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The Path To A Regenerative Medicine Cure

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Cell and Gene Meeting on the Mesa
October 12th - 16th, 2020

Forward-Looking Statements

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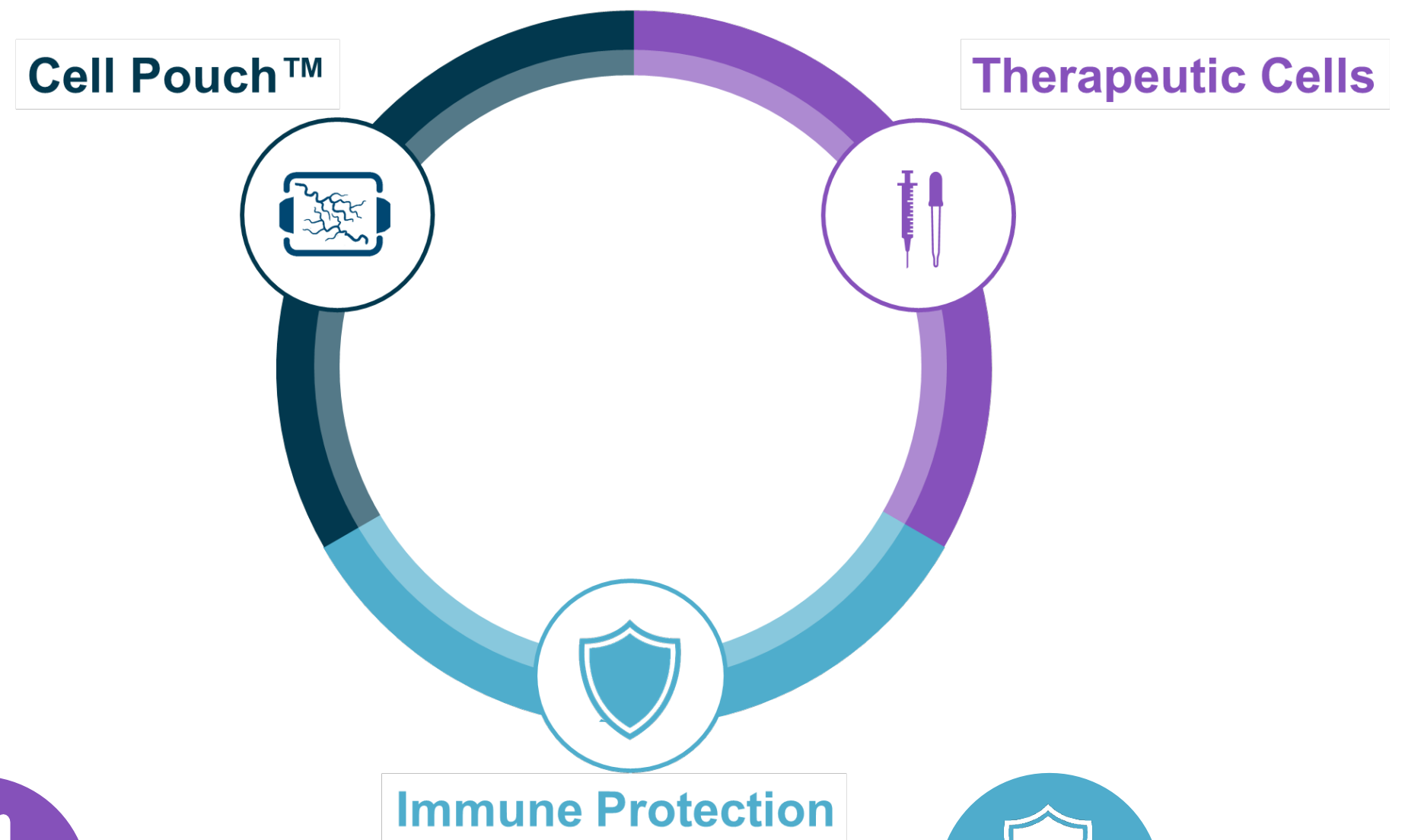
Sernova: Innovator & Leader

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

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

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

Sernova Pipeline

CELL POUCH CANDIDATE	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	DEVELOPMENT STAGE	INDICATION
HUMAN DONOR ISLETS, SYSTEMIC IMMUNE PROTECTION					PHASE I/II INITIATED DEC 2018	HYPOGLYCEMIA UNAWARENESS
LOCALLY IMMUNE-PROTECTED STEM CELL DERIVED CELLS		T1D			ANTICIPATED 2 ND APPROVAL FOR DIABETES	ALL INSULIN DEPENDENT DIABETIC PATIENTS
CORRECTED PATIENT CELLS		Hemophilia A			PRE-CLINICAL	SEVERE HEMOPHILIA A PATIENTS
ALLOGRAFT IMMUNE-PROTECTED CELLS					EARLY DEVELOPMENT	BROADER HEMOPHILIA A PATIENTS
THYROID CELLS		Thyroid			PRE-CLINICAL	THYROIDECTOMY PATIENTS FOLLOWING HYPERTHYROIDISM

Therapeutic Cells

Therapeutic Cell Options

- Human donor cells enable early safety / efficacy testing in the clinic for indications & patients with unmet needs & advanced disease (i.e. diabetes HU patients). Supply is limited; however, they enable Cell Pouch validation in preparation for stem cell technologies.
- Stem cell derived cells enable expanded availability to an unlimited supply of cells for large market opportunities (i.e. all T1D patients & other indications)

Stem Cell Derived Technologies

- Exclusive worldwide license to a diabetes stem cell derived technology unlocking potential access to all T1D subjects & 30% of TD2 who convert to insulin use
- Big Pharma collaboration on other best in class stem cell derived technologies to advance partnering opportunities

Immune Protection

- Transplanted therapeutic cells must be protected from a natural immune system attack response.
- While established systemic transplantation immuno-suppression (anti-rejection) drugs can be effective, local immune protection (LIP) is optimal. LIP alternatives present different opportunities & challenges.
- Multiple approaches to optimize indication match, therapeutic solution delivery & benefit, & eliminate the need for drugs & their associated side effects.

IMMUNE PROTECTION APPROACH	SYSTEMIC (S) or LOCAL (L)	DEVELOPMENT PROFILE					SERNOVA ACTIVITY
		Proof of Concept	Clinic Entry Timing	Side Effects	Development Risk Profile	Regulatory Complexity	
Immuno-suppression drugs	S	Proven	Achieved	Medium	Low	Low	In clinic
Immuno-protected macro device	L	Failed	Achieved	Medium	High	Medium	Never pursued
Cell encapsulation (conformal coating)	L	Proven	Near term	Low	Low	Low	Moving toward clinic
Cell tolerance (gene editing)	L	TBD	Mid term	Under Evaluation	Under Evaluation	Medium	Under evaluation

Immune Protection

Conformal Coating Technologies:

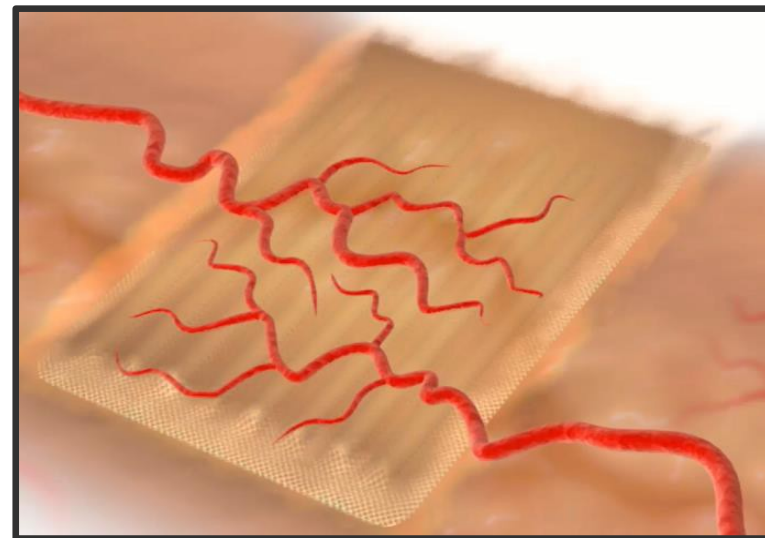
- Sernova's proprietary cellular conformal coating technology - developed and optimized with years of research
- It consists of a thin biocompatible porous polymer hydrogel coating surrounding therapeutic cells (islets, stem cells)
- Proven to allow for physiological transfer of insulin and glucose unlike 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:

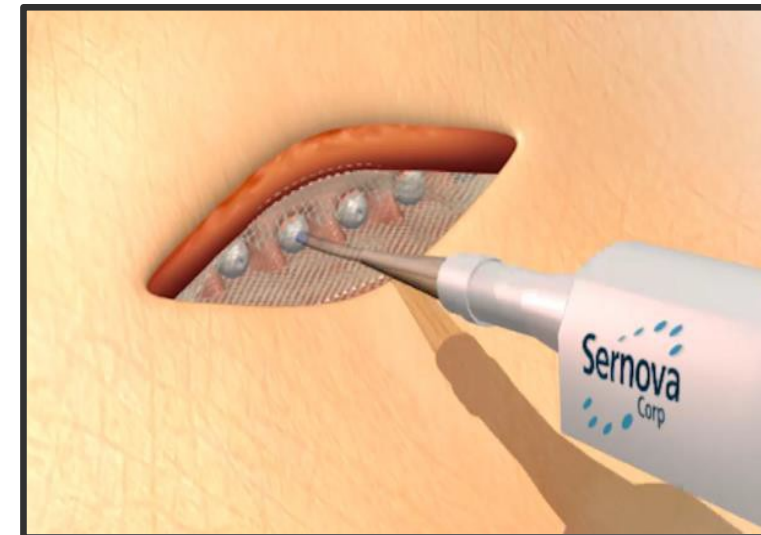
- Sernova entered in a collaboration to evaluate the potential of Sernova's pluripotent stem cell-derived pancreatic islet beta cells, and hemophilia cells engineered with AgeX's UniverCyte technology, to evade human immune detection.
- UniverCyte uses a modified form of HLA-G, a potent immunomodulatory 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

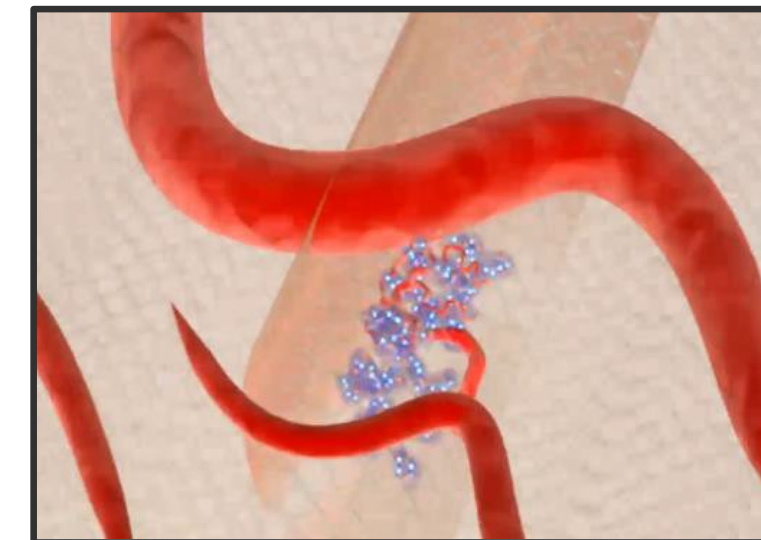
Cell Pouch Implantation & Therapeutic Cells Delivery Process



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

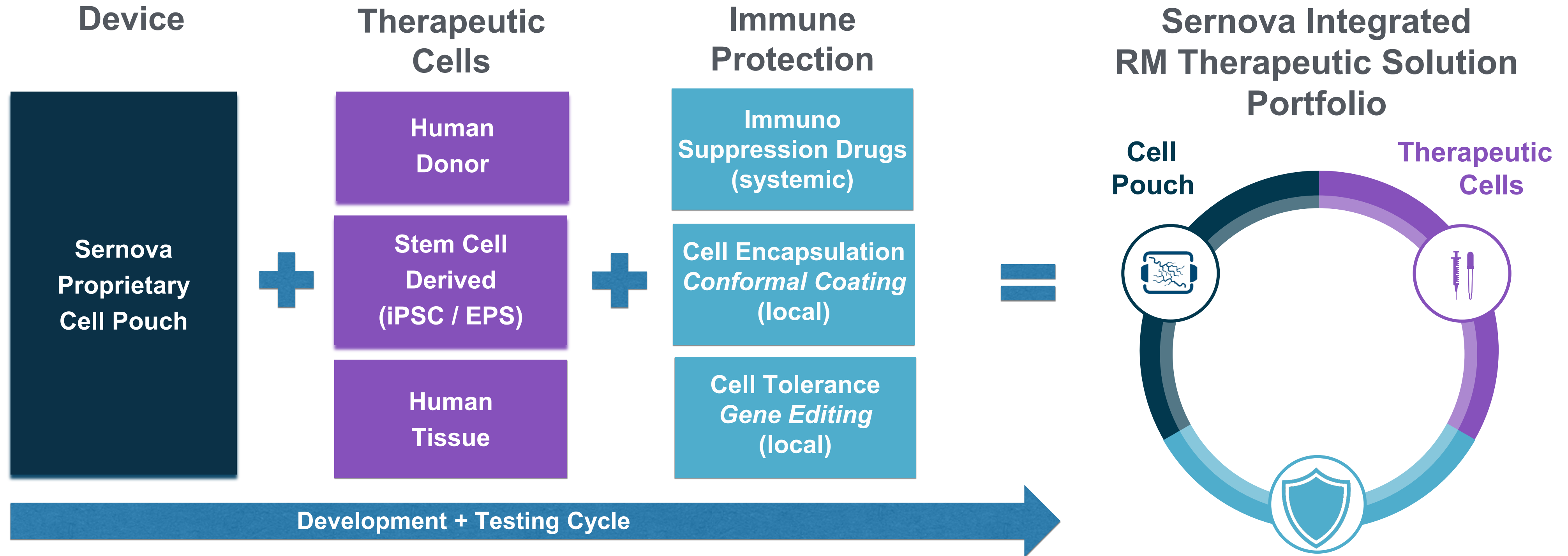


Therapeutics cells are transplanted directly into the vascularized tissue chambers of the proprietary Cell Pouch



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

Strategic Development Approach



Systematic stepwise "building-block" process deployed to:

- minimize unknown variable interdependencies
- de-risk development outcomes

vs. "all-in-one" failures by other RM cell therapy companies

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

Diabetes Clinical Progress Summary

Pre 2018

- Completion of first-in-human proof-of-concept study for diabetic condition HU
- Clinical protocol & regulatory package development for US Ph I / II clinical trial for diabetic HU condition (T1D Study)
- FDA IND clearance to commence T1D Study
- T1D Study funding grant awarded by JDRF

2018

- Prominent diabetes clinical investigator Dr. Witkowski joins T1D Study
- UChicago IRB approval obtained
- Clinical Trial & Consulting Services (CTI) engaged as T1D Study CRO
- Medtronic contracted for T1D Study CGM
- T1D Study patient screening & recruitment initiated, 1st patient enrolled

2019

- Cell Pouch implantation into first T1D Study patient
- Human islet cells transplantation into Cell Pouch in first T1D Study patient
- T1D Study positive early safety & efficacy indicators observed
- Enduring level of fasting C-peptide in bloodstream observed

2020

- Positive DSMB Review & Recommendation for Continuation of Ph I/II clinical trial
- Positive Efficacy Endpoint – Survival of Endocrine Tissue
- Ongoing T1D Study patient enrollment, treatment & 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



US Ph I/II Case Study Early Findings

US Ph I/II Safety, Tolerability, Efficacy Study

Safety Findings (90 days post-transplant)

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

- **No incidences of AEs** determined to be probable or highly probable to the Cell Pouch
- **Cell Pouch well-tolerated & safe** 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

WHY IS THIS IMPORTANT?

Demonstrated Cell Pouch safety is a prerequisite for its use in multiple therapeutic indications

CONCLUSION: Safety findings met the first measure of the primary endpoint

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

*presented at IPITA Q3 2019 in Lyon, France

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

- showed increase in blood levels of C-peptide
- showed increase in blood levels of insulin

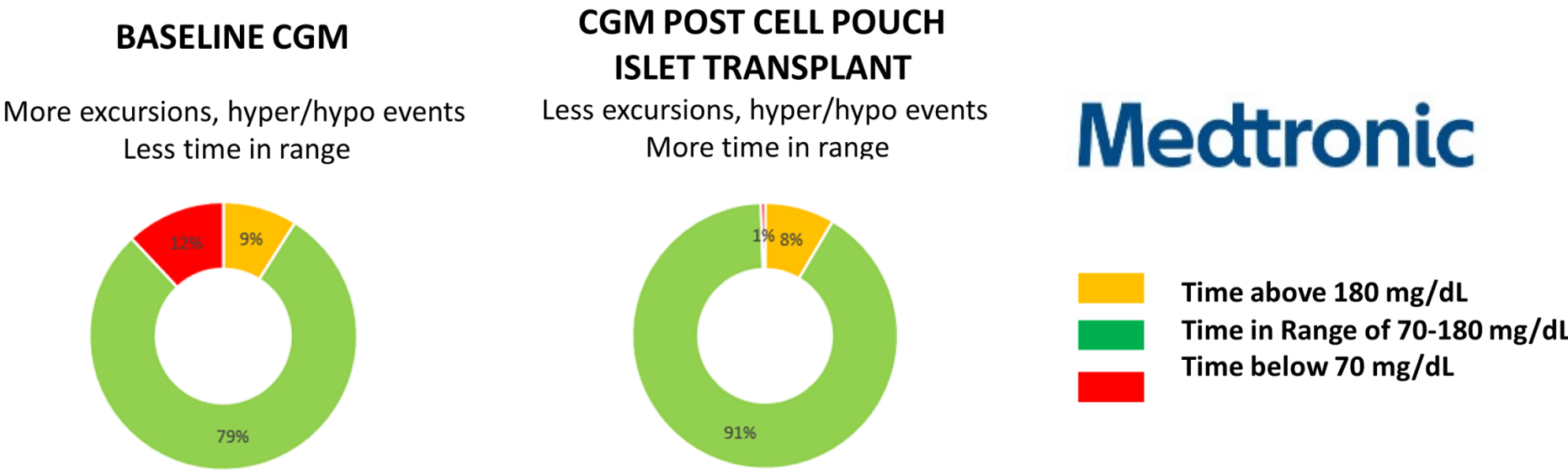
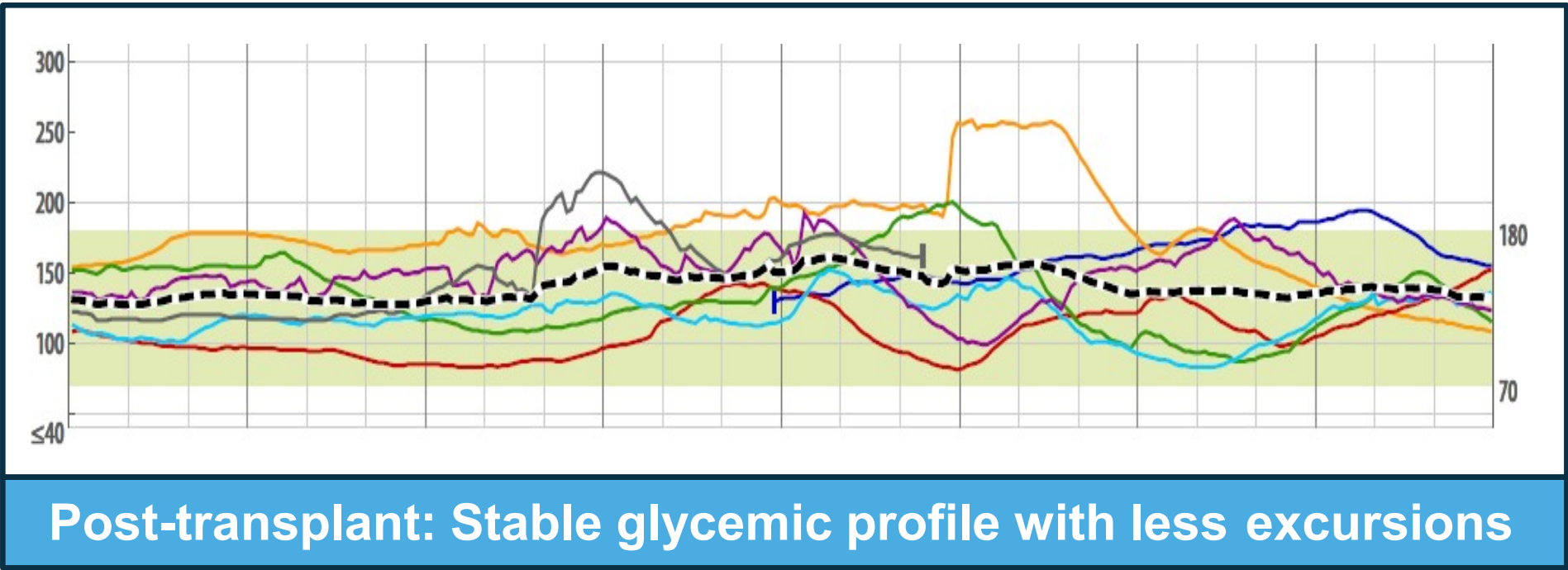
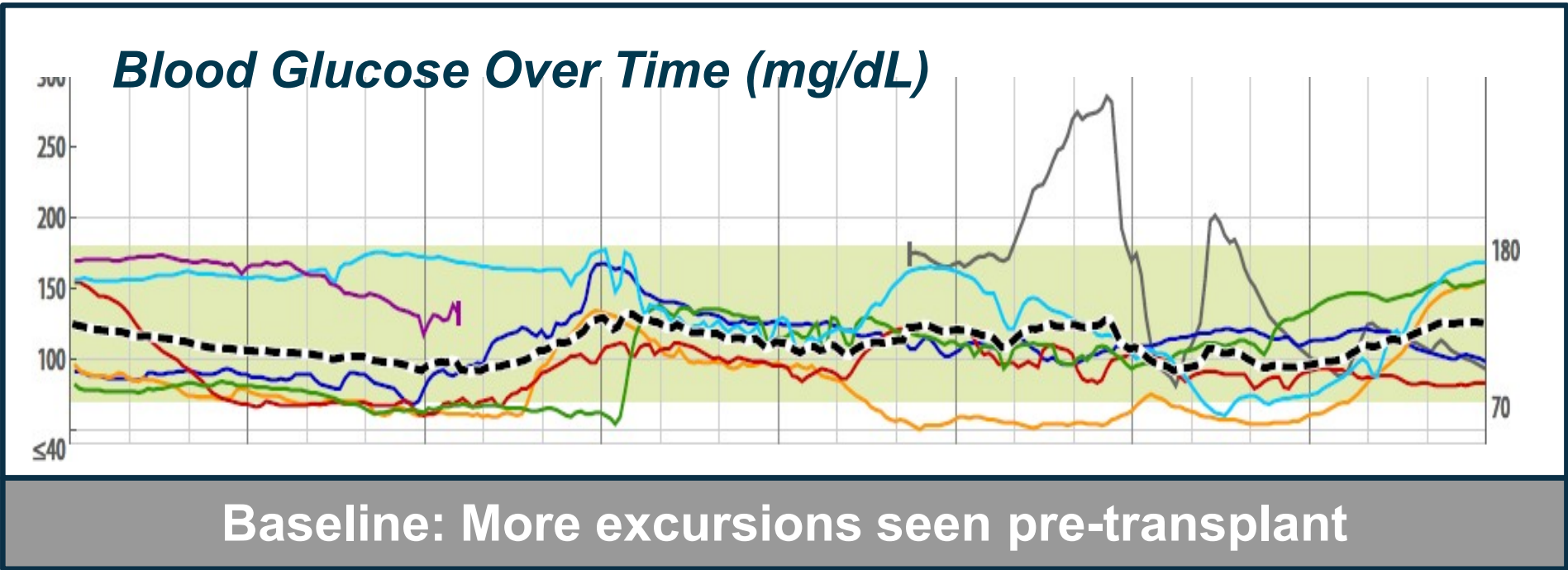
WHY IS THIS IMPORTANT?

C-peptide is a biomarker confirming insulin production by cells

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

US Ph I/II Case Study Early Findings

Improvement in ALL CGM Parameters



Parameter	Baseline	Post-transplant
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.

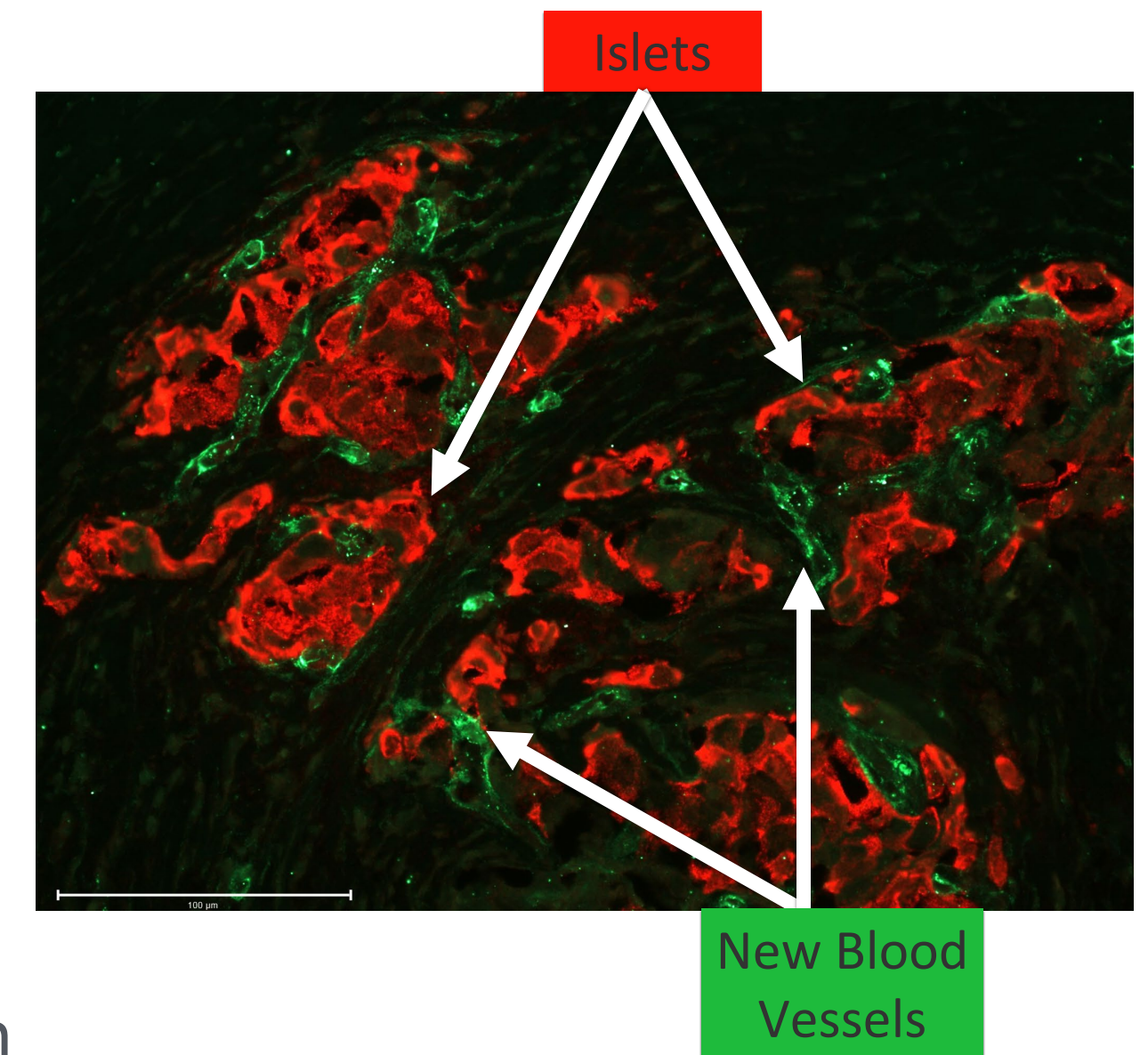
US Ph I/II 90-Days Post Transplant

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



Earlier First-in-Human Study

First-in-World Successful Proof-of-Concept

Study Design

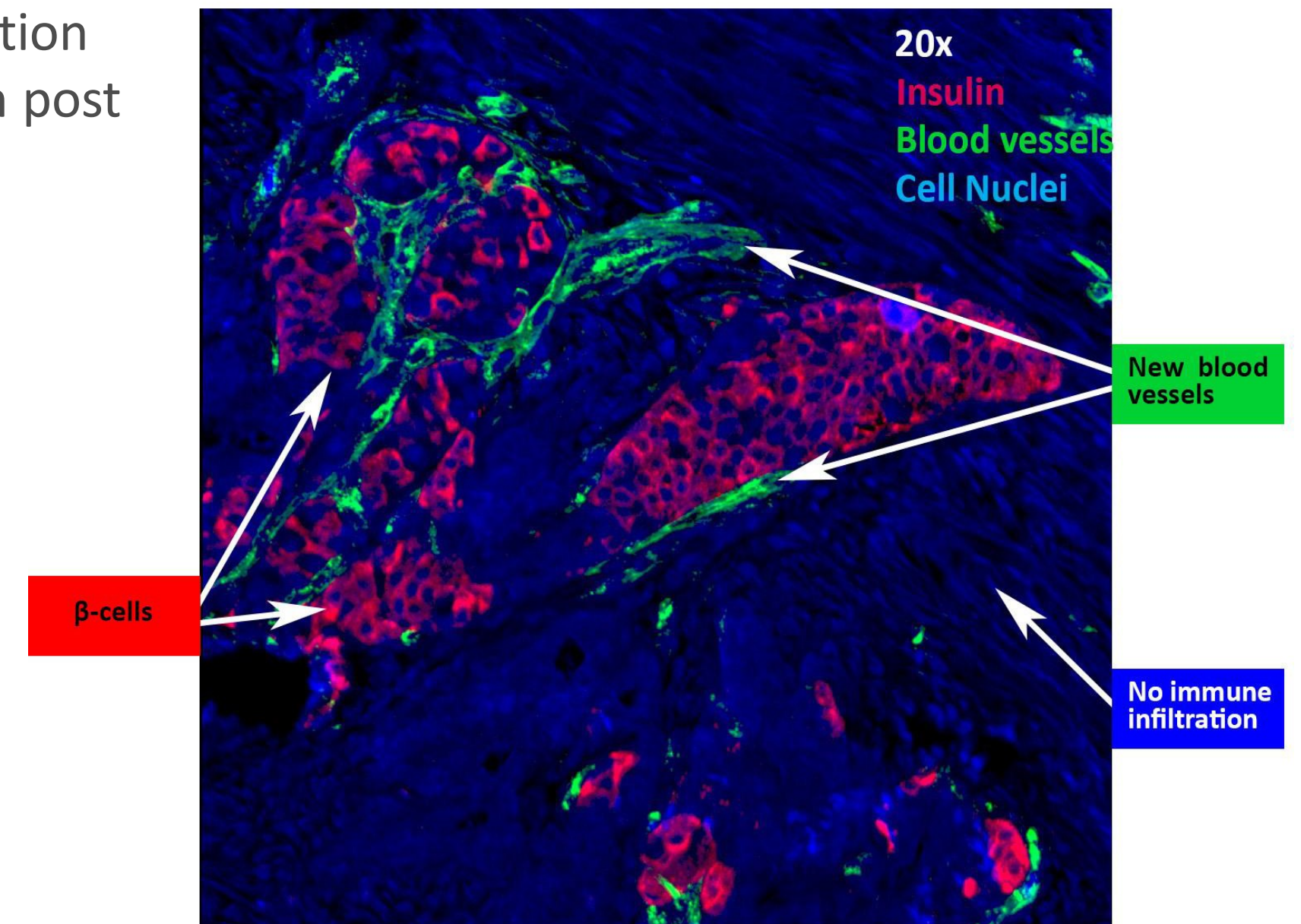
- T1D subjects with HU & a history of severe hypoglycemic episodes
- Open-label, single-arm
- Donor islet transplantation 2 – 24 weeks post Cell Pouch implantation
- **Primary Endpoint:** Safety post Cell Pouch implantation & 1-month post islet transplantation

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



Hemophilia A Program

Benefits of Sernova's Cell Pouch with factor VIII releasing cells:

- Reduce / eliminate factor VIII infusions
- Maintain constant blood levels of factor VIII
- Reduce joint bleeds
- Improve long-term efficacy
- Improve QOL

Therapeutic Benefits

Estimated Market

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

Standard of Care

- 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

Therapeutic Goals

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

Sernova Approach

- 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

Status

- Completed pre-clinical proof-of-concept
 - Cell manufacturing process developed
 - Corrected patient cells survive & produce factor VIII in pre-clinical hemophilia model [21]
- Further development being scoped



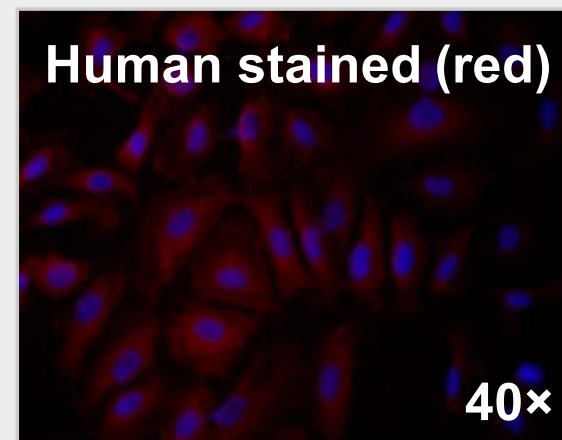
Horizon 2020
European Union Funding
for Research & Innovation

Hemophilia A - Pre-Clinical Success

Pre-Clinical Safety & Efficacy of Hemophilia Cell Therapy in the Cell Pouch

Human factor VIII corrected blood outgrowth endothelial cells (BOECs) were implanted within the Cell Pouch in a hemophilia A murine model

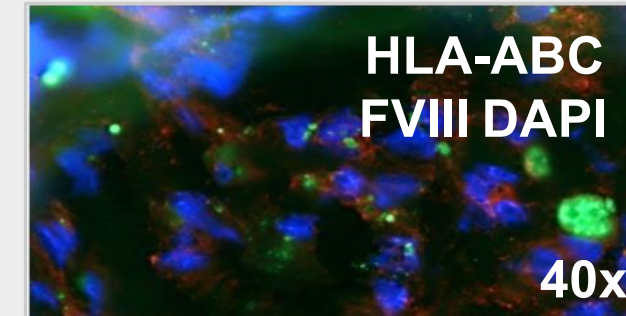
Confirmed
Release-tested
BOECs



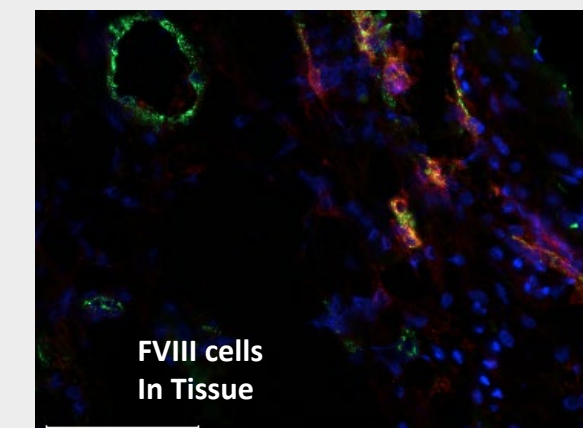
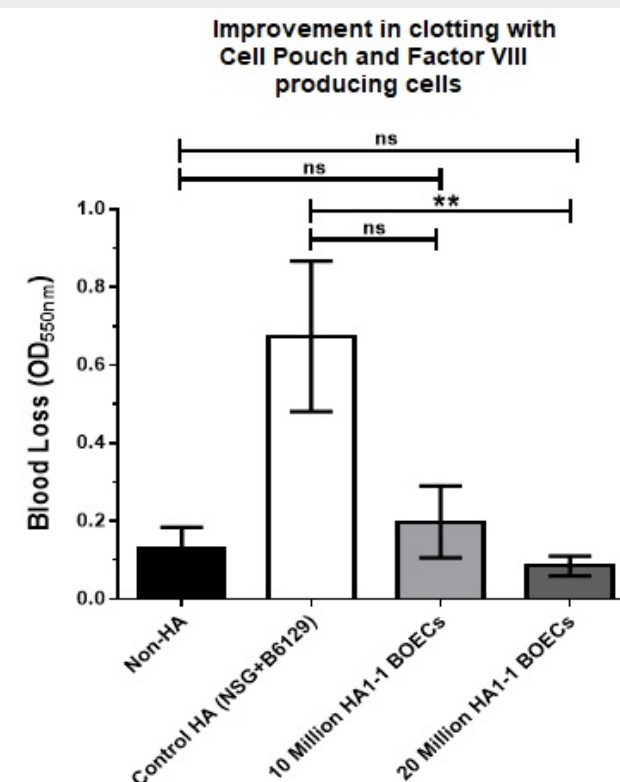
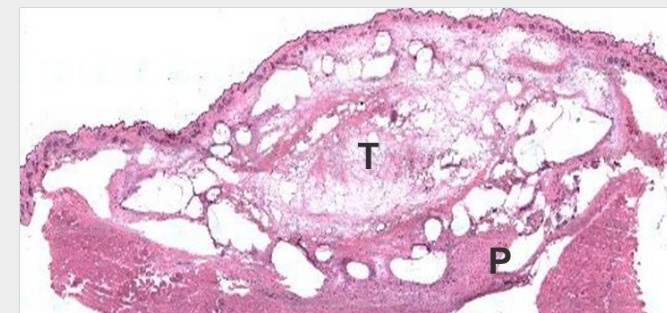
Non-transplanted Cell
Pouch Awaiting Cells



T – Transplant area of
Cell Pouch
P – Peritoneum



Cell Pouch Transplanted with Cells



Factor VIII corrected human BOECs arranged into blood vessels within the vascularized Cell Pouch at 4 months post-transplant (mouse model)

Human corrected BOECs transplanted into the Cell Pouch improved clotting in hemophilia A, providing scientific rational for next step development

Thyroid Disease Program

Benefits of Sernova's Cell Pouch with Thyroid releasing cells:

- 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 QOL

Therapeutic Benefits

Estimated Market

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

Standard of Care

- Patients require lifelong thyroid hormone replacement therapy
- Various oral / IV / other therapies may also be needed depending on underlying condition

Therapeutic Goals

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

Sernova Approach

- Thyroidectomy patient healthy tissue isolated & transplanted into the Cell Pouch
- Patient cells survive within the Cell Pouch & produce thyroid hormone

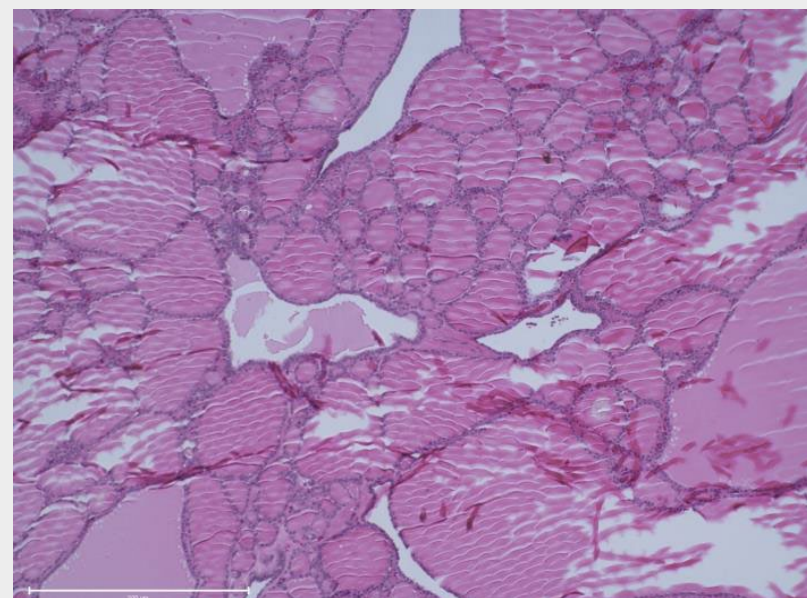
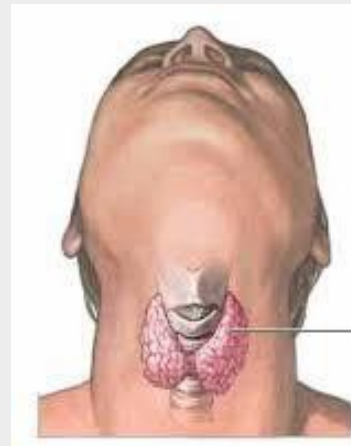
Status

- Completed pre-clinical proof-of-concept
- Clinical program under development

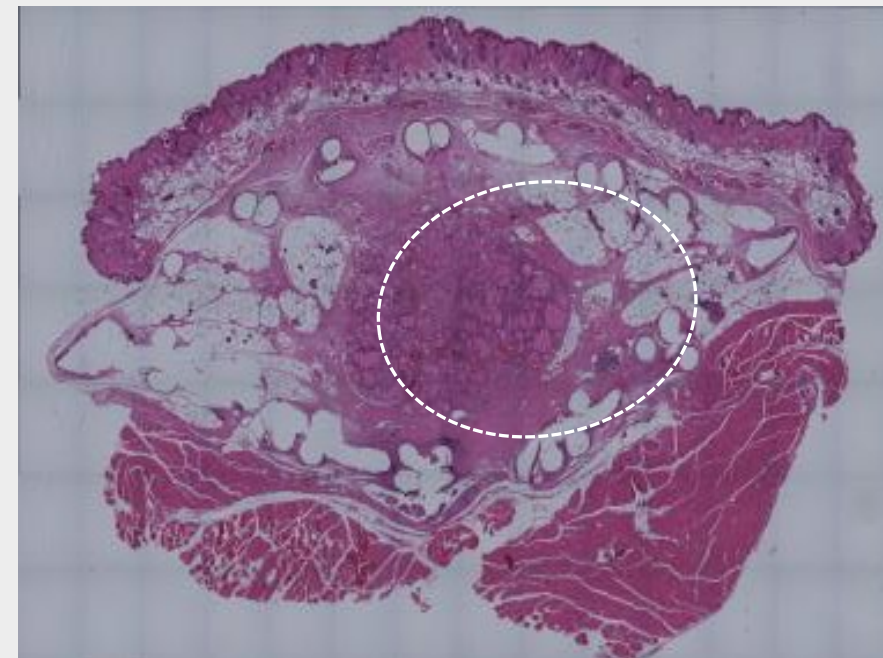
Thyroid - Pre-Clinical Success

Pre-Clinical Safety & Efficacy of the Thyroid Tissue Therapy in the Cell Pouch

Human Thyroid Tissue

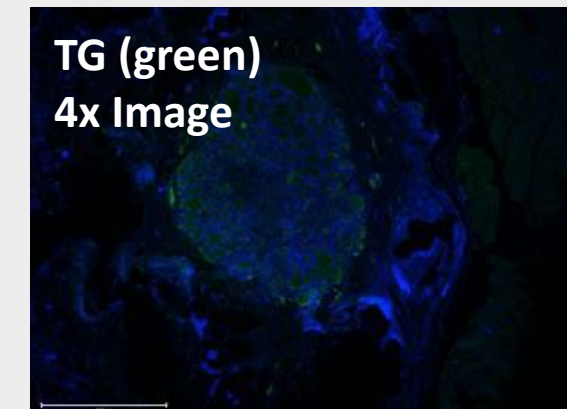


Cell Pouch Transplanted
with Healthy Human
Thyroid Tissue

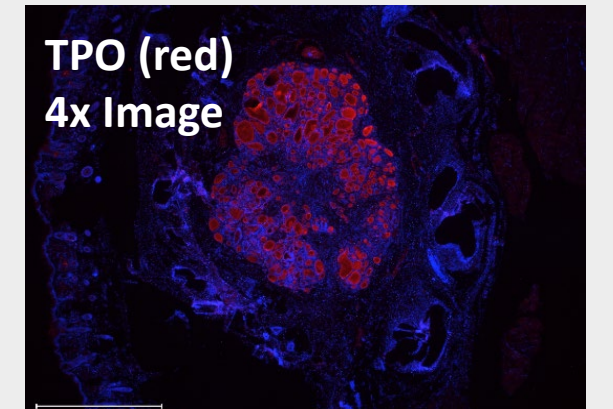


Human Thyroid Tissue Surviving
in Cell Pouch in mouse model
(3 months post-transplant)

TG (green)
4x Image

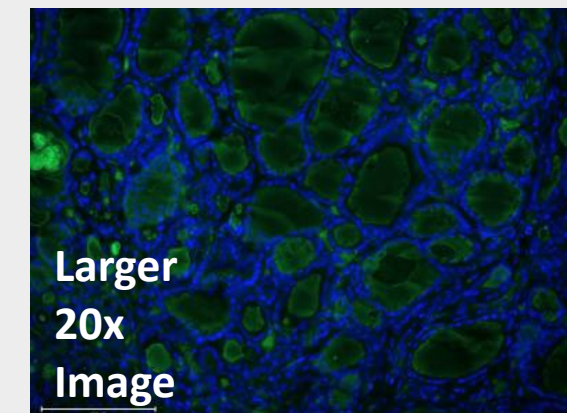


TPO (red)
4x Image

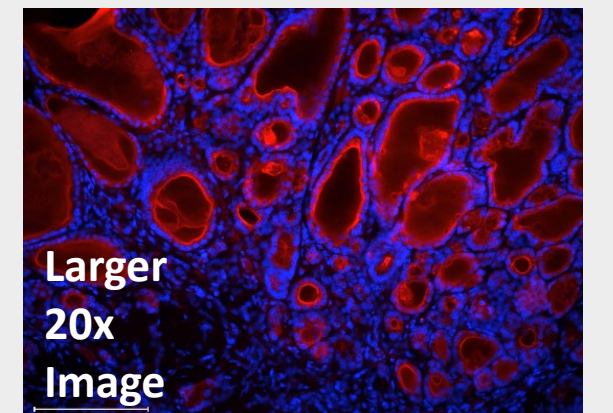


Human Tissue producing
Human Thyroid Hormones
Thyroglobulin (TG) &
Thyroglobulin Peroxidase (TPO)

Larger
20x
Image



Larger
20x
Image



NEXT STEPS – Action Plan

Platform Technology	<ul style="list-style-type: none"> ➤ 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
Diabetes T1D	<ul style="list-style-type: none"> ➤ Complete T1D Study patient enrolment ➤ Continue T1D Study patient treatment & follow up ➤ Ongoing T1D Study safety & efficacy data evaluation ➤ Strategic pharma / medtech collaboration(s) expansion
Hemophilia A	<ul style="list-style-type: none"> ➤ HemAcure study results conference presentation & publication ➤ Market & product positioning assessment ➤ Regulatory & Clinical plan development
Thyroid	<ul style="list-style-type: none"> ➤ Complete Pre-Clinical studies ➤ Prepare & submit FIM regulatory package



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