Sernova Corp - 2017 Presentation

Improving the Quality of Life for Patients with Chronic Disease
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Our Therapeutic System

The Total Regenerative Medicine Solution

1. **Cell Pouch™**
   - An implantable medical device for therapeutic cells placed under the skin
   - Proven biocompatible and safe in humans

2. **Therapeutic Cells**
   - Cells that produce and release missing (or needed) proteins or hormones into the bloodstream (human donor cells, xenogeneic cells, stem cell derived cells)
   - Proven safety & initial efficacy in humans

3. **Immune Protection**
   - Providing local immune protection of the therapeutic cells within the Cell Pouch eliminating the need for antirejection drugs
   - Proof of concept Safety & Efficacy
# Sernova’s Therapeutic Pipeline

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Over 50 patents and patent applications in 10 families:

- Composition and use of medical devices for cell delivery and cell transplantation
- Glucose responsive insulin producing stem cell technologies
- Local immune protection technologies
Sernova’s GMP manufacturing Quality System is compliant with:

- ISO 13485
- MDD 93/42/EEC
- US FDA Quality System Regulations (QSR) 21 CFR 820
- Canadian Medical Device Regulation (CMDR)

Stability tested, sterilized, manufactured in multiple sizes
Diabetes Treatment Overview

-> Main Problem: Outdated Treatment Methods

-> Current technologies are inadequate
   1. Insulin injections, pumps, medications, etc., or
   2. Transplant of donor islets into the portal vein

-> Numerous limitations
   - Inconvenient (Insulin injections 4-6x day)
   - Constant monitoring lowers patient’s quality of life
   - Painful needles & infection prone
   - Poor compliance ➔ serious side effects
   - Expensive

-> No significant disruptive developments or permanent alternatives to treat diabetes for the last 70+ years

Goals of Sernova’s Cell Pouch technologies:

- Reduce exogenous insulin
- Reduce hypoglycemia unawareness
- Improve glucose control
- Improve long-term efficacy
- Improve Quality of Life
Sernova: Diabetes Therapeutic

Performs as an artificial pancreas – eliminates needles, injectables, pumps

- Patient population: Insulin injections, insulin pumps, Edmonton Protocol

- Sernova therapeutic goals: Reduce hypoglycemia unawareness; reduce exogenous insulin; improve patient QOL, improve glucose control; improve long-term efficacy

- Clinical status: Phase I/II clinical POC: Interim device and cell safety results released
Hemophilia Treatment Overview

► Main Problem: Treatment methods expensive, blood trough levels not sufficient to eliminate joint issues

► Current Product Options
  • Recombinant Factor VIII infusions, or
  • Clotting factor concentrate derived from blood

► Limitations of Current Products
  • Prophylactic therapy: ≈2-3X weekly Factor VIII infusions
  • Repeated infusions reduce patient quality of life
  • On demand treatment not sufficient to reduce joint effects
  • Poor compliance leads to increased bleeds ➔ joint damage
  • Many patients untreated
  • Expensive (>$200k/yr)

Goal of Sernova’s Cell Pouch with Factor VIII releasing cells:

Reduce/eliminate exogenous Factor VIII infusions

Maintain higher blood trough levels of Factor VIII

Reduce joint bleeds

Improve long-term efficacy

Improve QOL
Sernova Hemophilia A Therapeutic

$5B/yr Orphan indication for patients whose blood is missing a critical clotting agent

→ Patient population: Hemophilia A ≈20,000 NA/EU

→ Hemophilia Therapy: GMP Factor VIII Gene corrected cells transplanted into the Cell Pouch to maintain constant blood levels of Factor VIII

→ Therapeutic goals: Improved efficacy with prophylactic treatment; reduced cost; improved patient QOL; reduction of disease side effects

→ Development status:

  ➔ Horizon 2020 Producing a GMP autograft cell source for Cell Pouch, and formal preclinical Sernova to produce GMP allograft, immune protected cell source for Cell Pouch
Cell Pouch System™ Preclinical Overview

→ Manufacturing
  Cell Pouch™ contract manufactured in U.S. under GMP & ISO 13485 standards in a semi-automated process
  The Cell Pouch™ has completed and passed sterility testing
  The Cell Pouch™ is fully scalable and comes in multiple sizes for preclinical and clinical evaluation
  The Cell Pouch™ has successfully completed a 2-year package and product stability study

→ Biocompatibility
  Cell Pouch™ is biocompatible (all required ISO 10993 studies completed)
  - elution cytotoxicity test, guinea pig maximization test, intracutaneous maximization test, acute systemic injection test, USP rabbit pyrogen test, bacterial mutagenicity assay (Ames test), In vitro mouse lymphoma test, and a subchronic 30 day and 12 week subcutaneous implant study

→ Preclinical Safety
  Safety confirmed in 4 animal models: rodent, pig, non-human primate
  Long-term Cell Pouch implant/explant re-implant safety study

→ Preclinical Efficacy
  Efficacy Confirmed: isograft (rat, mouse), autograft (pig), allograft diabetes models (pigs)
  - Glucose control hormones demonstrated
  - Insulin independence for 100 days in independent assessment (Shapiro)

→ Local Immune Protection
  Encapsulated islets within the Cell Pouch™ shows islet survival, safety and efficacy
Preclinical Proof of Concept

Cell Pouch™ Islet Transplant Efficacy in Small Animals

(A) Severely diabetic animal. Cell Pouch™ & therapeutic cells transplanted. Achieve normal glucose level for 100 days and then device removed and animals return to diabetic state.

(B) Positive glucose tolerance test. Meaning: Sugar injected into the bloodstream is able to be removed. The insulin released from the Cell Pouch™ brings sugar levels back to the normal state.

Photograph of islets within the Cell Pouch™ after 100 days.
Red = insulin, Green = blood vessels, Blue = live cells

Conclusion: Proves safety & efficacy of islets within the Cell Pouch™ in small animals
A long-term large animal implantation study confirms development of stable vascularized tissue chambers for transplantation at the 12 months time point. Cell Pouch design does not result in fibrosis.
Porcine Diabetes Autograft Transplant: Proof of Safety and Efficacy

Cell Pouch™ Islet Transplant in Large Animals

Cell Pouch™ developed tissue chambers rich in micro-vessels for cell transplant

 Implanted Cell Pouch™ chamber ready for transplant

Sustained large animal efficacy

Sugar levels rise following Cell Pouch™ removal
Porcine Diabetes Autograft Transplant: Proof of Islet Survival and Function

Cell Pouch™ Islet Transplant in Large Animals

12 Weeks Post Cell Pouch™ and Islet Transplant

Healthy Islets in the Cell Pouch™ (purple);
Micro-vessels (red arrows)

Islets showing insulin (red) and supporting blood vessels (green)

Insulin and C-peptide co-localized. These images are the same section, showing co-localization of both insulin and C-peptide.
Porcine Diabetes Allograft Transplant: Proof of Islet Survival and Function

Marginal Islet dose 2,500 IEQ/kg;
Standard human islet transplant is 10,000 IEQ/kg

Insulin and C-peptide co-localize to the same area, therefore these images are the same section, showing co-localization of both insulin and C-peptide
Clinical Evaluation: Proof of Concept

First in Human pilot assessment conducted in subjects with hypoglycemia unawareness

“A Phase I/II Study of the Safety and Efficacy of Sernova’s Cell Pouch™ for Therapeutic Islet Transplantation”

Primary endpoint: Safety
Measures of Cell Pouch and islet safety are demonstrated

Safety successfully met for the Cell Pouch™
Cell Pouch histology assessed by independent pathologists
  Islets housed within a natural tissue matrix
  Islets are well vascularized
  Islet safety successfully met
  Islets show evidence of insulin, somatostatin, & glucagon
  No evidence of inflammatory reaction
  No evidence of immune destruction of transplanted islets
Cell Pouch™ Clinical Histology
Insulin staining islets with microvessels

β-cells
New Blood Vessels
No immune infiltration
Sernova: Next Steps

- The Cell Pouch™ is safe and efficacious in multiple preclinical models of diabetes

- In First in Human Clinical Assessment the Cell Pouch™
  - Is safe
  - Shows consistent islet vascularization
  - Islets show presence of glucose regulatory hormones in patients with hypoglycemia unawareness

- Next Steps
  - Human Islet Assessment
    - US FDA clinical study to assess safety, tolerability and efficacy of a of human islets within the Cell Pouch
    - Combination product: PMA

  - Complete Regenerative Medicine Diabetes Product
    - Cell Pouch™
    - Unlimited supply of cells (i.e. stem cells, porcine cells),
    - Locally protected with advanced micro-capsules
A Safety Tolerability and Efficacy Study of Sernova’s Cell Pouch for Clinical Islet Transplantation

JDRF-Sernova Collaboration

**Study design:** A U.S. prospective, single-arm study of islet transplantation into the Sernova Cell Pouch™ implanted subcutaneously. Islets will be transplanted into the Cell Pouch after Cell Pouch implantation and stable immunosuppressive activity

**Primary Objective:** To demonstrate the safety and tolerability of islet transplantation into the Cell Pouch™ for the treatment of T1D

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

**Status:** Anticipated initiation 2017
Achieving a Complete Solution for People with Chronic Diseases

- Implantable therapeutic device (Cell Pouch)
- Unlimited supply of glucose responsive cells
- Local immune protection of cells

Micro-encapsulated Islets/Cells in the Cell Pouch™
Immune Protection: Microencapsulation

- The Cell Pouch™ is an implantable scalable device consistently shown capable of housing islets within a natural tissue matrix supported by microvessels.

- Microencapsulated cells are housed in a polymer sphere with pores to keep out immune cells but allowing flow of nutrients and insulin.

- Microvessels within the Cell Pouch™ associate with encapsulated cells.

- This approach is expected to reduce or eliminate the need for antirejection drugs, and provide a safe environment for unlimited sources of cells.

- Preclinical Safety, encapsulated islet survival and efficacy have been shown in a large animal immune competent diabetes model within the Cell Pouch™.

Sernova Secures Exclusive Worldwide Commercial Rights to Proprietary Stem Cell Derived Technologies

- Agreement with the University Health Network of Toronto (UHN) to gain exclusive access to worldwide rights for the advancement of stem cell derived insulin-producing glucose responsive cells for the treatment of patients with insulin-dependent diabetes

- UHN agreement transitions Sernova to an integrated therapeutic cell regenerative medicine Company

- Sernova has access to the full complement of UHN Stem Cell technologies necessary to develop an advanced cell-based treatment for the millions of people who have insulin-dependent diabetes based on these cells, Sernova’s Cell Pouch and local immune protection with microencapsulation

- **Status:** Agreement with CCRM (Canadian Center for Regenerative Medicine) to conduct tech transfer, optimize cell production process and produce cells for testing within the Cell Pouch.

  - Robust cell production process has been developed where cells consistently reach or exceed release criteria
Why Invest in Sernova?

→ Robust international device and therapeutic cell patent portfolio which includes U.S. and foreign patents – key to pharma licensing deals

→ Total regenerative medicine solution: Cell Pouch; cells; local immune protection

→ Sernova is the only regenerative medicine company with a disruptive technology with multi billion dollar market potential for each of its clinical indications

→ Diabetes
  ➤ Key diabetes preclinical safety and efficacy islet therapy treatment with confirmatory human clinical data; key FDA human clinical study in preparation
  ➤ Sernova licensed and initiated development work for its stem cell derived diabetes cell program for diabetes to provide an unlimited source of cells for >40M diabetic patients
  ➤ Early M&A Potential - Potential for multiple licensing deals for Cell Pouch/ insulin producing cell technologies

→ Hemophilia
  ➤ Hemophilia EU Consortium Program for Cell Pouch (successful Horizon 2020 funding; $8.5M CDN); non-dilutive funding funds preclinical development in preparation for clinical trials; Licensing opportunity for Hemophilia allograft product

→ Management
  ➤ Experienced management w/ a track record of deals and buyouts w/ large pharma companies

→ Multiple near term valuation driver catalysts
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