



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

January 2024

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T1D Cohort 1 Patient Testimonial Speaks Volumes

Insulin Independent for >3.5 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 ~44 months as of November 2023

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

Sernova is Pioneering 'Functional Cures' for Chronic Diseases

A Leader in Technologies + Cell Therapy Treatments

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

Cell Pouch System™

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

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





Highly DeRisked: Partnerships, Technology, Portfolio

Why Invest Now: Technology & Lead Asset DeRisked with Robust Clinical Data, Validated by Collaborations

- May 2022: proprietary partnership with **Evotec** provides unlimited supply of iPSC islet-like clusters
Strategic collaboration; Sernova-Evotec teams work together on daily basis
Evotec invested CAD \$27M in Sernova (5% ownership)
- May 2023: collaboration with **AstraZeneca** evaluating stem cell therapy applications in Cell Pouch
- Robust **Intellectual Property** protection with >110 patents
- Orphan Drug Designation & Rare Pediatric Design Designation for Hem A
Priority Review Voucher granted upon approved BLA submission: potential value >\$100M
- **Conformal Coating** technology: preclinical development ongoing
- **Cell therapy + Cell Pouch POC** established in patients with Type 1 Diabetes (T1D)
Ongoing Phase 1/2 trial with pancreatic donor islets in T1D patients
 - 5 of first 6 patients in 1st Cohort achieved **100% insulin independence**
 - **Longest insulin independence duration is > 3.5 years and ongoing**
- Additional programs for **hypothyroidism** and **hemophilia A**
- Actively pursuing additional collaborations, licensing and/or partnerships

Pipeline Today – Multiple Indications

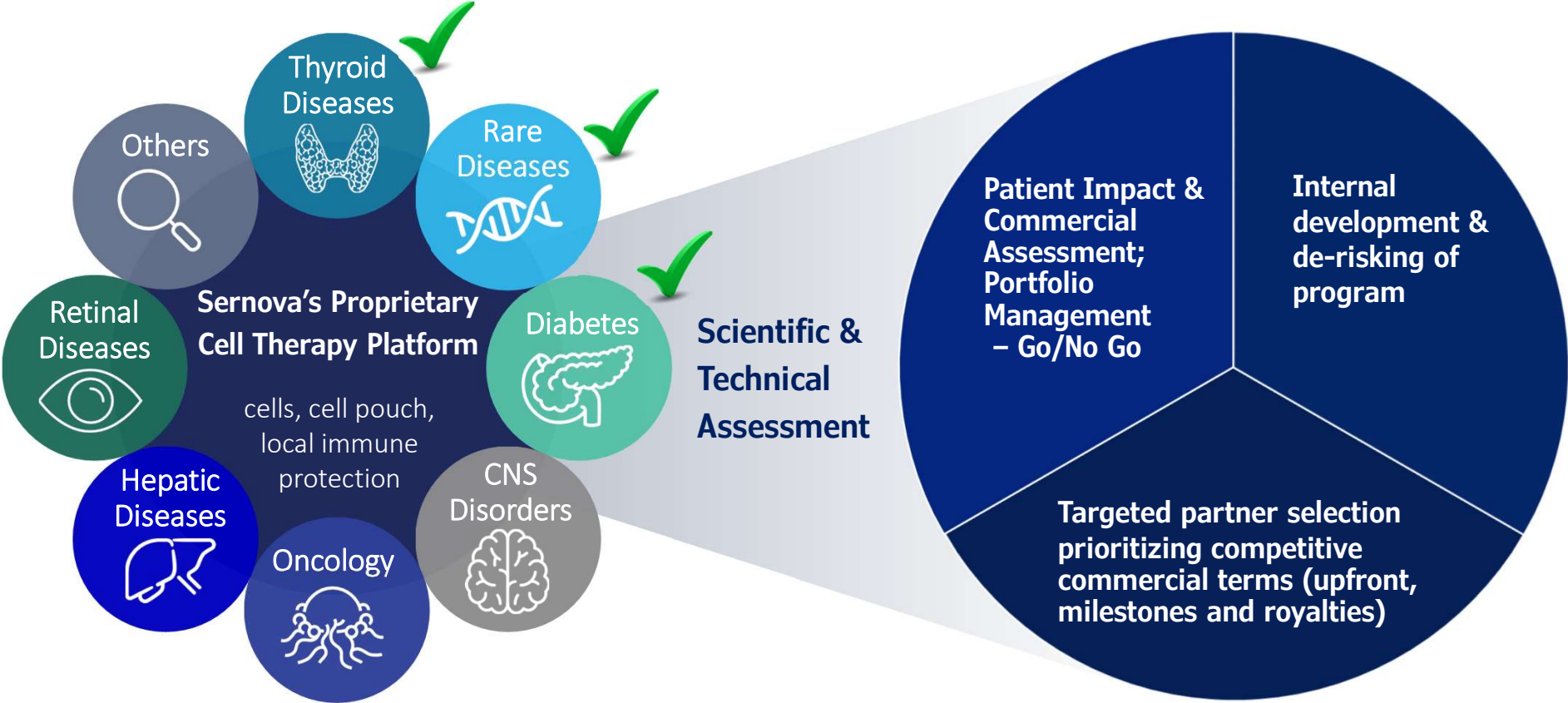
Creating Patient Impact & Shareholder Value

Indication	Therapeutic Cell Source	Immune Protection	Discovery	Pre-Clinical	Phase 1/2	Phase 3	BLA
Insulin-dependent Diabetes	Human donor islet cells	Immunosuppressives	●	●	●	○	○
	iPSC islets 	Immunosuppressives	●	●	○	○	○
	iPSC islets 	Local immune protection 	●	○	○	○	○
Hemophilia A – Severe	Corrected patient cells 	Autologous cells	●	●	○	○	○
Hemophilia A – all patients	Allograft immune protected stem cells	Local immune protection	●	○	○	○	○
Thyroid Diseases / Hypothyroidism	Thyroid cells	Autologous cells	●	●	○	○	○
	Allograft immune protected stem cells	Local immune protection	●	○	○	○	○



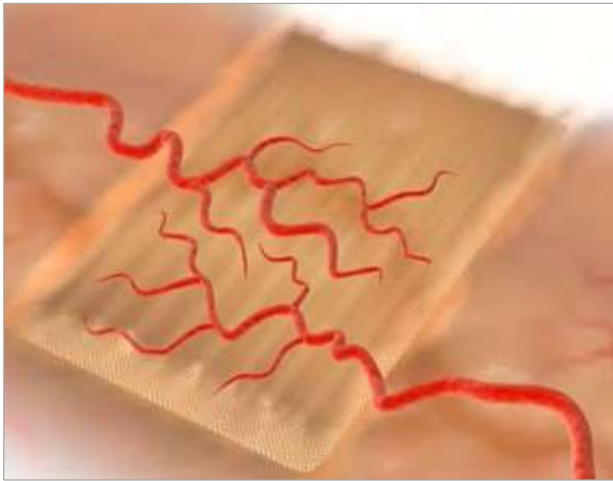
Our Portfolio Strategy is in Place

Multiple Opportunities to Expand Our Portfolio & to Extend Our Reach to More Patients

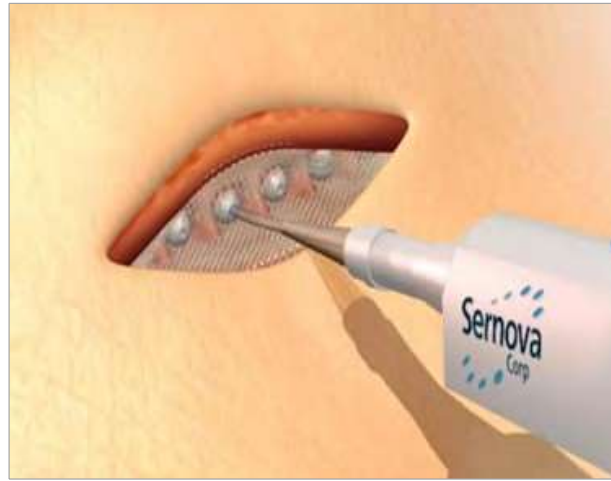


Cell Pouch System Provides Organ-Like Environment

Creates Vascularized Tissue Chambers to Allow Optimal Engraftment of Therapeutic Cells



- **Cell Pouch** is placed deep under the skin in a short ~15-minute 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

Conformal Coating Technology: Immune Protection

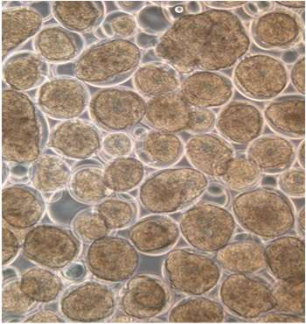
Sernova Holds Worldwide Exclusive License to Technology; Holds Potential to Eliminate Immunosuppressive Meds

University of Miami / Sernova Collaboration



 **Key Concepts**

- Proprietary biocompatible cross-linked polymer hydrogel forms a ‘Shrink wrap’ coating around therapeutic cells within Cell Pouch chambers
 - Offers immuno-protection to the islets
 - Provides for normal insulin and glucose kinetics
 - Enables transfer of oxygen and nutrients for islet survival
- GMP compliant manufacturing scale-up commenced; system design complete and includes all coating processes



 **Preclinical evidence of islet functionality and immune protection**

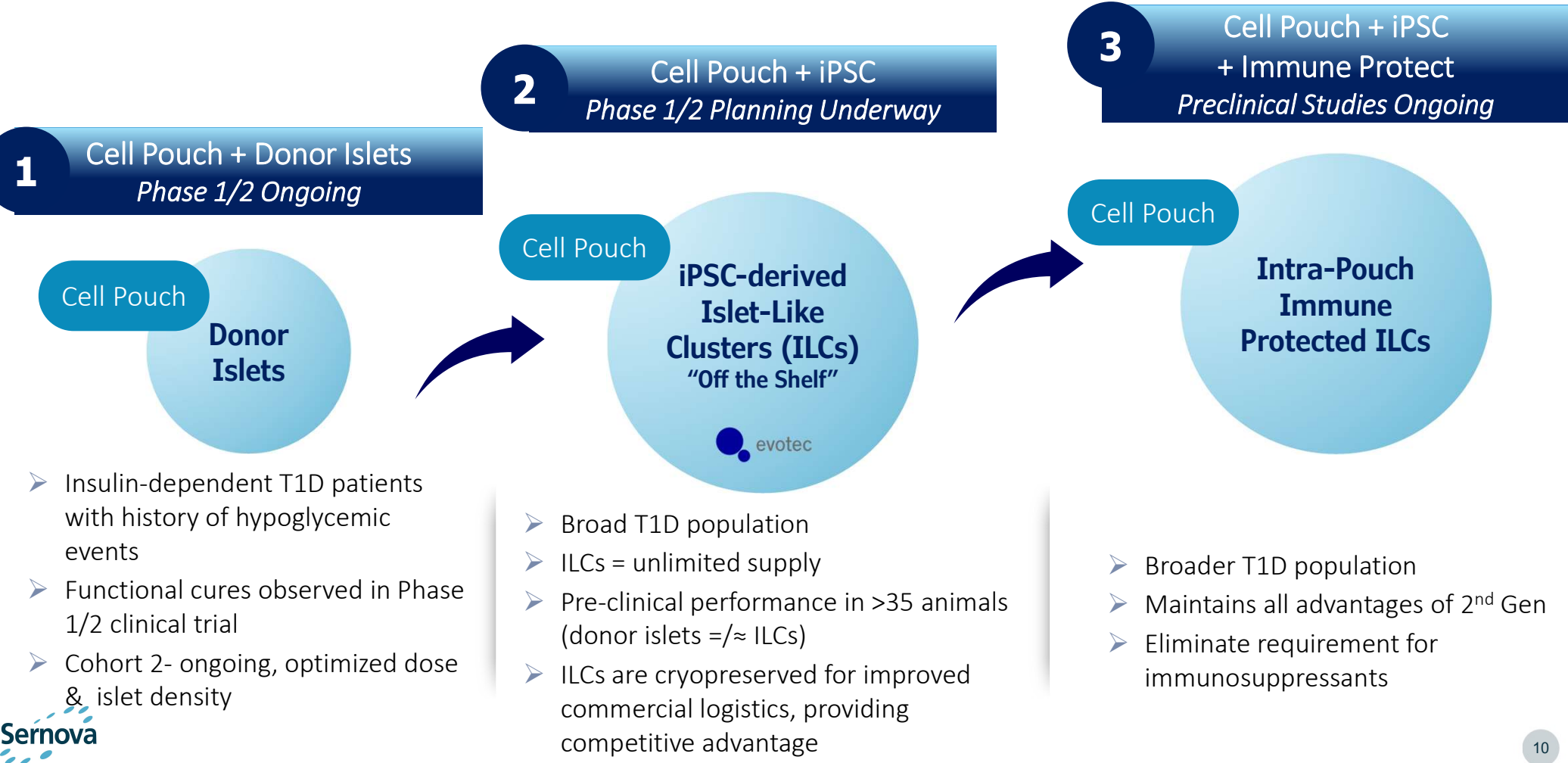
- Pre-clinical syngeneic studies showed that conformally coated islets in implanted Cell Pouch achieved normal blood glucose control (insulin independence) in T1D¹
 - Initial pre-clinical allogeneic studies showed that conformally coated islets within the implanted Cell Pouch achieved normal blood glucose control (insulin independence) supported by a selective immune response agent known to be clinically safe in humans
- **Benefit:** Cellular immune protection with conformal coating and a single agent taken intermittently is a significant advancement in the field of cellular immune protection relative to conventional lifelong daily immune suppression cocktails



¹ Source Dr. Alice Tomei at the IPITA Conference, October 2023

Product Innovation for Functional Cure in T1D

Evolution of program built to expand the treatable patient population





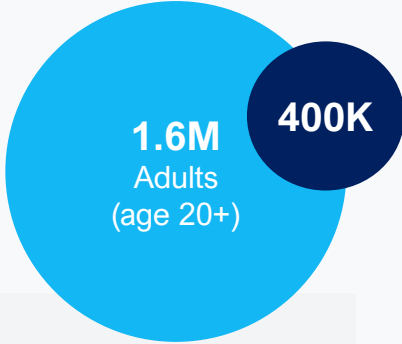
Type 1 Diabetes

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

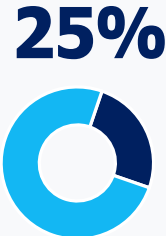
Large Addressable Market for a Functional Cure in T1D

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

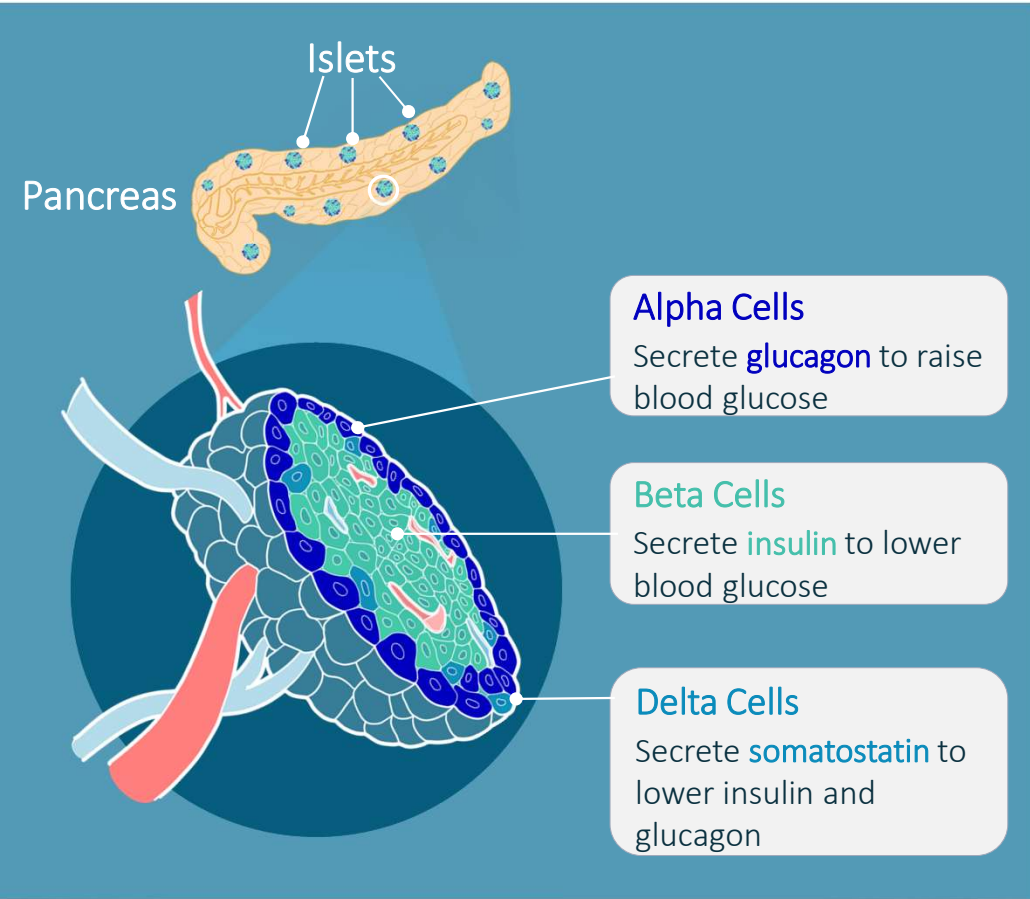


1%
share of the overall T1D
population would be
\$4.8 billion³



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

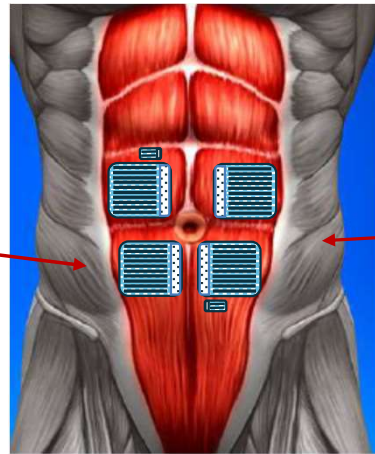
Placement of Cell Pouches has been carefully designed & controlled

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

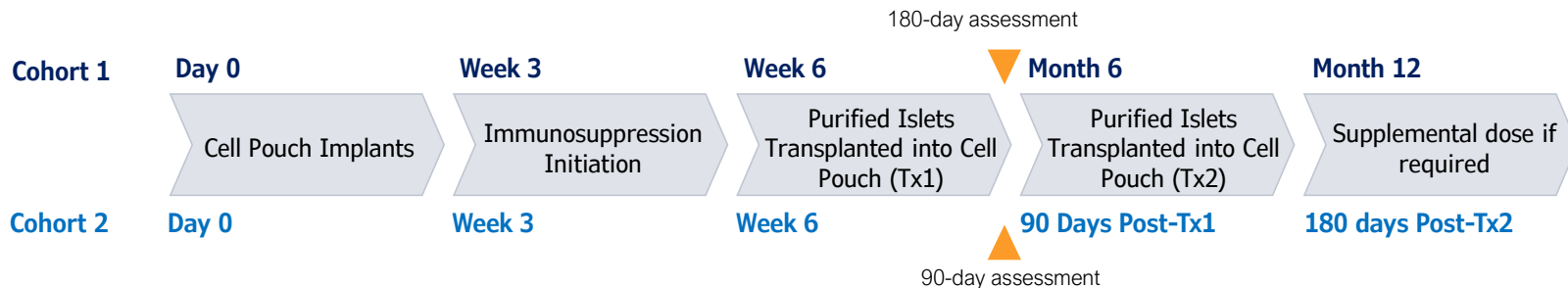
1st Cohort (n=6)

- 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)

- 6 of 7 enrolled
- 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



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

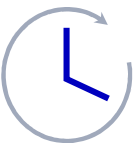


5 of 6 patients in first Cohort achieved complete insulin independence

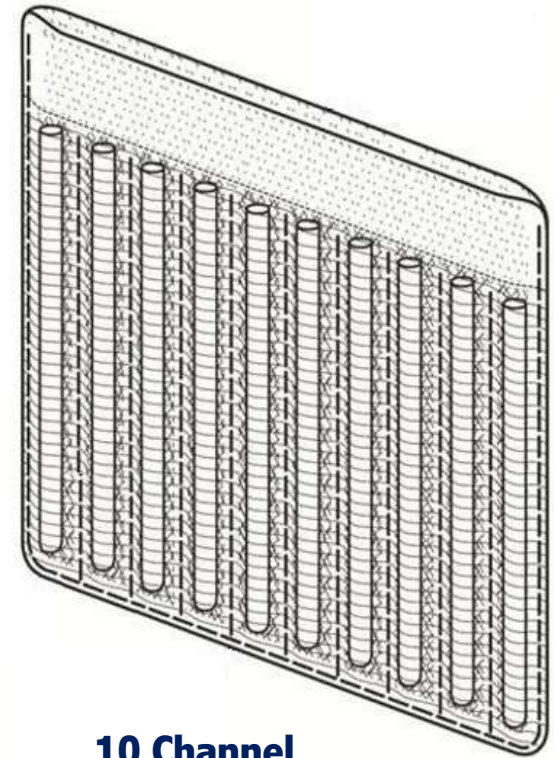
- Histological assessments demonstrate surviving, functional islets in Cell Pouches of all study patients that achieved insulin independence
- Following islet transplants to Cell Pouch, only a marginal islet dose transplanted via the portal vein was sufficient to **achieve and maintain insulin independence** for these patients - the longest continuing for **more than 3.5 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 doner islets)
- Additional interim clinical trial update anticipated Q1 2024



**10 Channel
Cell Pouch
Rendition**



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

Sernova | Evotec Partnership

Abundant Supply of iPSC-derived Insulin-Producing ILCs for T1D



Announced May 2022

- Sernova has option for exclusive global license for Evotec's ethically derived iPSC insulin producing ILCs for T1D and T2D
 - With any delivery approach including Sernova's Cell Pouch System
 - License transfers upon out-licensing of T1D asset
- Provides access to unlimited supply of insulin-producing islet cells
 - Removes a major obstacle to commercialization given supply constraints of human donor islets
- Evotec €20M / CAD \$27M equity investment in Sernova
 - Evotec owns equity ~5% of Sernova
- Evotec responsible for manufacture of iPSC-ILCs through commercialization
 - ILCs are cryopreserved at a late-intermediate stage of differentiation providing a commercially viable product



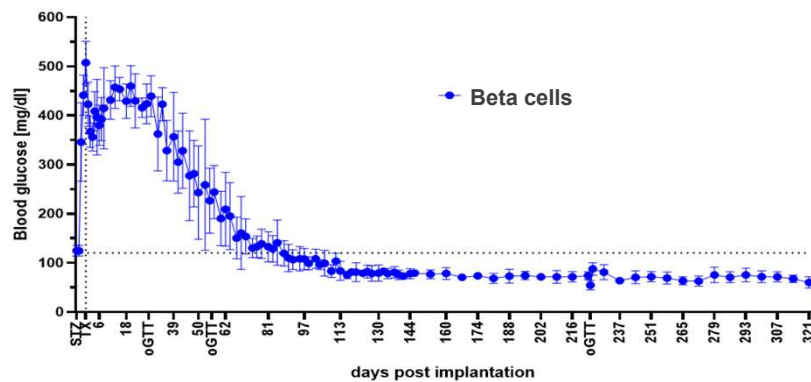
iPSC- Islet Like Clusters (ILCs): Long-Term Antidiabetic Efficacy

Robust, Durable Normalization of Glucose Control in Diabetic Mice

Preclinical

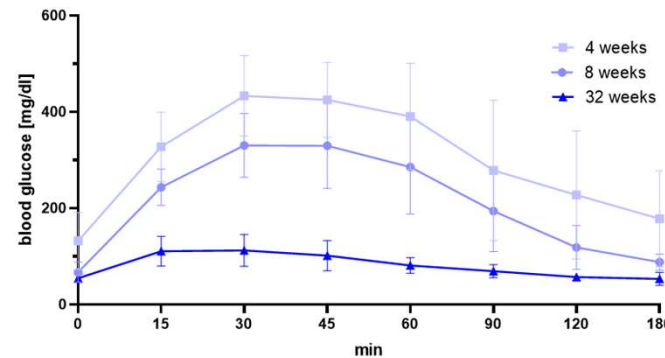
- ILCs demonstrated sustained normalization of blood sugar levels in diabetic mice throughout the 320-day study duration
- High insulin-producing beta cell content as well as glucagon and somatostatin (produced by alpha cells and delta cells, respectively), closely mimicking human islets
- Robust and 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

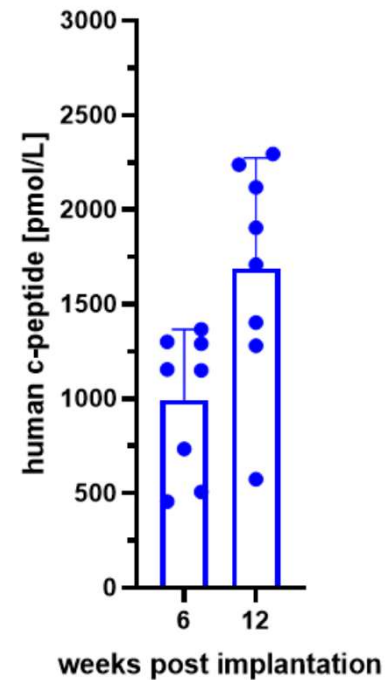


Oral Glucose Tolerance Test

Weeks 4, 8 and 32 post-ILC implantation



Circulating C-peptide

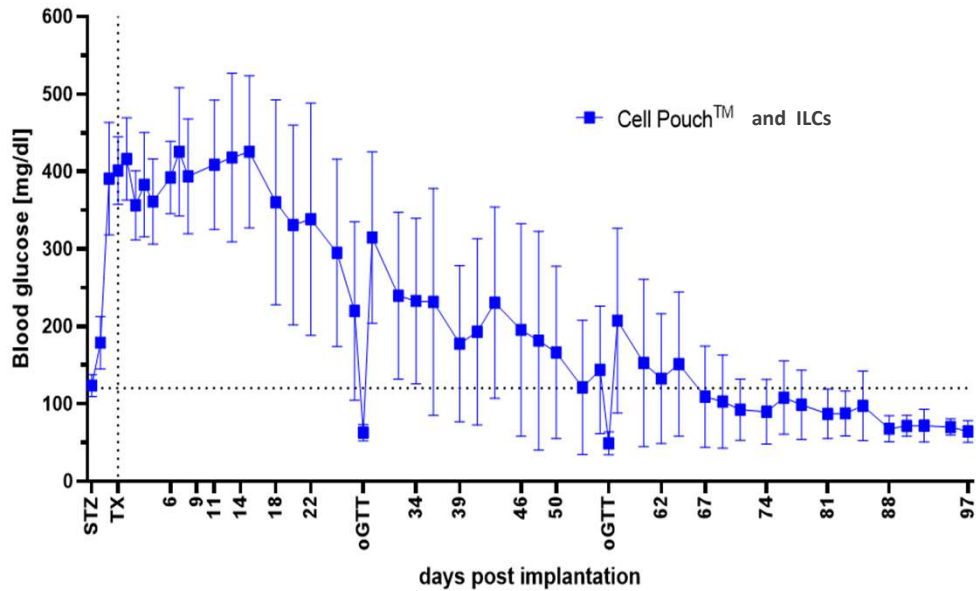


Strong Anti-diabetic Activity of ILCs in the Cell Pouch

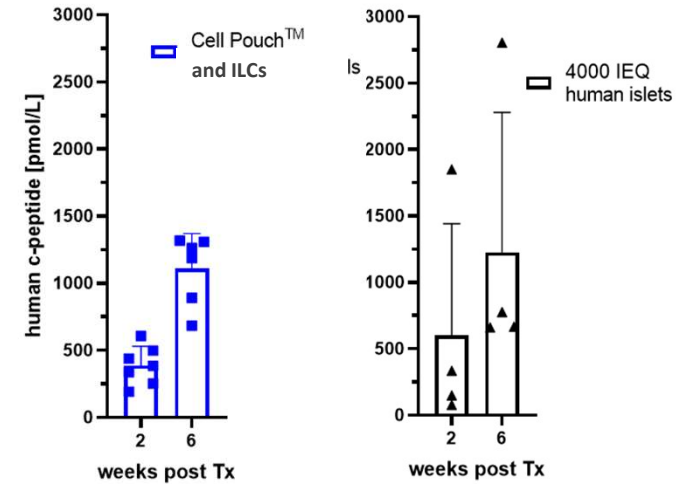
Rapid Normalization of Glucose Control with Human Islet-like Potency

Preclinical

Efficient normalization of random fed glucose

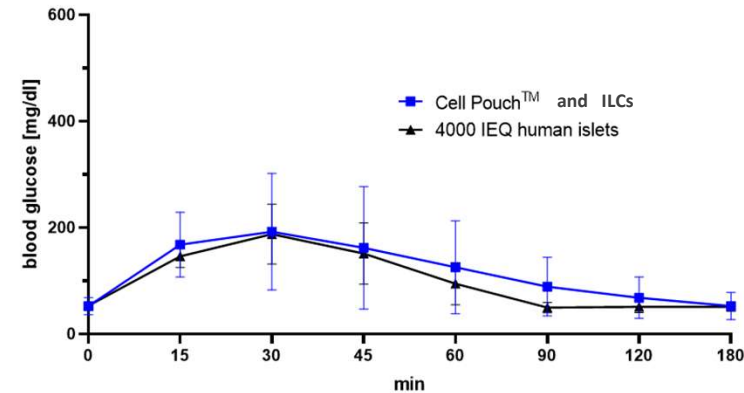


Robust circulating hC-peptide levels



Efficient glucose clearance, no hypoglycemias in oGTT

(8 week timepoint)





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

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



**Upcoming Catalysts &
Corporate Information**

2023 Selected Achievements & Plus View Into 2024

Increasing Patient Impact & Enhancing Value Creation

	Patient & Value Inflection Point	Date
✓	Sernova/Evotec iPSC development update (at IPITA conference)	2Q 2023
✓	T1D Phase 1/2 Cohort 1 results update (at ADA)	2Q 2023
✓	T1D Phase 1/2 Cohort 2 patient enrollment update	1H 2023
✓	Augmented Sernova LT	September 2023
✓	Conformal Coating update (press release)	September 2023
✓	Thyroid data update (poster presentation at ATA & press release)	September 2023
✓	T1D Phase 1/2 Cohort 2 clinical trial data updates (EASD & IPITA)	4Q 2023
✓	Conformal Coating technology program status update (IPITA)	October 2023
✓	Hemophilia Program update	4Q 2023

Select 2024 Milestones

	T1D Phase 1/2 Cohort 2 enrollment completion – Human Donor Islet Study	1Q 2024
	T1D Phase 1/2 IND Enabling Studies – (Evotec) iPSC ILCs	2024
	Cell Pouch + thyroid tissue: assessing pathway for accelerated development	2024
	T1D Phase 1/2 Cohorts 1 & 2 Multiple Data Updates – Human Donor Islet Study	Across 2024

Capital Structure | Select Information

EXCHANGE:

TSX: SVA

OTCQB: SEOVF

FSE / XETRA: PSH

FISCAL Y/E: 10/31

52-week Range	\$0.68 – \$1.28
Shares Outstanding	303.3M
Market Capitalization	\$221.4M
Average Daily Volume	266,356
Cash & Equivalents (Q3 7/31/23)	\$31.0M

Analyst Coverage



Note: market data via S&P CapitalIQ and public filings as of 12/4/2023 market close. Trading figures reflect TSX performance only. All figures in \$CAD

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