



*Advancing cell therapeutics
to provide 'functional cures'*

TSX: SVA
OTCQB:SEOVF
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Forward looking statements

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Capital Structure / Select Information

EXCHANGE:

TSX: SVA

OTCQB: SEOVF

FSE / XETRA: PSH

FISCAL Y/E: 10/31

52-week Range ¹	\$0.69 - 2.22
Shares Outstanding	303 million
Market Cap ¹	\$300 million
Average Daily Volume ²	0.23 million
Cash (1/31/23)	\$45.6 million
Debt	\$0

Analyst Coverage



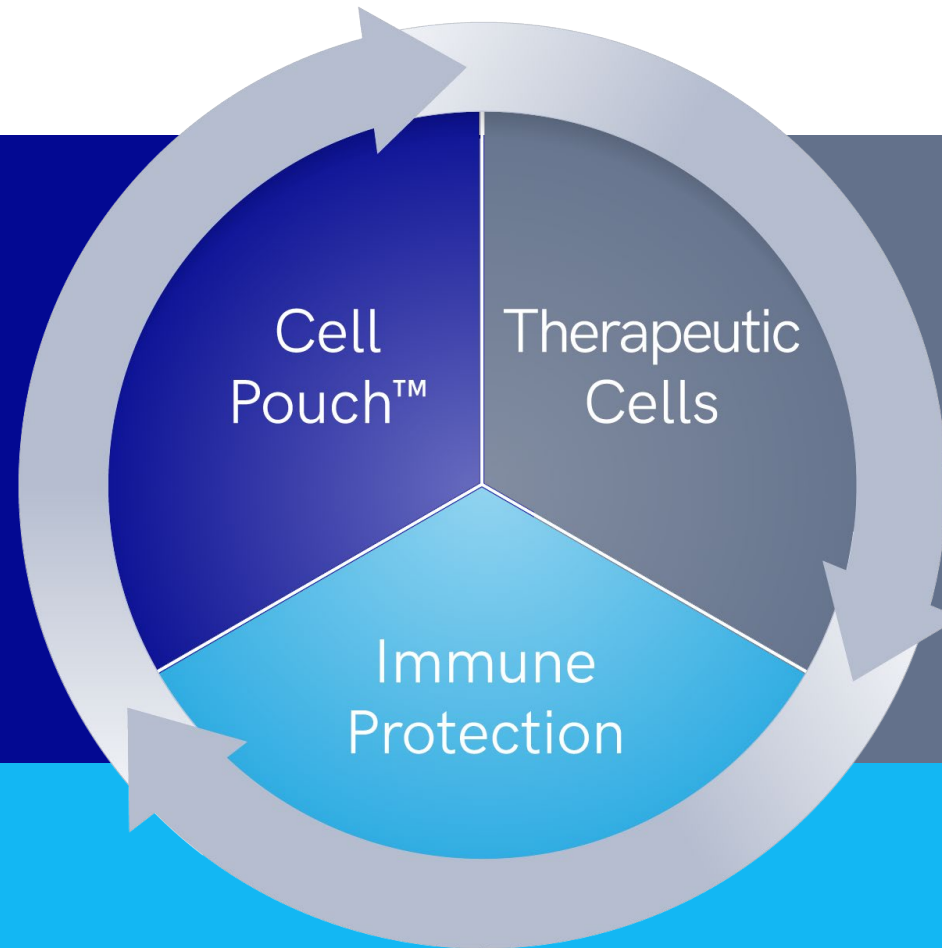
Sernova: Innovator and Leader

Cell Therapeutics: Paradigm Shift for Superior Treatment of High-Maintenance, Lifelong Conditions

- Sernova's integrated **Cell Pouch System™** provides the potential for a **'functional cure'** for chronic medical conditions with **multi-billion dollar market potential**
- **Cell Pouch** implantable device forms organ like environment for immune protected therapeutic cells to **naturally produce missing proteins or hormones**, overcoming barriers associated with cell survival and function – **no fibrosis**
- **Type 1 Diabetes (T1D) lead program**, additional programs for **hypothyroidism and hemophilia A**
- Current **US Phase 1/2 clinical study** interim data **demonstrating insulin independence in multiple long-term T1D patients with hypoglycemia**; longest patient > 3.0 years
- **Partnership with Evotec (NASDAQ: EVO)** will provide **ethically derived best in class, commercially viable iPSC islet clusters** with potential to treat all insulin dependent patients
- **Strong cash position** through key milestones

Sernova's Integrated Cell Therapeutics Solution

- Proprietary implantable medical device
- Provides vascularized environment for therapeutic cells to survive for long periods of time – creating an organ-like environment



- 1st generation utilizes human donor cells
- 2nd generation off-the-shelf stem cell derived cells
 - i.e. Evotec iPSC islet clusters for T1D

- 2nd generation utilize technologies to protect therapeutic cells from immune system attack – reducing or eliminating need for immunosuppressives

Pipeline – Life Cycle Iterations and Multiple Indications

Lead Program Has Demonstrated POC Efficacy & Excellent Safety in Type 1 Diabetes

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

DIABETES



GLOBAL DISEASE = GLOBAL MARKET



Diabetes is one of the most prevalent **diseases** and most pervasive **medical problems** impacting society and **quality of life** today.

537 million people are affected worldwide with diabetes; another estimated 179 million people have it without knowing it. **By 2045**, projections show this number rising to some **783 million diabetics globally***.

Sernova's Cell Pouch System for **type 1 diabetes** will enter a **commercial market of ~\$30 billion** and could have true blockbuster potential. It could potentially provide a future free from insulin injections for millions of patients.

Commissioned payor survey supports potential pricing in the \$200,000-\$400,000 range per patient.

Capturing just 1% of the 1.6m people in the United States with T1D on an annual basis = more than US\$6B in revenue.

**IDF Diabetes Atlas 10th Edition, 2021 & Grandview Research.*

Diabetes statistics:

\$966B

Health Expenses related to Diabetes

\$22.35B

Global human insulin market for 2019

\$1,045B

Projected Health Expenses related to Diabetes in 2045

10%

Prevalence of T1D

The Advantages Of Pancreatic Islets Over Insulin Injection

Insulin: A Single Component of Glucose Regulation

Insulin is only one way the body controls glucose. Using solely insulin to treat type 1 diabetes can only lower blood glucose, which can be dangerous and potentially life threatening.

Alpha Cells

Alpha cells secrete the hormone **glucagon** in response to **low blood glucose**.

The effect of glucagon is to raise blood glucose.

Beta Cells

Beta cells secrete the hormone **insulin** in response to **high blood glucose**.

The effect of insulin is to lower blood glucose.

Delta Cells

Delta cells secrete the hormone **somatostatin** in response to **high levels of insulin or glucagon**.

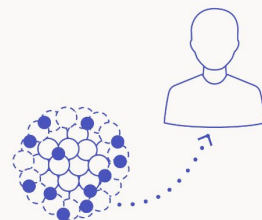
The effect of somatostatin is to keep blood glucose from dropping too low or elevating too high by inhibiting the secretion of both hormones if they reach too high a level.

Pancreatic Islets: The Complete Approach

Pancreatic islets are the primary mechanism behind the **global regulation** of blood glucose. Islets are organized groups of cells that have the full complement of glucose-regulating functions and hormones in normal pancreatic tissue. The contents of islets maintain glucose within a healthy range, not too high and not too low, and can regulate blood glucose constantly. Tight control of blood glucose, with a normal HbA1c, can decrease the risk of side effects from diabetes and improve quality of life.

Sernova's Cell Pouch System™

Evotec is manufacturing pancreatic islet-like clusters (ILCs) that mimic the function of human islets. Sernova's Cell Pouch, in combination with Evotec's ILCs, operates similarly to native pancreatic tissue that globally controls blood glucose, resulting in a commercial-scale potential 'functional cure' for insulin-dependent diabetes.



Pancreas

Phase 1/2 T1D Study Design – First Cohort

Patients with Type 1 Diabetes and Hypoglycemia Unawareness

Trial Overview



Study Design

- Open label, single-arm, single-center trial (n=7)
- Insulin-dependent T1D patients **with hypoglycemia unawareness**
- Cell Pouch implant followed by two sequential human donor islet transplants to Cell Pouch
- Supplemental marginal dose intraportal vein islet cell top-up
- Standard of care for immunosuppression
- PI: Dr. Piotr Witkowski - Director, Pancreatic and Islet Transplant Program; University of Chicago



Key Inclusion Criteria

- T1D patients with a history of **severe hypoglycemic events**
- No glucose-stimulated systemic C-peptide



Key Objectives and Endpoints

Key Objectives

- Demonstrate the safety & tolerability of islet transplantation into the Cell Pouch
- Establish islet cell quality and dosing (IEQ/kg) criteria that are predictive of clinical transplant outcomes into the Cell Pouch

Primary endpoint

- Safety and tolerability

Secondary endpoints

- Survival of endocrine tissue in Cell Pouch
- Proportion of subjects with a reduction in severe hypoglycemic events
- Proportion of subjects with HbA1c reduction >1%
- 20 additional endpoints

Phase 1/2 T1D Study Interim Results – First Cohort

ADA Presentation June 2022



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



- **All patients who had favorable immunosuppression achieved complete insulin independence**
 - **First three transplanted patients** presented positive serum C-peptide values confirming active insulin production after islet transplantation into the Sernova Cell Pouch
 - Supplemental marginal dose islet transplantation via the portal vein was sufficient to allow those three patients to **achieve and maintain insulin independence** for **over 3 years, 18 months and 12 months** respectively
 - Insulin-independent patients have **HbA1c in the normal range: 5.0, 5.2, and 5.2%** respectively
 - Three additional patients on study did not maintain optimal immunosuppression, which has now been resolved enabling those patients to receive further protocol-defined islet transplants



New Second Cohort: enrolled patients will test efficacy with higher capacity 10 channel Sernova Cell Pouch

Phase 1/2 Study – Cohort 1 Informed / Guided to Cohort 2

Advancing With A Higher Capacity Cell Pouch Product

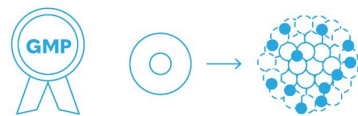
- Cohort 1 (6 patients)
 - Patients demonstrated a **clear safety profile** for **Cell Pouch System**
 - Established threshold for islet dose and density optimization
 - Cohort 1 update coming at American Diabetes Association Meeting (podium presentation)
- Cohort 2 (up to 7 patients) – Provides optimized dosing regimen and shorter dosing timelines
 - Implementation of **10 channel Cell Pouch** with **>50% more islet capacity**
 - released to trial site for implantation commencing **November 2022**
 - first 4 patients enrolled **including Cell Pouch implantation**
 - **first 2 patients transplanted with the first dose of islets** – next transplants pending
 - intra-implantation cell dosing interval **reduced from 6 to 3 months**
 - engaged new patient recruitment agency for rapid enrollment of remaining study patients
 - Initial interim data with 10 channel Cell Pouch and islet transplants anticipated **H2 2023**
- Results from this study will inform the Phase 3 program and **support anticipated Biologic License Agreement (BLA) submission to FDA**

- Secured **exclusive option on exclusive global license** for Evotec's ethically derived iPSC insulin producing islet clusters for use with Sernova's Cell Pouch System or alone with other technologies
- 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 strategic equity investment** in Sernova and co-developing / co-funding preclinical development program(s) until IND
- Evotec will manufacture cells through commercialization
- **Anticipated Phase 1/2 Clinical Trial - 2024**
 - Sernova has right to exercise exclusive option for exclusive global license at any time up to 45 days after IND filing
 - Sernova will owe small milestone payments upon license option exercise and on first patient dosed
- Evotec has option for co-funding of clinical development
 - Standard royalty participation upon commercialization based on level of funding commitment

Sernova and Evotec's Cell Therapy Commercial Approach for the Treatment of Type 1 Diabetes

The Evotec iPSC-Based Manufacturing Process

The Evotec induced pluripotent stem cell (iPSC)-based manufacturing process allows for the commercial-scale production of best-in-class pancreatic islet-like cell clusters (ILCs). These ILCs can be cryopreserved, and as a result, can be shipped around the world, differentiating them from others in the industry. In combination with Sernova's Cell Pouch System™, these technologies offer a potential 'functional cure' for patients suffering from insulin-dependent diabetes.



1 Using Good Manufacturing Practices, the iPSCs are differentiated (developed) into the target pancreatic islet-like clusters.



3 Storage or shipment of islet clusters (frozen).



2 Controlled freezing (cryopreservation), essential for making cells commercially viable on a large scale. Extensive quality control.



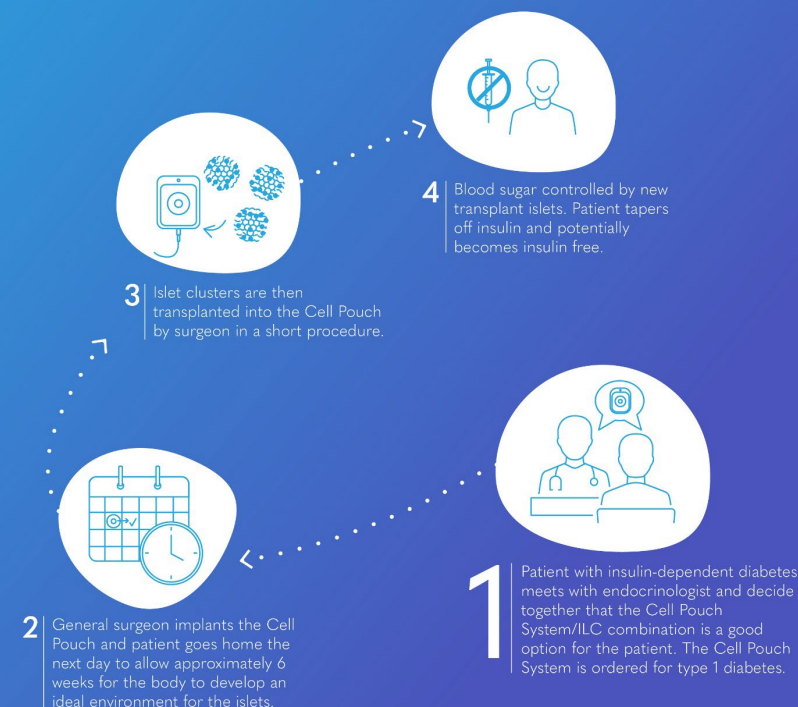
4 Thawing of cells to patient-ready form. Additional assurance that cells meet the rigorous standards set forth for cells to be transplanted into patient.



5 Temperature-controlled shipping for patient transplant.

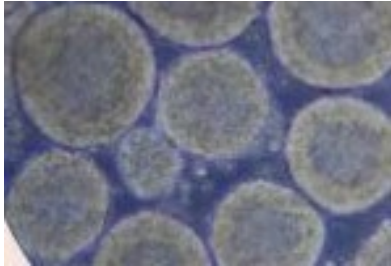
The Patient Experience

Patients with insulin-dependent diabetes face an extreme burden of constant blood glucose checks, multiple daily insulin injections, and the risk of a potentially life-threatening complication of the inability to recognize the symptoms of low blood sugar. Sernova has developed the Cell Pouch System as a cutting-edge solution that allows for natural vascularization and free exchange of nutrients, oxygen, and hormones. In combination with Evotec's pancreatic islet-like clusters, operating similarly to native pancreatic tissue that controls blood glucose, the result is a commercial-scale potential 'functional cure' for insulin-dependent diabetes.



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

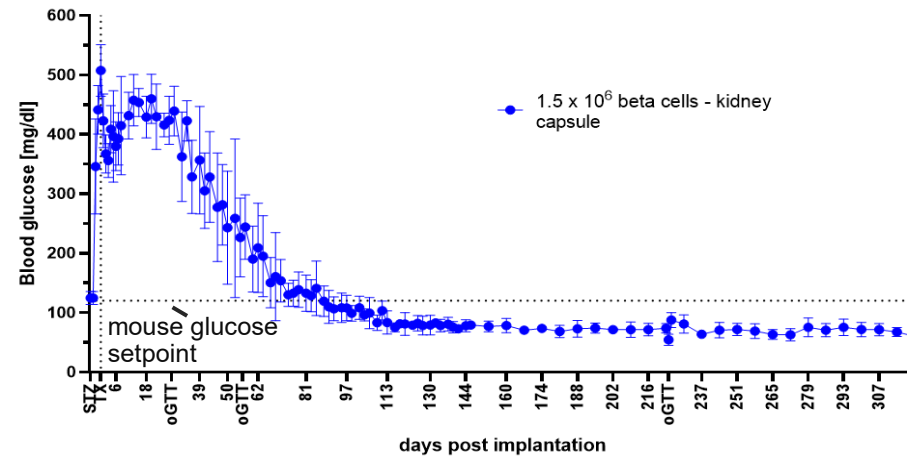
Robust, durable normalization of glycemic control in diabetic mice



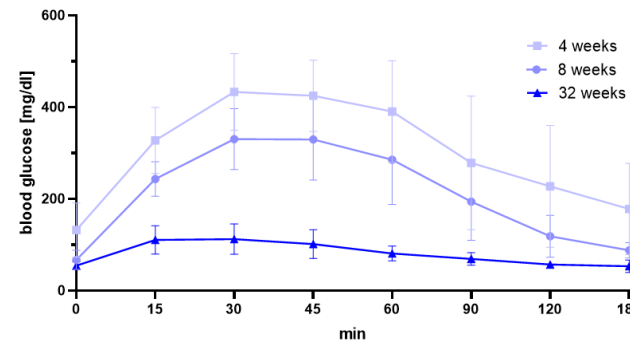
Evotec GMP manufacturing site near Modena/Italy

- We have developed a scalable, GMP-compatible process for ILC manufacturing from a GMP iPSC line
- Drug product with completed endocrine differentiation and optimized beta cell fraction
- We target an immature (KCl responsive) beta cell state for a short manufacturing process and high product resilience
- Manufacturing involves a cryopreservation step, and is currently implemented at Evotec's GMP manufacturing site

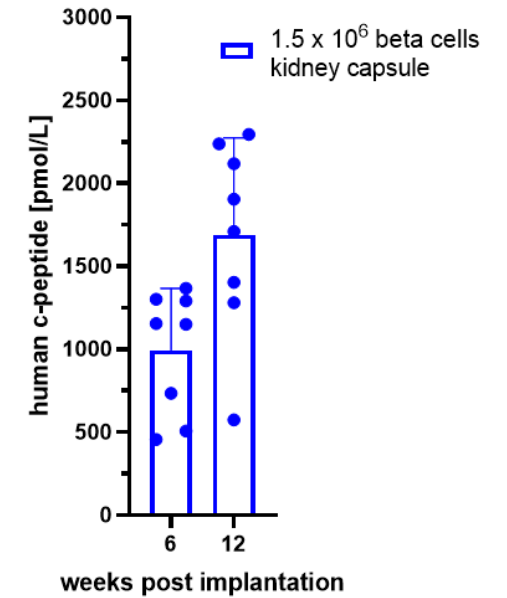
Efficient normalization of random fed glucose by kidney capsule-implanted ILCs



oGTT at weeks 4, 8 and 32 post ILC implantation



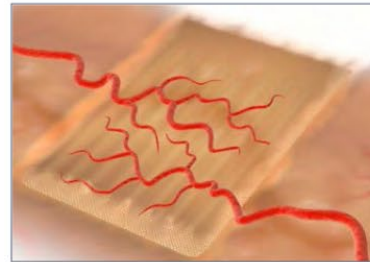
Circulating hC-peptide



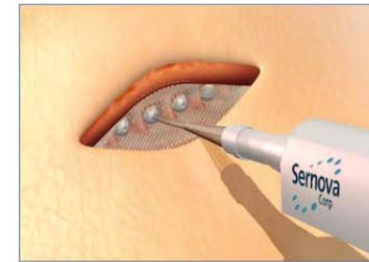
- The Sernova Cell Pouch™ is a pre-implanted, vascularized device providing an optimal environment for therapeutic cell function¹
 - Accessible/retrievable implantation site
- Sernova has promising clinical data with isolated human islets in the Cell Pouch™
- Evotec and Sernova collaborate to develop a combination of ILCs in the Cell Pouch™ for diabetes cell therapy
- Initial patient population will be immunosuppressed patients with T1D

Cell Pouch Containing Therapeutic Cells

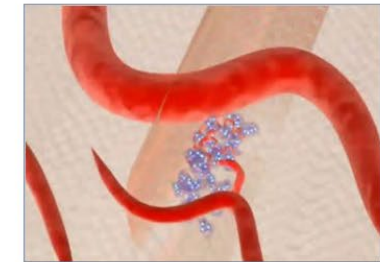
Biologically compatible delivery process – allows natural vascularization



Proprietary Cell Pouch is placed deep under the skin, allowing for vascularization & creating a natural environment for long-term function of therapeutic cells



Therapeutic cells are transplanted directly into the vascularized tissue chambers of the proprietary Cell Pouch

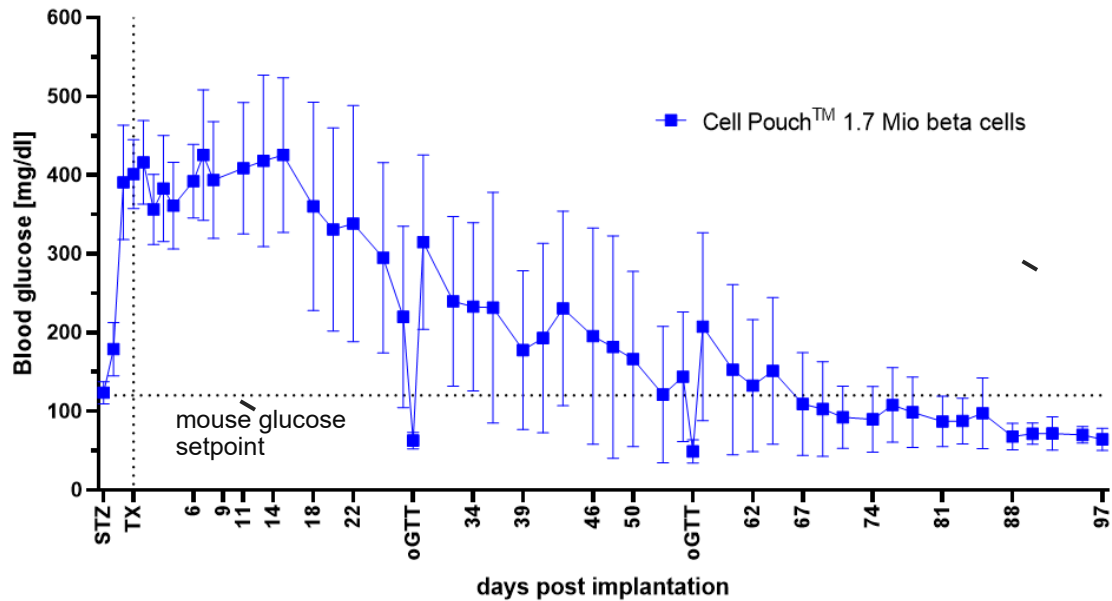


Therapeutic cells are responsive to endogenous regulation and release missing proteins or hormones into the bloodstream to correct biological dysfunction

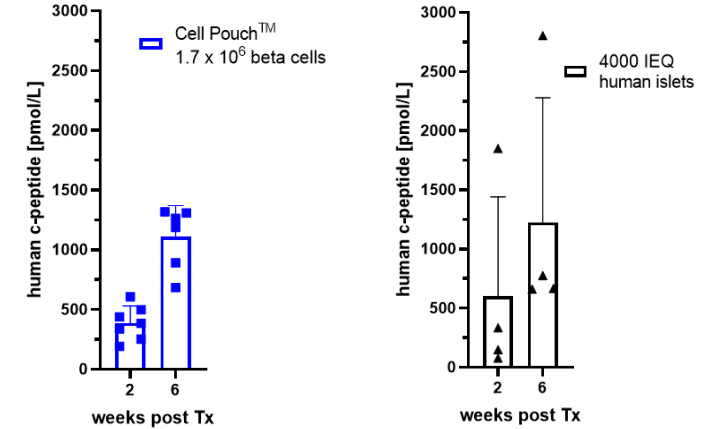
Excellent Anti-Diabetic Activity of ILCs in the Cell Pouch™

Rapid normalization of glycemic control with human islet-like potency

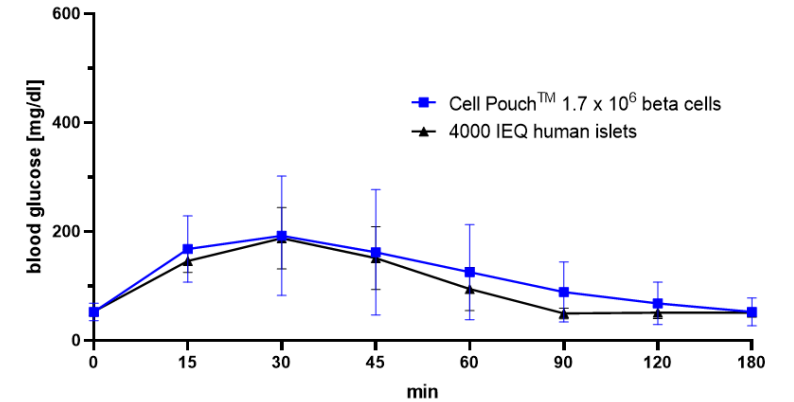
Efficient normalization of random fed glucose



Robust circulating hC-peptide levels



Efficient glucose clearance and no hypoglycemias in oGTT (8 week timepoint)



Excellent Anti-Diabetic Activity of an ILC/Cell Pouch™ Combination

Summary

- We have set up a scalable GMP manufacturing workflow from GMP iPS cells to ILCs, yielding a high beta cell fraction drug product
 - ILCs are cryopreserved at a late intermediate stage
 - Endocrine differentiation is complete – no post-implantation variability of cell composition
 - Immature beta cells to ensure a cost-effective manufacturing process, improved cell shipping and post-implantation survival
 - ILCs deliver rapid onset of physiological function, and human islet-like potency on a per-beta-cell basis after maturation is complete
- The Evotec ILC/Sernova Cell Pouch™ combination delivers excellent graft integration, vascularization and potent anti-diabetic function
 - Cell implantation in the Cell Pouch™ also ensures retrievability
- The project is at GMP manufacturing stage and on track for clinical testing in humans in 2024

Conformal Coating Technology – for Immune Protection

- Thin biocompatible cross-linked polymer hydrogel coating that surrounds therapeutic cells

Conformal Coating –
University of Miami /
Sernova Collaboration



- Selectively permeable
 - Immuno-protective
 - Allows for physiological transfer of insulin and glucose

- ‘Shrink wrap’ properties allows volume of transplanted cells into the Cell Pouch to be unaffected

- Sernova holds worldwide exclusive license to technology

Potential to eliminate the need for chronic immunosuppression

Cell Pouch System for Hypothyroidism & Hemophilia A

Therapeutic Benefits & Estimated Market

Hypothyroidism

Hemophilia A



Estimated Market Size

- **150,000** thyroidectomies performed annually in the US alone
- **\$2.2B** market opportunity
- Potential near-term revenue with patient own tissue
- Stem cell-derived technology for treatment of broad population


- **20,000** patients across North America and EU
- **\$10B** orphan indication



Benefits of Sernova Cell Pouch Technology

- Reduce / eliminate daily life-long thyroid medications
- Recover natural feedback loop of thyroid hormones
- Reduce side effects from low thyroid hormone levels
- Improve long-term efficacy
- Improve **Quality of Life**

- Reduce or eliminate factor VIII infusions
- Maintain constant blood levels of factor VIII
- Reduce joint bleeds
- Improve long-term efficacy
- Improve **Quality of Life**



Clinical Approach

- Positive preclinical proof-of-concept
- Clinical study regulatory submission in process
- **Anticipated Phase 1/2 trial initiation**

- **First generation**
AUTOGRAFT: Patient's own blood outgrowth endothelial cells (BOEC) are isolated, expanded and after gene correction by lentiviral transduction, transplanted back in the patient into the Cell Pouch
- **Next generation**
ALLOGRAFT: Off-the-shelf gene editing stem cell technology for hemophilia A patients

Upcoming Catalysts

Anticipated Milestones and Data

2023

- Immune protection update
- US Phase 1/2 T1D second cohort patient enrollment update
- US Phase 1/2 T1D first cohort clinical update
- US Phase 1/2 T1D second cohort clinical update
- FDA interactions regarding potential US Phase 3 design for donor islets / Cell Pouch

H1 2023

H1 2023

Q2 2023

Q4 2023

Q4 2023

2024

- IND filing with Cell Pouch and Evotec islet clusters
- Phase 1/2 initiation of Cell Pouch with Evotec islet clusters

2024

2024

Note – dates above are based on calendar year



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