.2 billion³



1%

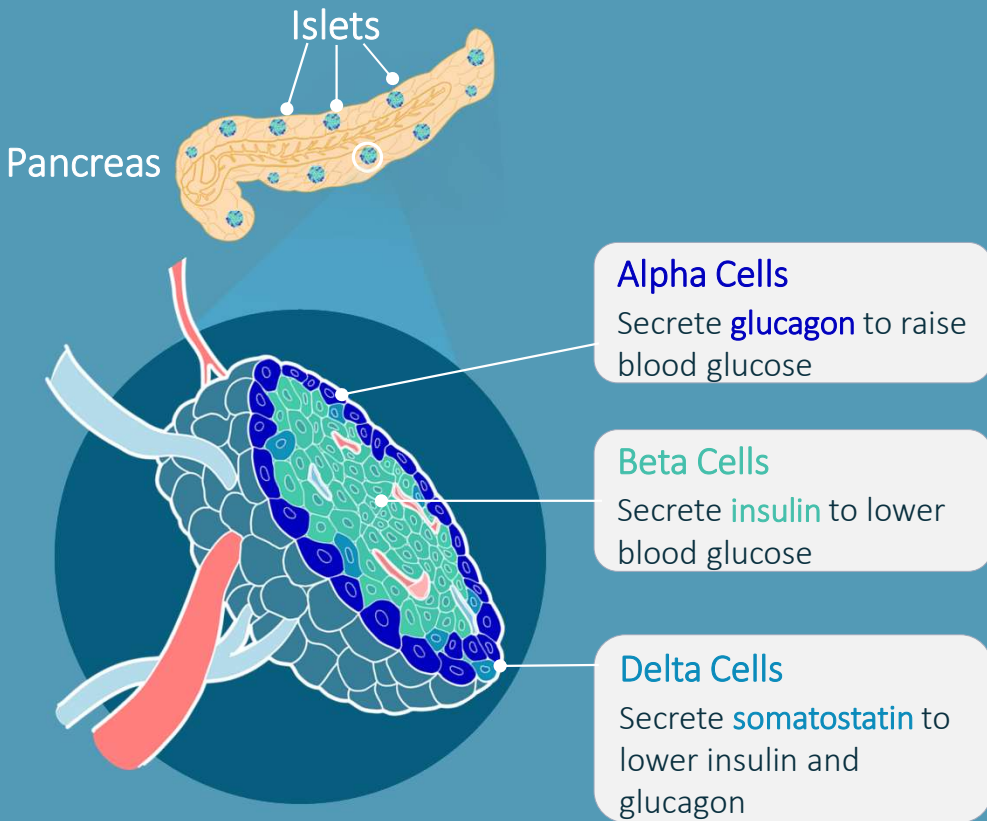
share of the overall T1D
population would be

\$4.8 billion³



1. Diabetes Research Institute Foundation & U.S. Centers for Disease Control ; 2. US Pharmacist Nov 16, 2023; 3. At pricing supported by payor survey

Advantages of Pancreatic Islet Cell Therapy vs. Insulin Injection



Pancreatic Islets

- Clusters of specialized cells responsible for global regulation of blood glucose
- In T1D a patient’s islets become dysfunctional requiring daily insulin injections

Insulin Injections

Only provides one component of blood glucose control provided by islets



Islet Cell Therapy

Provides natural restoration of islet function to return normal glucose regulation for T1D patients *without* insulin injections

- The tight control of blood glucose by islets can reduce or eliminate T1D side effects of heart & kidney disease, blindness & amputations

Sernova Cell Pouch System

- Provides a natural, organ-like system - similar to a native pancreas - when populated with donor or stem cell-derived islets
- Multiple **advantages** over insulin injections for tighter blood sugar control from the combination of alpha, beta and delta cells for a potential “**functional cure**” for T1D

Phase 1/2 T1D Multi-Cohort Trial Design

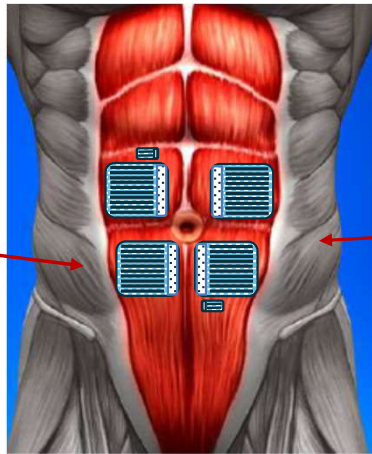
Placement of Cell Pouches has been carefully designed & controlled

Insulin independence was not an endpoint –
but has been achieved

Endpoints	
Primary	Secondary
Safety and tolerability	Survival of islets in Cell Pouch Reduction in hypoglycemic events Proportion of subjects with HbA1c reduction >1% Proportion of C-peptide events + 20 other endpoints

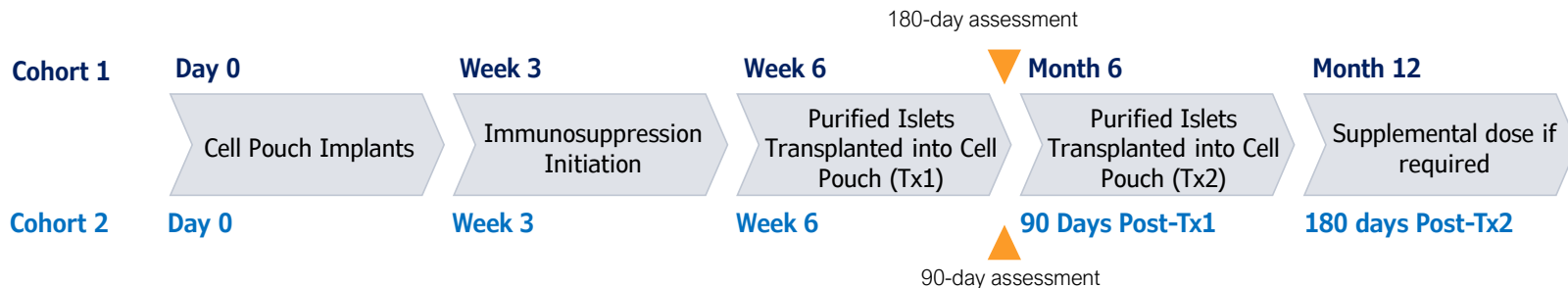
1st Cohort (n=6)

- Enrollment completed
- 8-Channel Cell Pouch
- 180-day post-Tx1 evaluation
- Cell Pouch Placement
 - Subfascial
 - Below umbilicus (4)
- Immunosuppression
 - Thymo - Tacrolimus, MMF, Etanercept



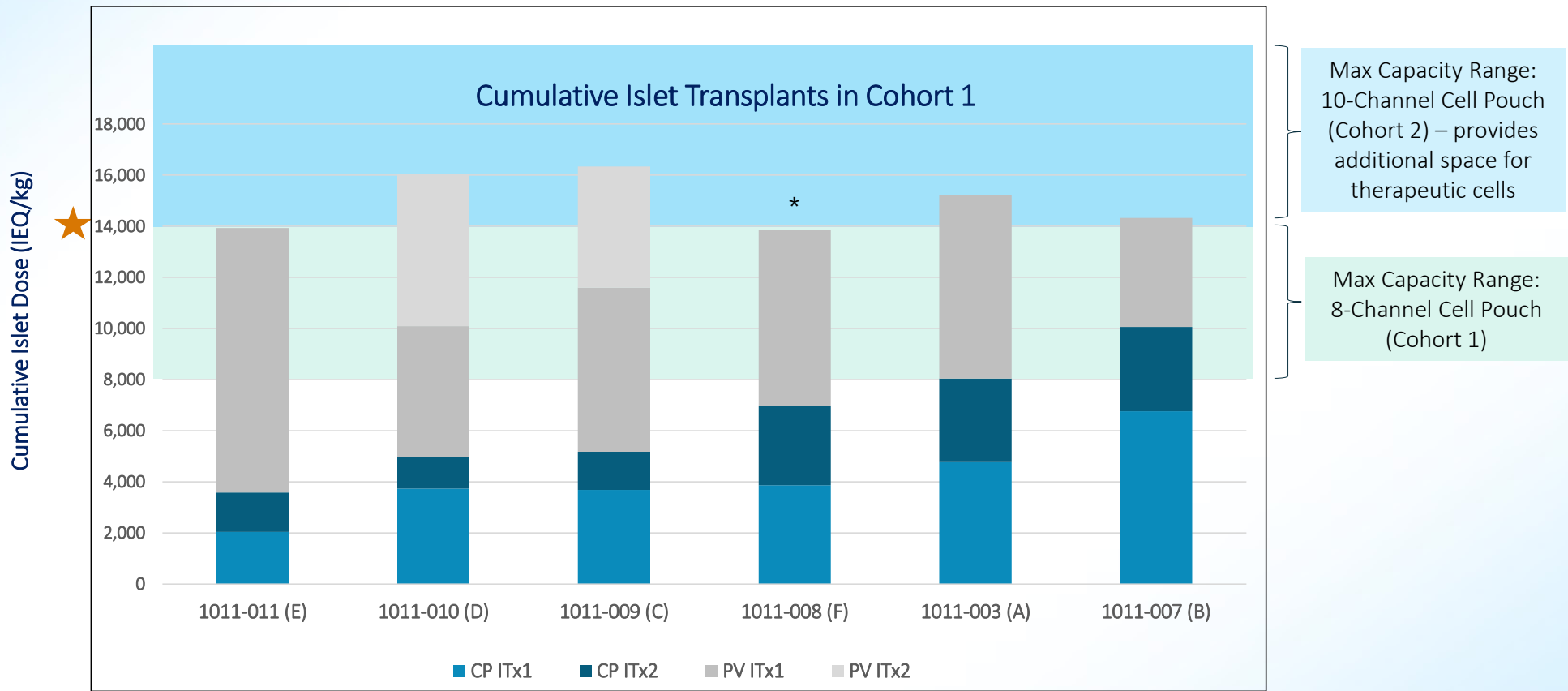
2nd Cohort (n=7)

- **Fully recruited**
- 10-Channel Cell Pouch (>50% greater capacity)
- 90-day post-Tx1 evaluation
- Cell Pouch Placement
 - Subfascial
 - Above (2) and below (2) umbilicus
- Immunosuppression
 - Thymo - **Belatacept**, ↓ Tacro, Etanercept



Insulin Independence Achieved in 5 of 6 Patients, Cohort 1

Clinical POC that Cell Pouch supports the engraftment & therapeutic function of transplanted cells.



1. Total islet dose to achieve insulin independence has been determined ★
2. More islets administered via the Cell Pouch, the fewer required in the portal vein



*Following portal vein islet transplant, graft function remains sub-optimal for Patient "F", only - Insulin therapy reduced but ongoing

CP – Cell Pouch

PV – Portal Vein

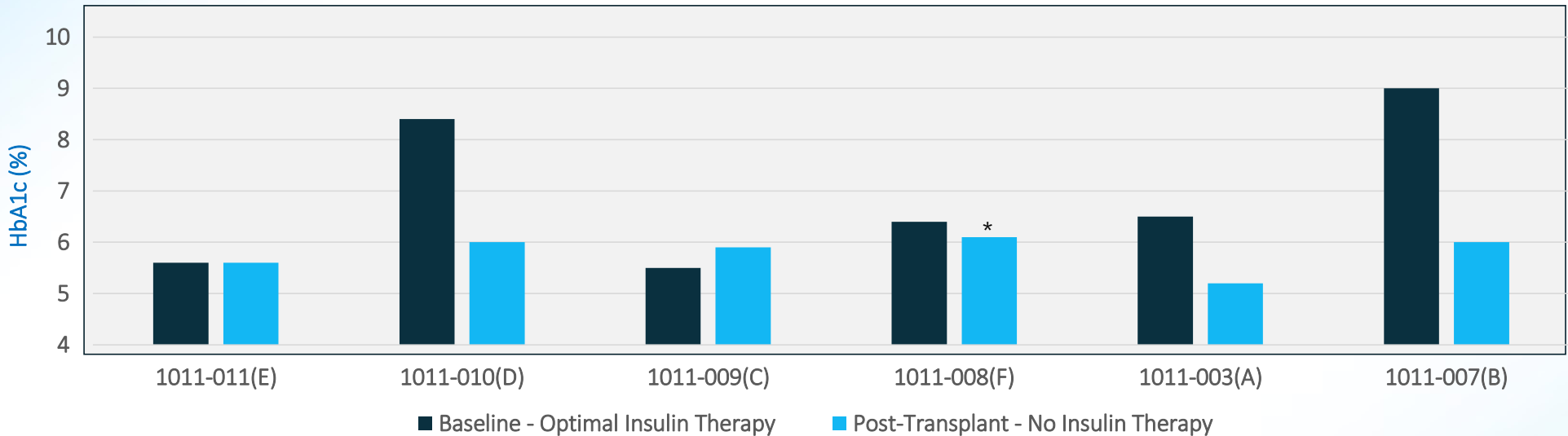
ITx – Islet Transplant

POC – Proof of Concept

Glucose Control in the Non-diabetic Range for All Subjects

T1D Phase 1/2 human donor islet study - Cohort 1

Blood Glucose Control – HbA1c



- 5 of 6 patients discontinued insulin therapy
- All patients achieved HbA1c values in the non-diabetic range ($\leq 6.5\%$)¹

5 of 6 Patients Achieved 100% Insulin Independence

Phase 1/2 interim update demonstrates safety & tolerability; 1st cohort provided dosing & cell density insight



Surgical implantation of the Cell Pouch was found to be well tolerated with a favorable safety profile

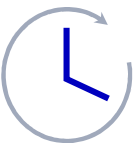


5 of 6 patients in first Cohort achieved complete insulin independence

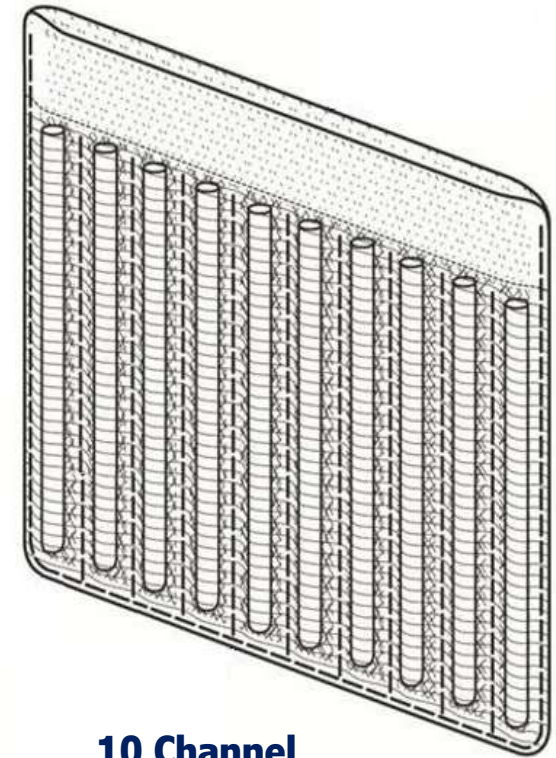
- Histological assessments demonstrate surviving, functional islets in Cell Pouches of all study patients that achieved insulin independence
- Following islet transplants to Cell Pouch, only a marginal islet dose transplanted via the portal vein was sufficient to **achieve and maintain insulin independence** for these patients - the longest continuing for **close to 4 years**
- Patient 6 (final patient in first Cohort) continues to be followed with a decreased daily insulin dose and HbA1c level in the non-diabetic range
- Insulin independence in 1st Cohort with protocol-defined islet transplants led to an understanding of optimal dosing and initiation of 2nd Cohort using Cell Pouches with 50% greater cell capacity

2nd Cohort – Favorable First Clinical Update

Higher capacity allows for higher dosing with optimal islet concentration



- Patient enrollment with implantation commenced November 2022
- 6 patients enrolled and implanted with higher capacity 10 channel Cell Pouches
 - 5 patients have received first islet transplant to Cell Pouch
- First assessable patient demonstrating consistent fasting and stimulated serum C-peptide after just one islet dose – *initial confirmation of optimal dose and dose density approach*
 - Patient achieved insulin independence with single Cell Pouch transplant and marginal dose portal vein transplant (2nd Cell Pouch transplant removed without issue due to post-transplant finding of contaminated donor islets)
- Additional interim clinical trial update anticipated Q1 2024



**10 Channel
Cell Pouch
Rendition**



Clear demonstration of full containment and retrievability with the Cell Pouch



Sernova | Evotec Partnership
iPSC-Derived Islet-Like Clusters (ILCs)

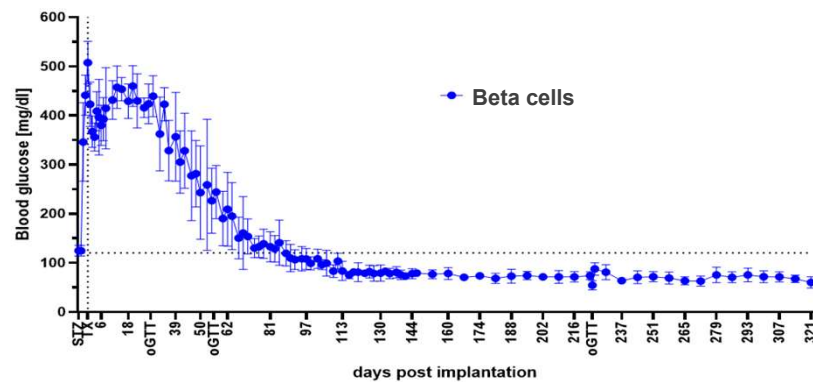
iPSC- Islet Like Clusters (ILCs): Long-Term Antidiabetic Efficacy

Robust, durable normalization of glucose control in diabetic mice

Preclinical

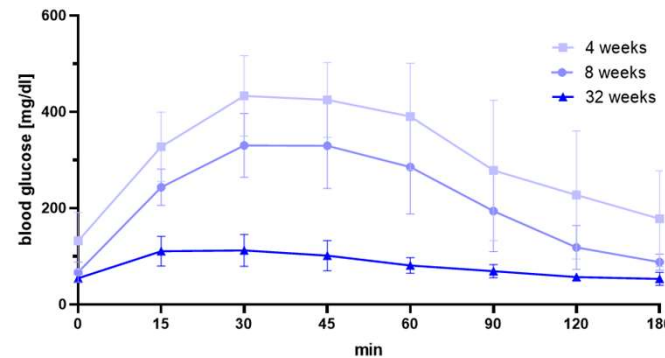
- ILCs demonstrated sustained normalization of blood sugar levels in diabetic mice throughout the 320-day study duration
- High insulin-producing beta cell content as well as glucagon and somatostatin (produced by alpha cells and delta cells, respectively), closely mimicking human islets
- Robust and durable insulin independence established in diabetic mice, with blood C-peptide levels and glucose tolerance test results equivalent to a comparator group with human islets

Efficient normalization of random fed glucose by kidney capsule-implanted ILCs

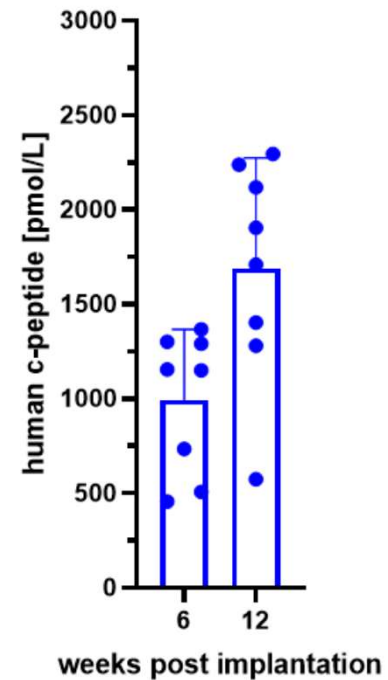


Oral Glucose Tolerance Test

Weeks 4, 8 and 32 post-ILC implantation

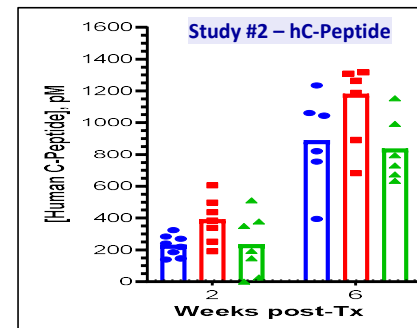
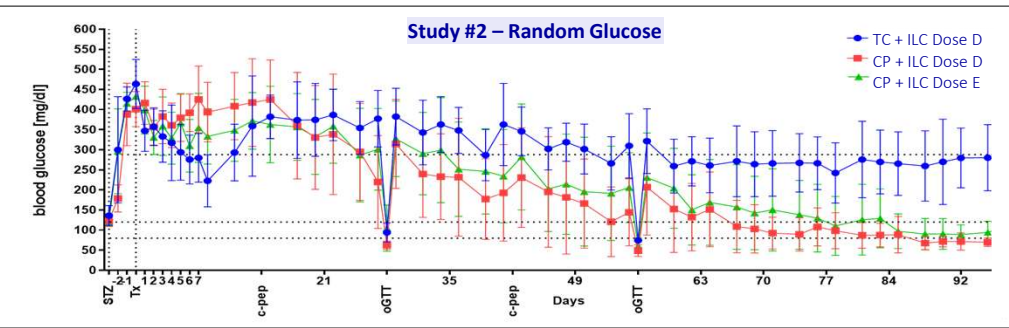


Circulating C-peptide

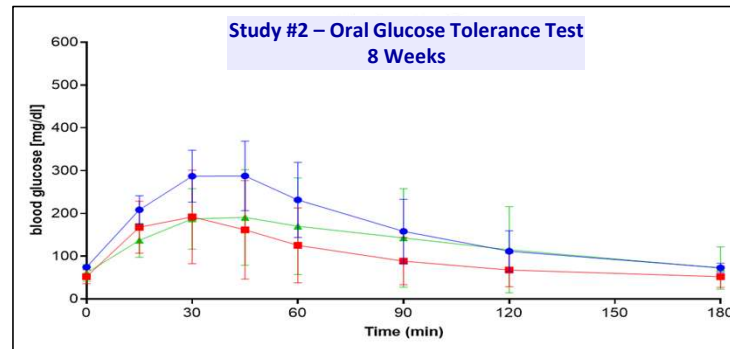
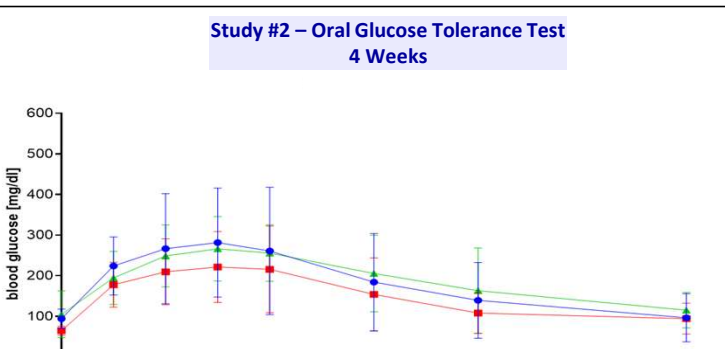


Dose- and Cell Pouch-Dependent Blood Glucose Normalization & C-peptide Levels

Evotec iPSC ILCs + Sernova Cell Pouch



- Better glucose responsiveness and control with Cell Pouch (CP) compared to control device (TC) with same ILC dose
- Similar glucose control with high and moderate doses
- Improved glucose clearance (OGTT) after 8 weeks compared to 4 week time point indicate maturing ILC engraftment and function
- Highly consistent results across three separate studies with duration up to 6 months
- Consistency of results across multiple preclinical studies with ILCs in Cell Pouch supported **selection of clinical dose for evaluation in human trials**



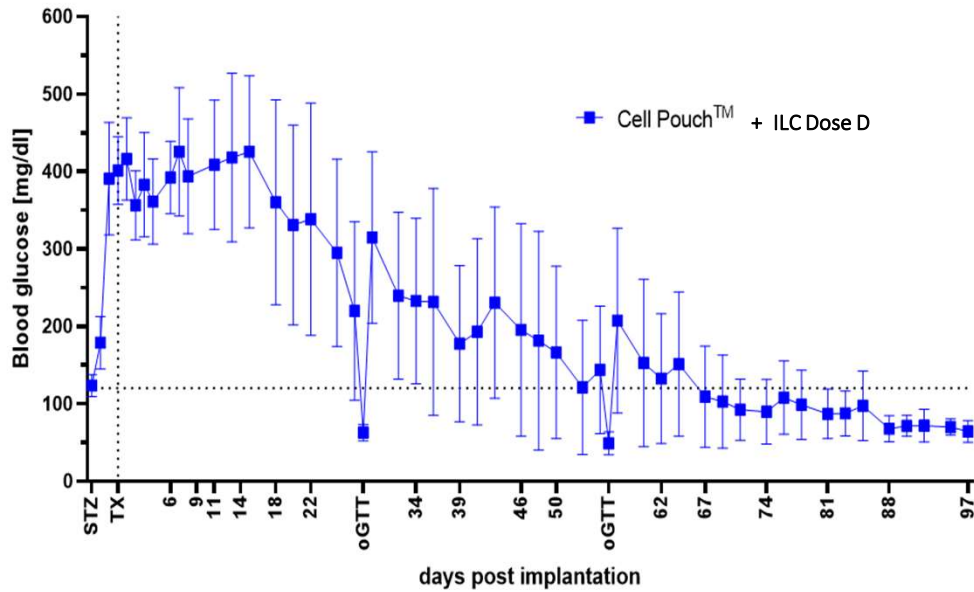
TC = Theracyte device

Strong Anti-Diabetic Activity of ILCs in the Cell Pouch

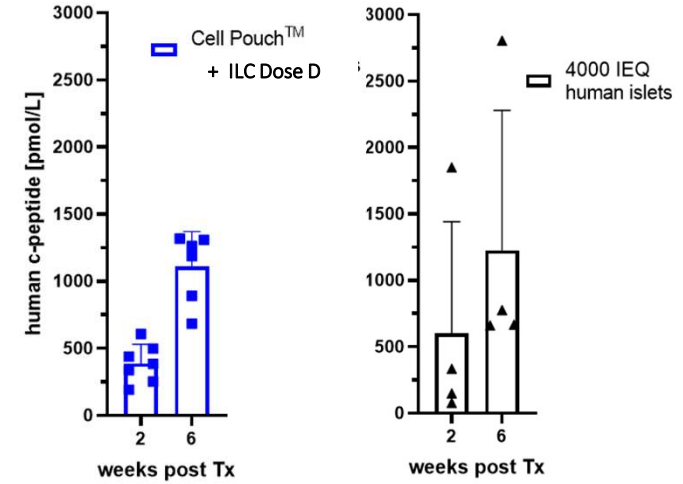
Selected clinical dose equivalent provides rapid normalization of glucose control with human islet-like potency

Preclinical

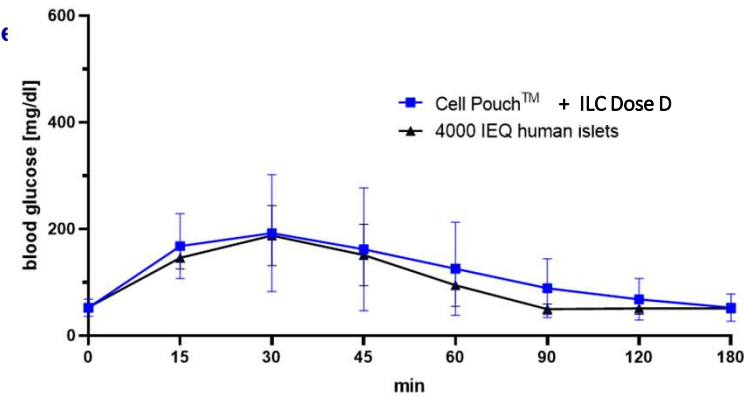
Efficient normalization of random fed glucose



Robust circulating hC-peptide levels comparable to human islets



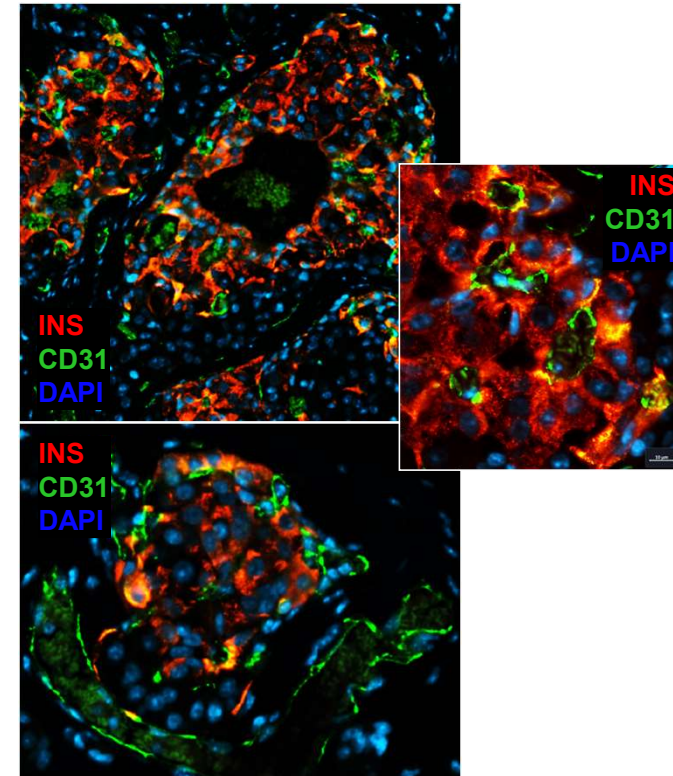
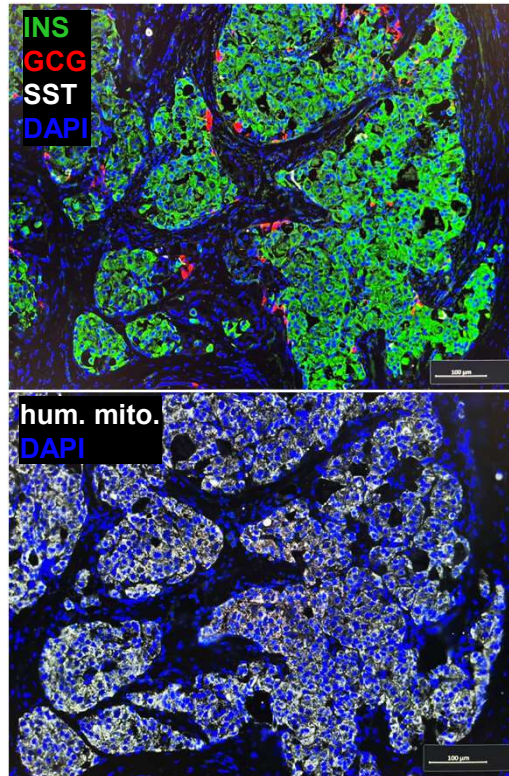
Efficient glucose clearance in oGTT comparable to human islets at 8 weeks timepoint



High β -Cell Fraction & Abundant Vascularization of ILCs Implanted to Cell Pouch in Diabetic Mouse Model

Histological Assessment at 24 Weeks

- Abundant endocrine cells with high beta cell fraction detectable
 - Alpha and delta cells are observed at lower frequencies
- ILC cells are embedded in host-derived tissue matrix
- High level of vascularization is visible (CD31) throughout ILC graft in Cell Pouch





Additional Pipeline

Cell Pouch System for Thyroid Diseases | Hypothyroidism

One-and-Done treatment provides attractive alternative to life-long medications

Therapeutic Benefits & Estimated Market



Estimated Market Size

150,000¹ thyroidectomies performed annually in the US alone

\$3.6B² market opportunity

First generation product would utilize patients' own tissue

2nd generation stem cell-derived technology for treatment of broader population



Benefits of Sernova Cell Pouch Technology

- Reduce / eliminate daily life-long thyroid medications
- Recover natural feedback loop of thyroid hormones
- Improve clinical **symptoms** from low thyroid hormone levels
- Improve **quality of health and life**



Clinical Approach

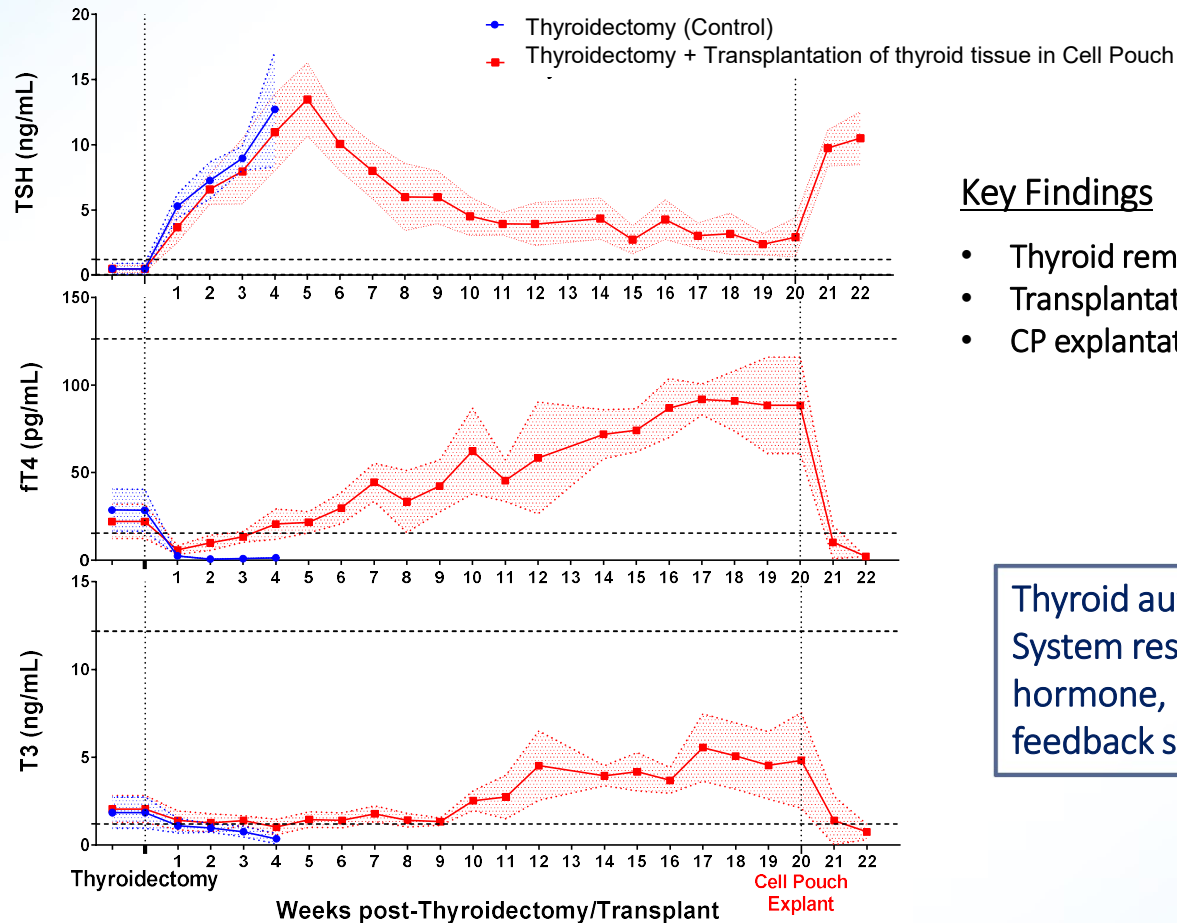
Positive preclinical proof-of-concept

IND-enabling activities ongoing

➤ Phase 1/2 trial preparations are underway

Thyroid Program: In Vivo Efficacy, Proof of Concept in Rat Study

Thyroid auto-transplantation into Cell Pouch – Measured Blood Hormone Levels



Key Findings

- Thyroid removal --> T3/fT4 decreased and TSH increased
- Transplantation --> restored T3/fT4 and normalized TSH
- CP explantation --> T3/fT4 decreased and TSH increased

Thyroid auto-transplantation via the Cell Pouch System restored endogenous circulating thyroid hormone, preserving the brain-thyroid hormone feedback system in thyroidectomized rats

Cell Pouch System for Hemophilia A

Improved Safety Compared to Gene Therapy Approaches

Therapeutic Benefits & Estimated Market



Estimated Market Size

60,000¹ patients across North America and EU

\$18B in 2021 reaching \$27B by 2031² orphan indication at approx. US\$300k annual treatment cost²



Benefits of Sernova Cell Pouch Technology

- Reduce or eliminate factor VIII infusions; maintain constant blood levels of factor VIII
- Reduce joint bleeds
- Improve long-term **efficacy**
- Improve quality of health and life



Clinical Approach

First generation (autograft) – ongoing optimization of dosing

- Treatment involves correction of patient's own blood outgrowth endothelial cells (BOECs)
- FDA has granted Sernova both an **Orphan Drug Designation** and a **Rare Pediatric Disease Designation** for this therapeutic approach
- **Next generation (allograft)**
 - Off-the-shelf gene edited stem cell technology for hemophilia A patients

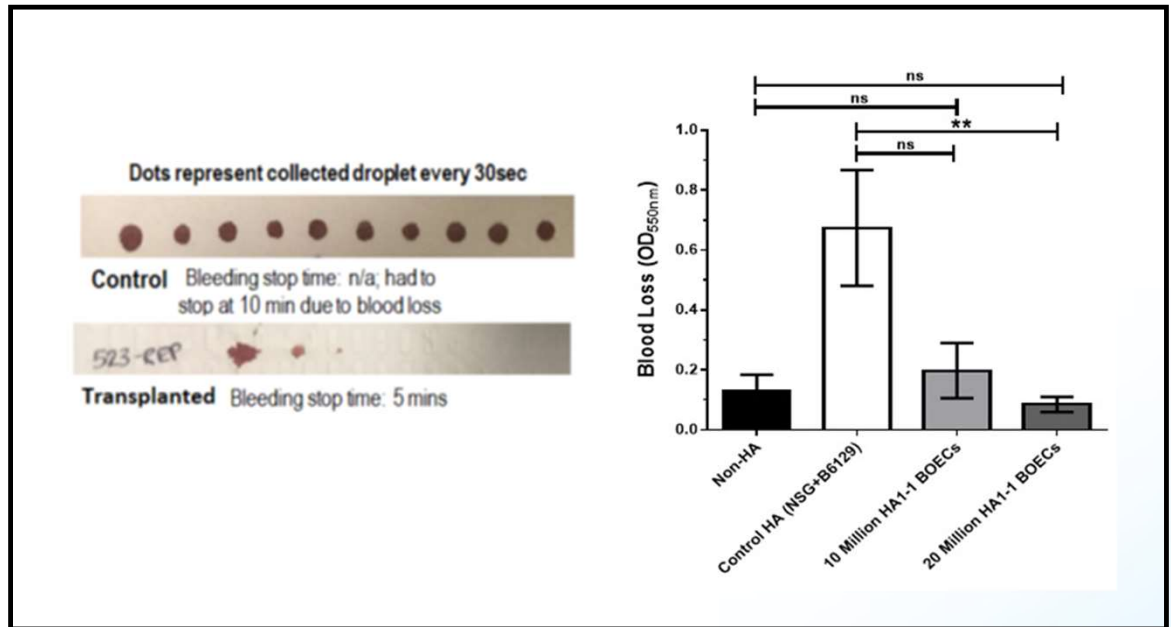
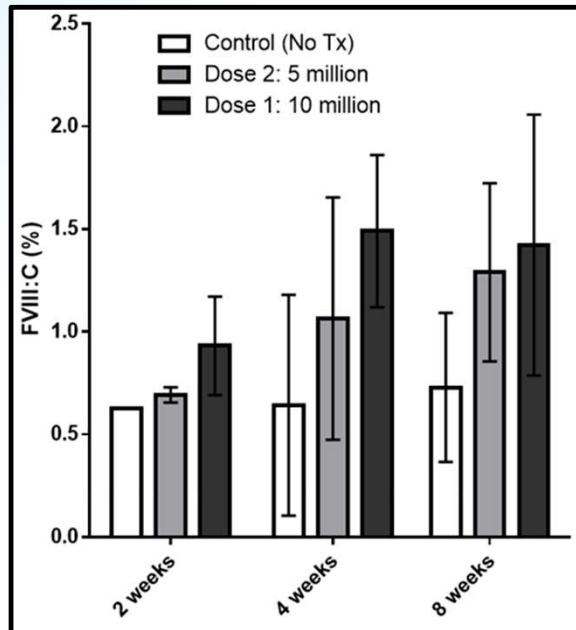


¹ US Centers for Disease Control & European Hemophilia Consortium

² National Bleeding Disorders Foundation (formerly National Hemophilia Foundation)

Hemophilia Program: In Vivo Efficacy of FVIII-BOECs Within Cell Pouch

FVIII-corrected BOECs transplanted into the Cell Pouch in NSG-Hemophilic mice



FVIII activity in the blood restored hemostasis in hemophilic mice



Corporate Information

Capital Structure | Select Information

EXCHANGE:

TSX: SVA

OTCQB: SEOVF

FSE / XETRA: PSH

FISCAL Y/E: 10/31

52-week Range	\$0.51 – \$1.21
Shares Outstanding	303.3M
Market Capitalization	\$210M
Average Daily Volume	271K
Cash & Equivalents (Q4/ 2023)	\$21.0M

Analyst Coverage



Note: market data via TSX Infobank as of 2/16/2024 market close. Trading figures reflect TSX performance only. All figures in \$CAD



TSX: SVA
OTCQB: SEOVF
FSE / XETRA: PSH

Head Office

700 Collip Circle, Ste 114
London, ON, Canada N6G 4X8
Tel: 1.877.299.4603
Tel: 1.519.858.5184
Fax: 1.519.858.5099
investor.relations@sernova.com

Investor Relations

Christopher Barnes
VP, Investor Relations
1.519.902.7923
christopher.barnes@sernova.com

Business Development

Modestus Obochi, Ph.D., MBA
Chief Business Officer
1.847.989.1674
modestus.obochi@sernova.com

