

The Path To A Regenerative Medicine Cure

Corporate Presentation January 2021





SEOVF TRADED ON OTEQB

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Regenerative Medicine - The Future Now

<u>Regenerative Medicine</u> (RM) is a rapidly evolving field of science developing new therapeutic solutions to treat disease:

- > with the repair or growth of new tissues & organs, i.e. organ regeneration
- > repairing cells at the gene level to prevent disease, i.e. gene therapy
- > with therapeutic cells (islets / stem cells) producing proteins or other factors, i.e. cell therapy

Why is RM important? Paradigm shift in chronic disease treatment & outcomes

> RM provides the potential of a **functional cure** vs. mask disease & long-term treatment of symptoms with prescription medicines

Sernova Well positioned for RM cell therapy success

- > intentional stepwise strategic development approach has led to success & leadership
- > RM companies assuming cell therapy technical barriers can be overcome with 'home run' approaches have experienced failures in the clinic to date



Sernova: Innovator & Leader

Publicly traded, clinical-stage RM therapeutics solution innovator & leader:

- Cell therapy therapeutics solution platform treating chronic diseases & enhancing daily QOL
- Integrated RM therapeutic solution (Cell Pouch™ + therapeutic cells or tissue + immune-protection)
- > Broad platform application potential: multiple large market indications
- > Cell Pouch overcomes current barriers associated with therapeutic cells survival & function by forming organ-like environment for the cells to produce missing proteins, hormones, etc.
- > Diabetes lead program & 1st company with RM therapeutic product showing insulin production & early clinical efficacy indicators for type 1 diabetes (T1D). Active US Phase I/II clinical trial.
- Pre-Clinical proof-of-concept demonstrated for hemophilia A & thyroid disease

















Sernova's Platform Approach

Cell Pouch™

Integrated RM Therapeutic Solution for Treatment of Chronic Diseases



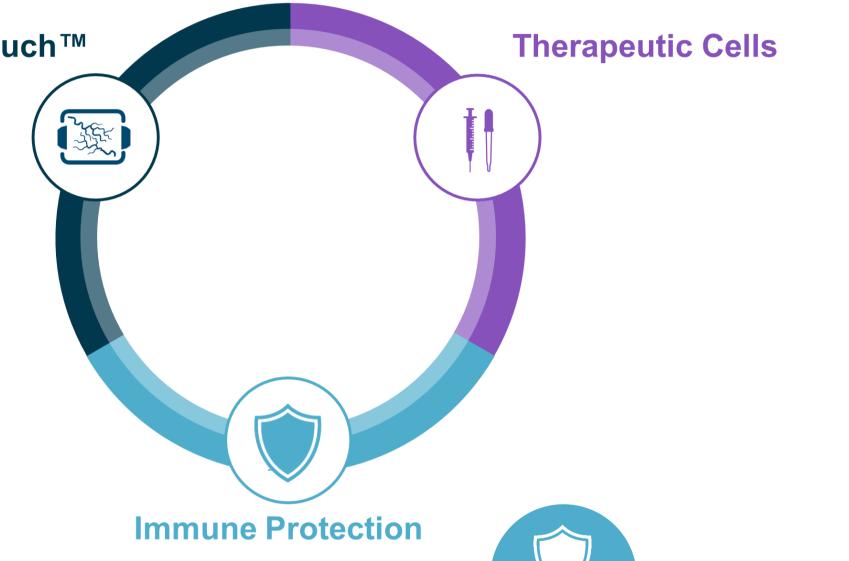
Cell Pouch

Implantable proprietary medical device that provides vascularized environment for therapeutic cells

Therapeutic Cells

Human cells (donor / stem) & tissues that produce & release missing proteins or hormones into the bloodstream





Immune Protection

Technologies to protect therapeutic cells from immune system attack

Cell Pouch[™] Manufacturing

Manufacture of the Cell Pouch[™] in multiple sized is conducted GMP by a US contract manufacturer in a Class VII Clean Room

Product and process development is conducted in accordance with manufacturer's Quality System

- ISO 13485
- EU Medical Devices Regulation MDR 2017/745
- US FDA Quality System Regulations (QSR) 21 CFR 820
- Canadian Medical Device Regulation (CMDR)

Two-year real-time Cell Pouch[™] product stability and package integrity



Manufactured GMP in a clean





Package Integrity testing completed

Cell Pouch™ Packaged Ready for Clinical Trials





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Worldwide IP / Patent Portfolio

International patents & patent applications portfolio in multiple patent families with broad application & continued expansion:

- Composition & use of medical devices for delivery & cell transplantation
- Glucose responsive insulin secreting stem cell technologies
- Local immune protection technologies

Broad geographic coverage:

- > North America
- South America
- **Europe**
- > Asia



Diabetes... Hope for a Functional Cure

The Reality: Diabetes is one of the most prevalent diseases & pervasive medical problems impacting society & everyday quality of life (QOL) today

- ➤ 463 million affected worldwide and nearly 10% of these individuals have T1D(1) T1D represents a potential commercial opportunity of \$30B+ for Sernova
- The Hope: A functional cure for everyone suffering from diabetes

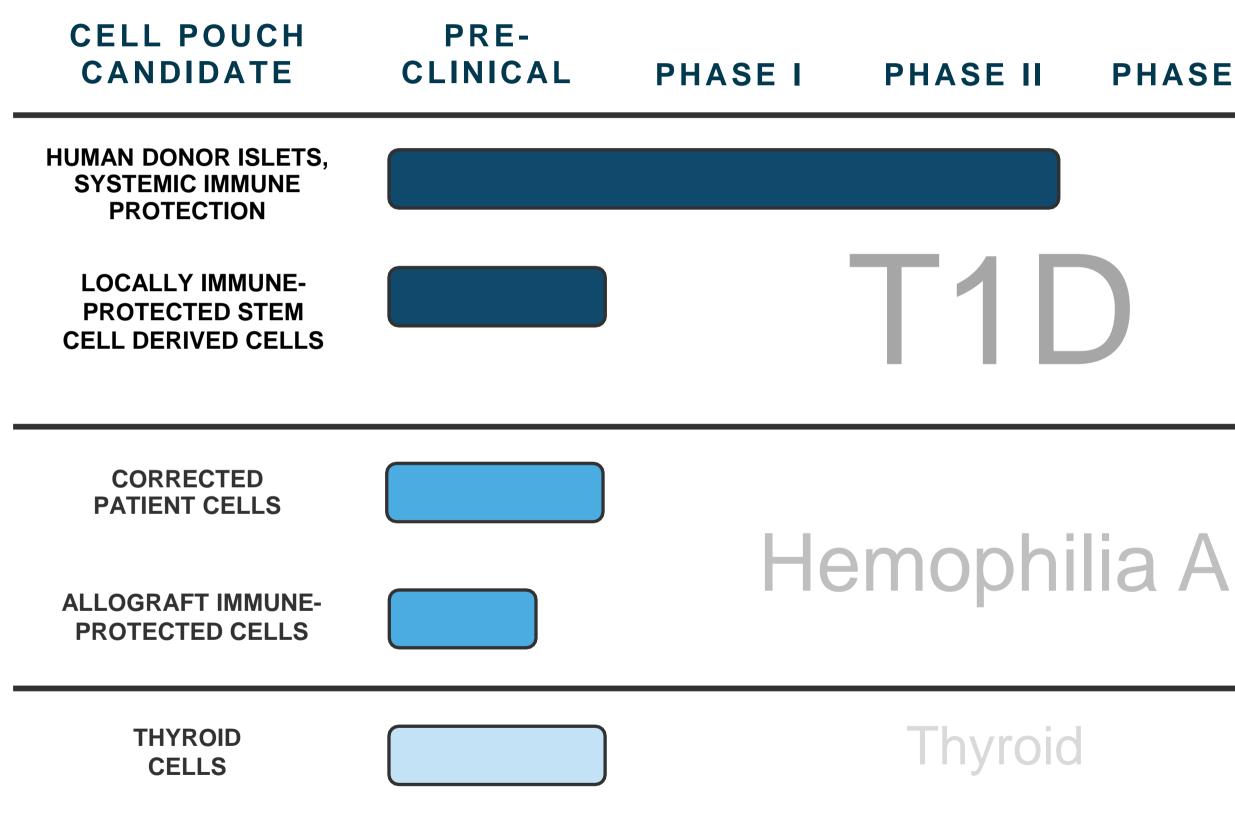
The Problem: Lack of integrated RM therapeutic solution

The Future: Blockbuster potential for Sernova's platform which could establish a new standard of care for diabetes treatment & management. Potential to be the biggest therapeutic advancement in diabetes treatment since insulin discovery 100 years ago.

(1) source: International Diabetes Federation



Sernova Pipeline





HASE III	STAGE	INDICATION		
	PHASE I/II INITIATED DEC 2018	HYPOGLYCEMIA UNAWARENESS		
	ANTICIPATED 2ND APPROVAL FOR DIABETES	ALL INSULIN DEPENDENT DIABETIC PATIENTS		
Δ	PRE-CLINICAL	SEVERE HEMOPHILIA A PATIENTS		

EARLY DEVELOPMENT

DEVELODMENT

BROADER HEMOPHILIA A PATIENTS

THYROIDECTOMY PRE-CLINICAL PATIENTS FOLLOWING HYPERTHYROIDISM

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Diabetes Market Opportunities

IP Status

2020 Potential Patient Population

(before market access considerations)

	Device / Method Patent	T1D Severe HU with Human Donor Islets	T1D Severe HU with iPSC	All T1D with iPSC	T1D Severe HU with Human Donor Islets	T1D Severe HU with iPSC	All T1D with iPSC
U.S.	Granted	~0.65 K Total Transplants	~240 K Patients	~1.6 M Patients	\$65 – 130 M (per year)	\$5 – 9.5 B (in total)	1 ?
EU5	Granted	~0.5 K	~195 K	~1.3 M	\$40 – 75 M	\$3 – 6 B	1?
APAC CHN & JPN only	Granted	~3.0 K	~1.0 M	~7.3 M	~\$225 M	~\$15 B	1 ?
Total	Sernova has a global IP portfolio across all key markets	~4.2 K Transplants	~1.4 M Patients	~10.2 M Patients	\$340 – 450 M (per year)	\$24 – 31 B (in total)	1 ?

HU = Hypoglycemia Unawareness

Hypolgly. = Hypoglycemia





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Potential Commercial Opportunity

RM Diabetes Competitive Landscape

Clinical Efficacy Data: Therapeutic C-peptide Levels Measured in Bloodstream

Device Vascularization Islet Engraftment Demonstrated in Humans





Phase I/II initiated late 2018 in T1D patients with HU^{1;} initial data demonstrates bloodstream Cpeptide in T1D patient after 90-days post implant & other efficacy indicators²



Interim data demonstrated highly vascularized tissue chambers in human patients & abundant surviving islets robustly producing insulin⁶





PEC-Direct initiated Phase I/II in 2017 in high risk T1D patients; initial data released in 2019 demonstrated cells produce sub-therapeutic C-peptide³

2014, paused due to poor engraftment

PEC-Encap initiated Phase I/II in

& restarted in 2019⁴



PEC-Direct vascularizes directly⁸ & is verified in human trial⁴:

PEC-Encap has surface diffusion⁸ but their trial was "paused" due to low levels of engraftment⁹ – to date human vascularization data is lacking





Expected to enter the clinic by 1H of 2020 for hypoglycemia unawareness; a broader trial for adult T1D patients is planned for 2020 H2⁵



Pre-Clinical PoC data in pigs demonstrated the vascularization capability of stem cell encapsulating device⁵ – to date human vascularization data has not been generated

1. Clinical Trials.gov; 2. Company Press Release; 3. Company Press Release; 4. JDCA; 5. Company Press Release; 6. Company Press Release; 7. Company Website; 9. Company Press Release; 10. Pitchbook Estimate; 11. Company Press Release HU: Hypoglycemia Unawareness; T1D: Type 1 Diabetes.



Local Immune Protection Technology		Financial Metrics (USD Millions)		
	Immuno-suppression is needed under current clinical trial regiment ¹ . Local immune protection technologies secured.	\$330 M	As of January 2021 Sernova's market cap	
× ?	PEC-Direct program requires long-term immunosuppression ⁷ ; PEC-Encap program may not require immunosuppression ⁷ – to date human validation has not been demonstrated	\$240 M	November 2018, raised \$80 M Series D financing - undisclosed valuation ⁹ ; total raised ~\$240 M to date ¹⁰	
?	Semma's proprietary delivery system is designed to protect cells from the immune system ⁵ though human validation is lacking to date	\$950 M	August 2019, Vertex acquired Semma for a \$950 M cash payment ¹¹	

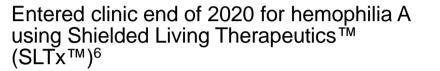


RM Diabetes Competitive Landscape





Clinical Efficacy Data: Therapeutic C-peptide Levels Measured in Bloodstream





In experimental animal models, SLTx[™] resisted fibrosis for up to 12 months¹⁰ – to date human vascularization data has not been generated

Published on TradingView.com, January 18, 2021 15:47:30 UTC BATS:SGTX, 60 35.46 A +1.30 (+3.81%) O:35.80 H:35.80 L:35.37 C:35.37



A Trading View



Device Vascularization Islet Engraftment Demonstrated in Humans



Local Immune **Protection Technology**

Sigilon believes SLTx[™] will negate the need for immunosuppression¹² though human validation is lacking to date

Sernova Valuation Relative to Peers

- Sernova's peer group SIGILON and SEMMA
- **SVA Advancements over Peer Group**
 - Sernova US Phase I/II clinical trial with positive interim clinical results presented at ASTS Jan 15, 2021 vs. peer group lack of clinical data
 - Sernova: Diabetes + thyroid + hemophilia A three indications with validated clinical/preclinical data vs. peer group single indication
 - SVA may well become a "must-have element" for ALL cell-based regenerative medicine providers and could thereby become a beneficiary of an a license fee from essentially the whole market of cell-based regenerative therapeutics

• SVA's value is "Peer Group Plus" - members SIGILON and SEMMA valued at approximately USD1bn

Sernova Valuation Calculation			
SEMMA Vertex sale September 2019	USD\$950M		
SIGILON NASDAQ Listing - Market cap as of Jan. 15 2021	USD\$1.1B		
SUM	USD\$2.079B		
Average Valuation	USD\$1.039.5		
Sernova Equivalent US/CDN share price	USD\$3.47; Canadian \$4.40		





Cell Pouch Solves Device Conundrum

The Device Conundrum

"We thought the cells would be the hard part and focused our efforts there. It's obvious now having a functional device will be the limiting factor and there are few current options."

The challenging device issues and hurdles conquered by Sernova:

- Natural cell environment - Vascularization - Scalability
- Fibrosis Cell engraftment - Biocompatibility
- Versatility: human cells & tissue, stem cell derived islet cells





Big Pharma executive at 2020 JPM

Immune Protection

Conformal Coating Technologies:

- Sernova's proprietary cellular conformal coating technology developed and optimized with years of research
- It consists of a thin biocompatible porous polymer hydrogel coating surrounding therapeutic cells (islets, stem cells)
- Proven to allow for physiological transfer of insulin and glucose unlike other encapsulation technologies
- Sernova is preparing for use within its Cell Pouch for islets, stem cell derived cells for multiple applications
- The potential to eliminate the need for anti-rejection medications significantly increases the number of treatable patients for Sernova's clinical products

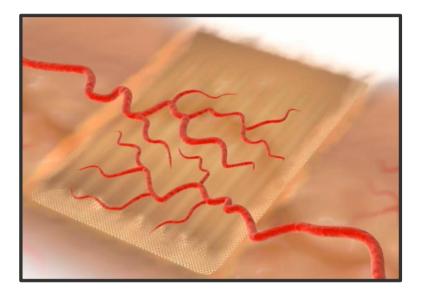
Gene-Editing Technologies:

- Sernova entered in a collaboration to evaluate the potential of Sernova's pluripotent stem cell-derived pancreatic islet beta cells, and hemophilia cells engineered with AgeX's UniverCyte technology, to evade human immune detection.
- UniverCyte uses a modified form of HLA-G, a potent immunomodulatory molecule, which in nature protects an unborn child from their mother's immune system. AgeX's modified HLA-G has the potential to allow for long-term, stable and high expression of the immunomodulatory effect.
- The complementary combination of technologies could enable the transplantation of therapeutic cells in patients with T1D in an off-the-shelf manner using Sernova's Cell Pouch, without human leukocyte antigen (HLA) tissue matching or concurrent administration of immunosuppressive medications



Biologically Compatible Delivery Process

Cell Pouch Implantation & Therapeutic Cells Delivery Process



Proprietary Cell Pouch is placed deep under the skin, allowing for vascularization & creating a natural environment for long-term function of therapeutic cells Therapeutics cells are transplanted directly into the vascularized tissue chambers of the proprietary Cell Pouch





Therapeutic cells release missing proteins or hormones in the bloodstream to correct biological dysfunction



Diabetes Clinical Progress Summary

Pre 2018	 Completion of first-in-human proof-of-concept st Clinical protocol & regulatory package developmed FDA IND clearance to commence T1D Study T1D Study funding grant awarded by JDRF
2018	 Prominent diabetes clinical investigator Dr. Witko UChicago IRB approval obtained Medtronic contracted for T1D Study CGM T1D Study patient screening & recruitment initiat
2019	 Cell Pouch implantation into first T1D Study patie Human islet cells transplantation into Cell Pouch T1D Study positive early safety & efficacy indicate Enduring level of fasting C-peptide in bloodstrear
2020	 Positive DSMB Review & Recommendation for Co Positive Efficacy Endpoint – Survival of Endocrine Ongoing T1D Study patient enrollment, treatment





- tudy for diabetic condition HU ent for US Ph I / II clinical trial for HU (T1D Study)
- wski joins T1D Study
- ted, 1st patient enrolled
- ent
- in first T1D Study patient
- ors observed
- m observed
- ontinuation of Ph I/II clinical trial
- Tissue
- nt & follow-up

Diabetes First Clinical Indication: HU

Hypoglycemia unawareness (HU), the most critical unmet need in diabetes, affects 15% of T1D patients (~240 K patients in the US alone)

- > clinically defined as a complication of diabetes in which the **patient is unaware of** a deep drop in blood sugar
- > patients do not experience hypoglycemia warning symptoms (palpitations, anxiety, excessive sweating, light headedness)
- harmful effects: diabetic ketoacidosis (DKA), coma & death

1st study population for Sernova's integrated RM therapeutic solution for lead indication of insulin-dependent diabetes



US Ph I/II Study Design

US Ph I/II Safety, Tolerability, Efficacy Study

Study Design: Company-sponsored IND. Open-label, single-arm study. Human donor islets are transplanted into the Cell Pouch after implantation & stable anti-rejection medication activity has been established.

Primary Objective: To demonstrate the safety & tolerability of islet transplantation into the Cell Pouch for the treatment of HU in T1D subjects with a history of severe hypoglycemic episodes.

Secondary Objectives: To establish islet release criteria that accurately characterize the islet product & are predictive of clinical transplant outcomes into the Cell Pouch, demonstrated through defined efficacy measures:

- Survival of endocrine tissue in the Cell Pouch
- > Proportion of subjects with a reduction in severe hypoglycemic events
- Proportion of subjects with a reduction in HbA1c >1mg%
- Over 20 additional endpoint analyses will occur

Status: Study Active & Ongoing

- ➢ IND allowance by FDA & protocol approved by IRB
- Multiple subjects implanted & transplanted
- Positive early findings announced
- Patient enrolment & recruitment ongoing



oglycemic events g%





US Ph I/II Safety

US Ph I/II Safety, Tolerability, Efficacy Study

Incidence & severity of adverse events associated with Cell Pouch were monitored:

- No incidences of AEs or SAEs determined to be probable or highly probable to the Cell Pouch
- **<u>Cell Pouch well-tolerated & safe</u>** during the implant & the time of transplant
- No reactions to the Cell Pouch implant
- > Cell Pouch well-incorporated with vascularized tissue & deemed suitable to receive the islet transplant

CONCLUSION: Safety findings continue to meet the primary endpoint of the study

DSMB Review Statement (2020): Recommendation that study continue as designed.



US Ph I/II Case Study Early Findings

US Ph I/II Safety, Tolerability, Efficacy Study

First Patient Observed Data Presented by Clinical Investigator*

Early Efficacy Findings

Islet Transplant Status:	Before	3 Mo. After	
Bodyweight	83kg	73kg	
Hemoglobin A1C	6.5	5.6	
Daily Use Of Long Acting Insulin Tresiba	14U	8U	
Daily Use Of Short Acting Insulin	15 – 16	14 – 15	
Severe Hypoglycem. Events	4 per week	1 per week	

90-day post-transplant glucose tolerance test (i.e. patient given a high sugar drink) was administered over several hours:

*presented at IPITA Q3 2019 in Lyon, France

SUBSEQUENT FINDING: Enduring blood levels of C-peptide & ongoing evidence of islet engraftment & durable therapeutic effect detected post-second Cell Pouch islet dose

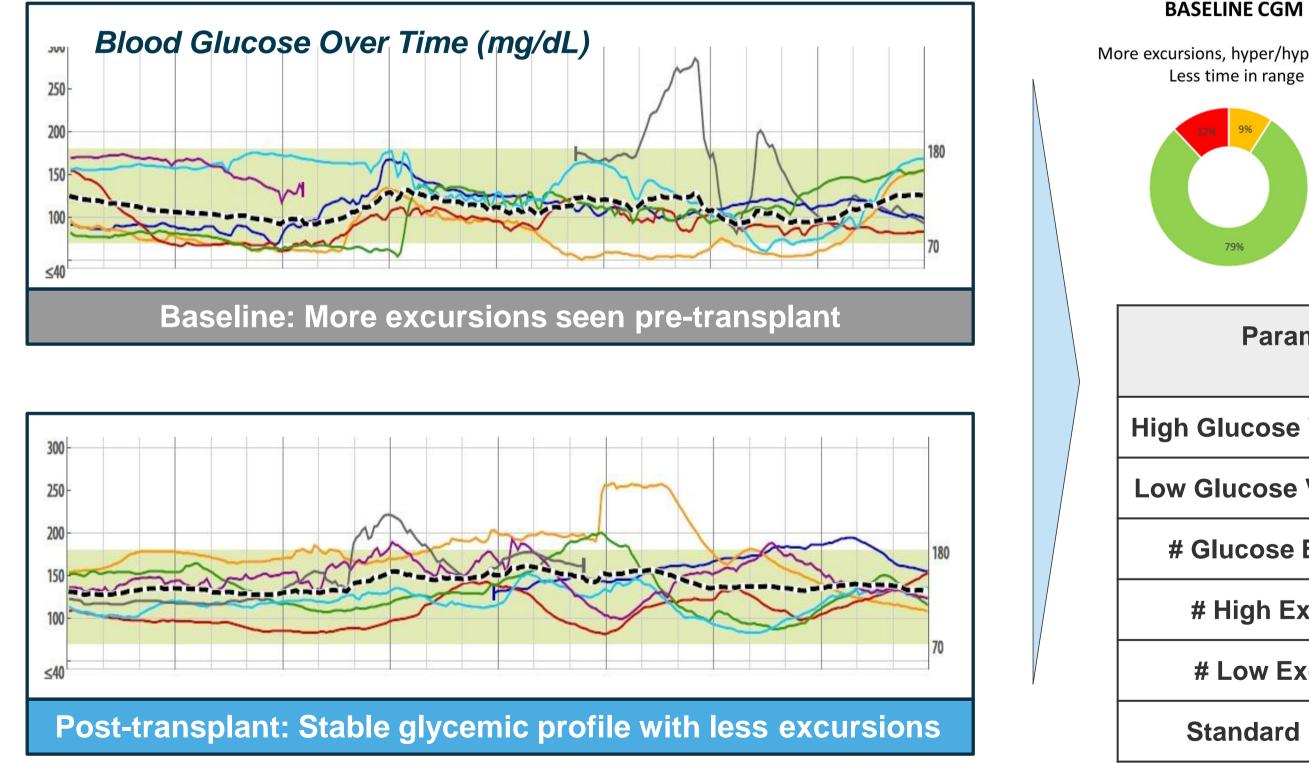


showed increase in blood levels of C-peptide

showed increase in blood levels of insulin

US Ph I/II Case Study Early Findings

Improvement in ALL CGM Parameters



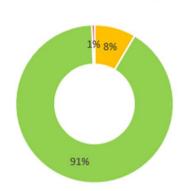


BASELINE CGM

More excursions, hyper/hypo events

ISLET TRANSPLANT Less excursions, hyper/hypo events More time in range

CGM POST CELL POUCH



Medtronic



Time above 180 mg/dL Time in Range of 70-180 mg/dL Time below 70 mg/dL

Parameter	Baseline	Post-transplant (90 days)
High Glucose Value (mg/dL)	285	231
Low Glucose Value (mg/dL)	50	66*
# Glucose Excursions	15	3
# High Excursions	7	2
# Low Excursions	8	1
Standard Deviation	37	31

* Lowest excursion was 66mg/dL and this occurred only once.

US Ph I/II 90-Days Post Transplant

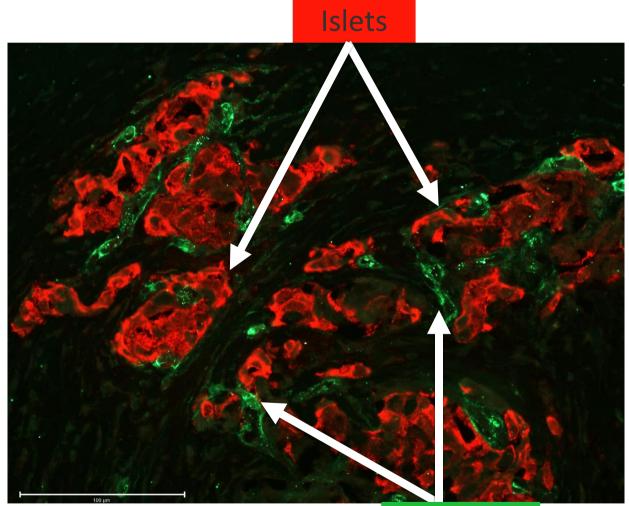
Achievement of Secondary Endpoint

"Survival of endocrine tissue in the Cell Pouch™ (defined by positive) staining of islets during histological analysis) [Time Frame: 90±5 days post-transplant for sentinel Cell Pouch[™]]"

Independent Pathologist reported:

- > abundant viable, organized islet cells
- intimately associated with blood vessels
- > within a collagen matrix
- > islet cells strongly express insulin
- Indicator of transplanted islet health in the therapeutic Cell Pouches remaining in the subject
- > Ability to produce insulin and deliver to the bloodstream
- Previously demonstrated by reported findings of blood levels of both glucose-stimulated & fasting C-peptide plus other efficacy indicators





New Blood Vessels



Clinical Study Update (Safety)

ENROLLMENT:

5 of the 7 patients have now been enrolled, implanted with Cell Pouches and are actively advancing through the transplantation phase of the study

- > 5 of 7 patients have been implanted with the Cell Pouch
- > 3 of 7 patients have received their first/one islet transplant
- > 2 of 7 patients have received their first and second islet transplant

Pre-screening is ongoing for the final two patients and full enrollment of the study is anticipated to be completed in the first quarter of 2021

SAFETY (Primary Endpoint):

- > Following implantation, consistent incorporation of the Cell Pouch with vascularized tissue providing a suitable environment for transplant of islets (insulin-producing cells)
- No incidence of Severe Adverse Events (SAEs) related to the Cell Pouch or islet transplant





Clinical Study Update (Efficacy)

Highlighting some of the trial efficacy findings with focus on clinical benefits to the T1D patients, the following trends have also been observed as of the presentation of Sernova's clinical investigator on January 15, 2021 at the ASTS Winter Symposium.

EFFICACY (Secondary Endpoint):

- > Absence of life threatening severe hypoglycemic events;
- Sustained blood levels of C-peptide (a biomarker for insulin produced by cells in the Cell Pouch);
- Reduction in HbA1c (a measure of long-term glucose control); and,
- Improvement in overall Continuous Glucose Monitoring (CGM) measured glucose control parameters (e.g., blood glucose 'Time in Range').

With the positive clinical benefit achieved in patients with Cell Pouch islets, one patient was later provided a single infusion of islets (portal vein). This top-up to the islets already received in the Cell Pouch contributed to this patient achieving and sustaining insulin independence. This patient has now been insulin free (requiring no injectable insulin) for nine months with optimal glucose control.



Earlier First-in-Human Study

First-in-World Successful Proof-of-Concept

Study Design

- > T1D subjects with HU & a history of severe hypoglycemic episodes
- > Open-label, single-arm
- Donor islet transplantation 2 24 weeks post Cell Pouch implantation
- Primary Endpoint: Safety post Cell Pouch implantation & 1-month post islet transplantation

Cell Pouch and Islet Safety Endpoints Met

- Safety successfully met for the Cell Pouch
- Cell Pouch histology assessed by independent pathologists blinded to the treatment:
 - Islets housed within a natural tissue matrix
 - Islets were well-vascularized
 - Islet safety successfully met
 - > Islets show evidence of insulin, somatostatin & glucagon
 - > Cell Pouch & islet biocompatibility met
 - Proof of islet protection from immune system attack

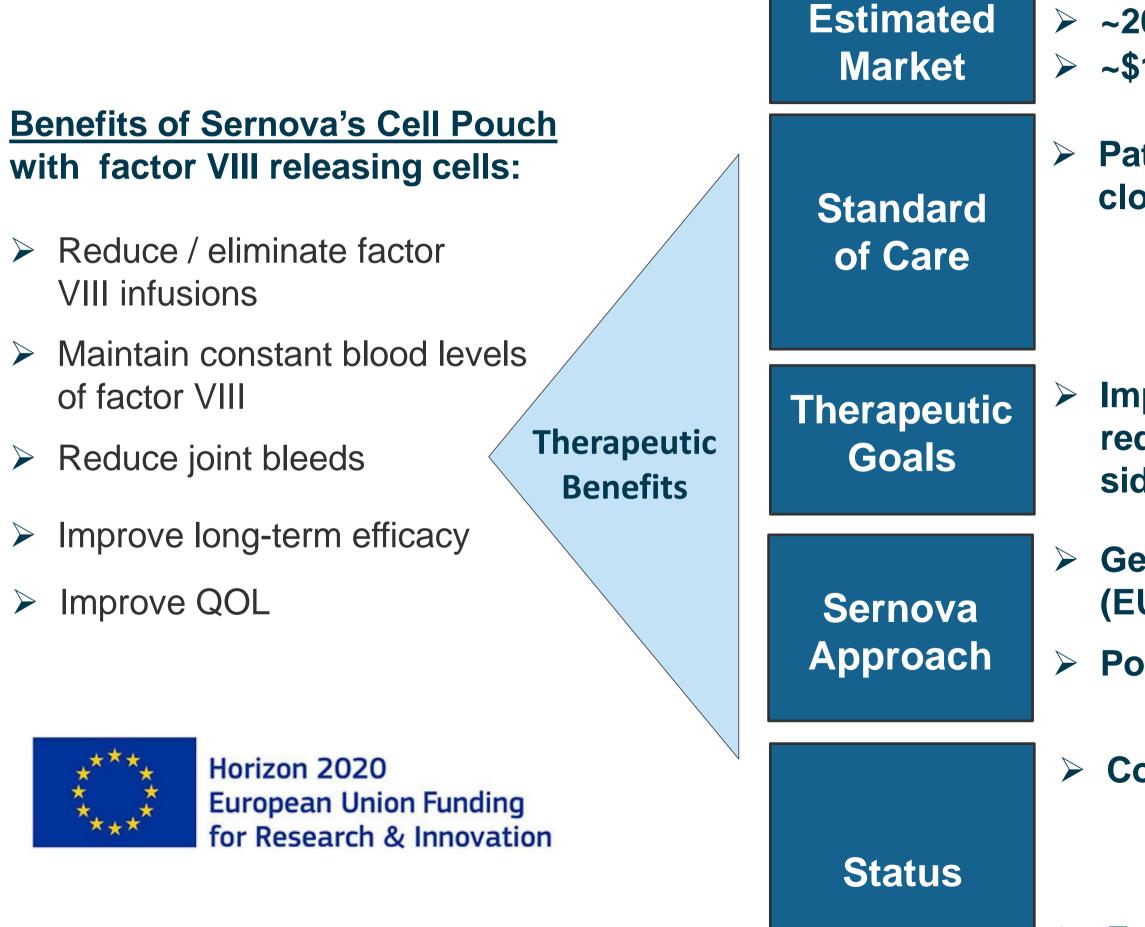


Cell Pouch[™] Clinical Histology Insulin staining islets with microvessels

20x Cell Nuclei lew blood essels **B**-cells No immune infiltration



Hemophilia A Program





~20 K patients across North America & EU ~\$10 B orphan indication

Patients receive regular infusions of missing clotting factors (i.e. factor VIII)

- Infusions are highly expensive & burdensome
- Select patients develop inhibitors, reducing the effectiveness of infusions

Improved efficacy with prophylactic treatment; reduced cost; improved patient QOL; reduction of side effects

Gene corrected own patient cells into the Cell Pouch (EU5.6M Horizon 2020 Consortium Grant)

Potential treatment for all patients

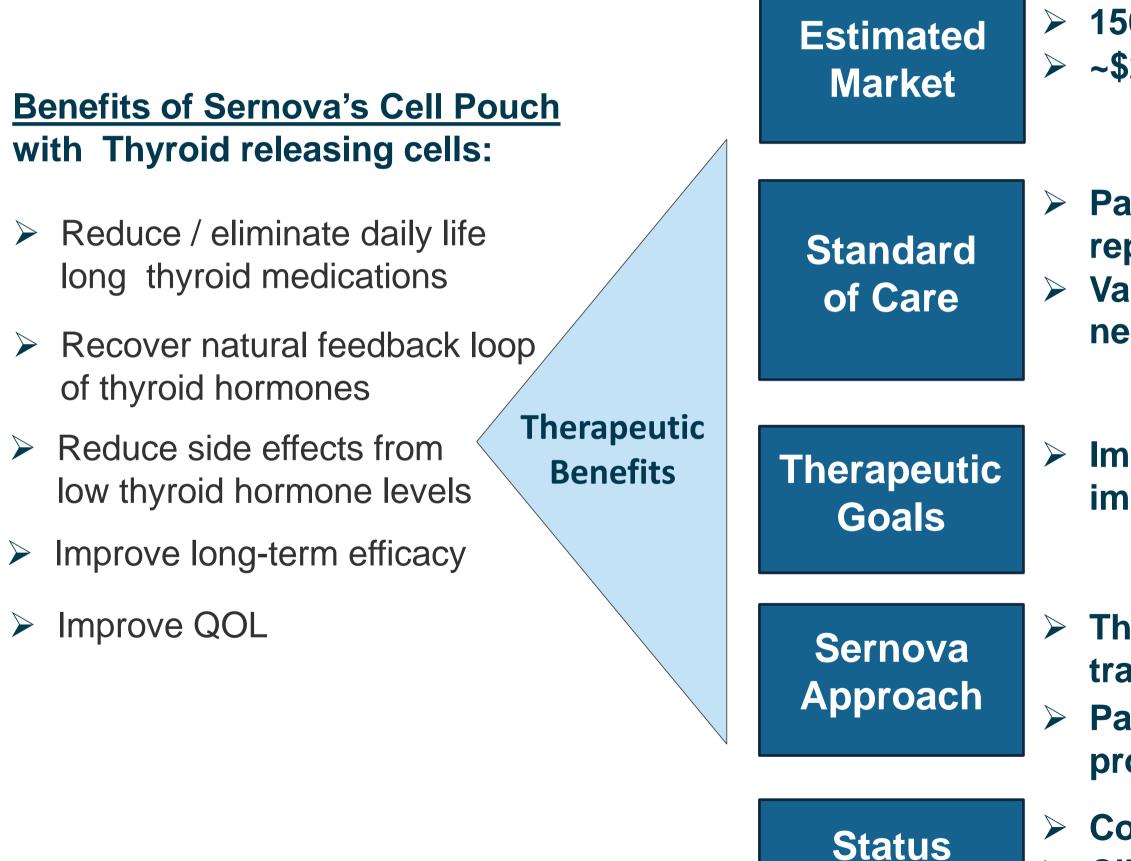
• Stem cell releasing factor VIII product

Completed pre-clinical proof-of-concept

- Cell manufacturing process developed
- Corrected patient cells survive & produce factor VIII in pre-clinical hemophilia model 27

Further development being scoped

Thyroid Disease Program





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150,000 thyroidectomies performed annually in US ~\$2.2 B market opportunity

- Patients require lifelong thyroid hormone replacement therapy
 Various oral / IV / other therapies may also be needed depending on underlying condition
 - Improved efficacy with prophylactic treatment; improved patient QOL; reduction of side effects
 - Thyroidectomy patient healthy tissue isolated & transplanted into the Cell Pouch Patient cells survive within the Cell Pouch & produce thyroid hormone
 - Completed pre-clinical proof-of-concept Clinical program under development

NEXT STEPS – Action Plan

Platform Technology

Diabetes T1D

Hemophilia A

Thyroid

- > Develop licensed/acquired local immune-protection technologies for therapeutic cells
- > Advance local immune-protected diabetes stem cell technology in preparation for First-in-Man (FIM) study
- > Expand existing strong worldwide multi-family patent portfolio
- Ongoing T1D Study safety & efficacy data evaluation Strategic pharma / medtech collaboration(s) expansion
- Complete T1D Study patient enrolment Continue T1D Study patient treatment & follow up
- HemAcure study results conference presentation & publication Market & product positioning assessment Regulatory & Clinical plan development

- Complete Pre-Clinical studies
- Prepare & submit FIM regulatory package



Management Team



Dr. Philip Toleikis

PRESIDENT & CEO

- > 20+ years experience in biotech management & product development in pharmaceutical & combination products.
- Previous Angiotech VP R&D (achieved \$2 B) market cap; product revenue \$200 M per year).



David Swetlow CPA, CA

CFO

- \geq 20+ years experience in life sciences (biopharma, combination products & devices) & high-tech industries, including Ondine, Protox, QLT, Xillix.
- > Various senior management, board & advisory roles. Nasdaq & TSX experience.

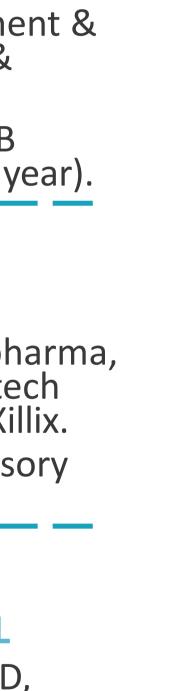


Delfina M. Mazzuca-Siroen

SR. DIRECTOR & HEAD OF R&D / CLINICAL

- 20+ years senior management roles in R&D, clinical, regulatory, product development.
- Biochemistry, translational cell biology, device & transplantation expertise.
- Publications & patents author / co-author.





Board of Directors

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