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LIFE NEVER STOPS MOVING FORWARD. NEITHER DO WE.

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Our Mission: CREATING A FUNCTIONAL CURE FOR TYPE 1 DIABETES



OVERVIEW

- U.S. / Canada based (TSX:SVA). Nasdaq uplist planned
- Lead program; human donor islet type 1 diabetes phase I / 2 study
 - Cohort A complete, 6 of 6 patients reached insulin independence!
 - Data on >4 years of patient insulin independence
 - Data on islet cell survival and function >5 years
 - Cohort B near complete, Cohort C planned 2025
 - Initiate iPSC islet clinical program 2026

- Partnered with Evotec and exclusive rights to iPSC islet like clusters
 - Positive pre-clinical data
 - Preparing for clinical trial 2026



 Signed LOI with GoldTrack Ventures and Kingdom of Saudi Arabia to fund T1D program

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OUR FOCUS

Type 1 Diabetes



OUR FOCUS – TYPE 1 DIABETES (T1D)

How insulin, glucagon, and somatostatin work to regulate blood glucose



Insulin: lowers blood glucose levels by helping glucose enter cells. The pancreas produces insulin in beta cells.



Glucagon: raises blood glucose levels by breaking down glycogen into glucose in the liver. The pancreas releases glucagon when blood sugar levels drop. The pancreas produces glucagon in alpha cells.



Somatostatin: balances insulin and glucagon by suppressing the release of both hormones. The pancreas produces somatostatin in delta cells.





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What's the **Problem?**



THE REALITIES OF T1D

- **~9 Million** T1D patients worldwide
- An estimated **40,000 people are diagnosed** with T1D in the US each year
- **182K people die** each year from T1D in US
- **35,000 deaths** annually are non-diagnosed people under 25.
- Patients have ~4,000 finger sticks / yr to check blood sugar
- Patients make >200 decisions per day re T1D care

CURRENT T1D TREATMENT

Lacks full hormonal control - insulin only, no glucagon or somatostatin, highly complex and psychologically burdensome:

- Strict blood glucose monitoring via continuous glucose monitors (CGMs) or blood glucose monitor.
- Multiple daily insulin injections or pump usage
- Dietary adjustments
- Constant vigilance against hypoglycemia (severe low blood sugar)



MORE THAN JUST A PANCREAS PROBLEM WITH MANY CO-MORBIDITIES

1 IN 10 DIE OF SEVERE HYPOGLYCEMIA





What's the Solution?



CELL POUCH™ BIO-HYBRID ORGAN

Restoring Function. Liberating Patients.

- Complete containment & retrievability
- Proven clinical safety and efficacy
- Thin, flexible, & credit-card-sized
- Made from biocompatible medical-grade surgical mesh
- Vascularized tissue environment facilitates long-term cell survival & function





Patient with insulin-dependent diabetes meets with endocrinologist and decide together that the Cell Pouch System/ILC combination is a good option for the patient. The Cell Pouch System is ordered for type 1 diabetes. General surgeon implants the Cell Pouch beneath the skin of the abdomen and patient goes home the next day to allow approximately 6 weeks for the body to develop an ideal environment for the islets.



Blood sugar controlled by new transplant islets. Patient tapers off insulin and potentially becomes insulin free.



Islet clusters are then transplanted into the Cell Pouch by surgeon in a short procedure.



A NEW WAY TO TREAT T1D. A FUNCTIONAL CURE.

Our unique fully retrievable Cell Pouch[™] Bio-Hybrid Organ works to restore the body's normal function and hormonal cycle control, so that patients with type 1 diabetes can focus on what matters most:

LIVING THEIR LIVES!



PRE-IMPLANT

- Implantable porous surgical mesh
- PTFE rods allow creation of cell chambers prior to removal after vascularization ~4-6 weeks
- Followed by impregnation with islet cells



POST REMOVAL - 5 YRS

- Patient insulin independent >4.5 yrs
- Simple surgical retrieval due to unrelated health issues 5 years after implantation
- Abundant islets producing insulin, glucagon, & somatostatin
- No fibrosis and full structural integrity maintained

FUNCTIONAL ISLETS THROUGHOUT CELL POUCH <u>>5 YEARS</u> FOLLOWING TRANSPLANTATION:

Cohort A; Patient 1

8 CHANNEL CELL POUCH TISSUE CHAMBERS:







- Positive immunofluorescent staining for Insulin, and vonWillebrand Factor (blood vessels), Glucagon & Somatostatin
- Rich vascularization of abundant insulin-producing cells and no evidence of detrimental fibrotic tissue

COMPARISON OF HUMAN ISLETS TO CELL POUCH BIO-HYBRID ORGAN ISLETS

Islets Residing In Cell Pouch For >5 Years Have Similar Appearance and Expression as Islets Residing In Native Pancreas



CLINICAL PATIENT

Islets in Cell Pouch explanted
 >5 years after transplant

HEALTHY HUMAN PANCREAS



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Does It Work?

Phase 1 / 2 Clinical Trial Summary

PHASE 1 / 2 ADAPTIVE TRIAL



After having T1D for more than 47 years, I can easily state how absolutely wonderful life is, to be free of always thinking of how to manage my diabetes....My only wish is that it could have been done sooner!

-Cohort A, Patient 1

INSULIN INDEPENDENCE ACHIEVED:

Cohort A

- 6 of 6 patients receiving islet transplants to Cell Pouch + PV top up achieved insulin independence ranging from 18 months to >4 years
- Patient 1 Cell Pouch provides organ like environment for functioning Islets > 5 years
- All patients achieved HbA1C in the non-diabetic range i.e., $\leq 6.5\%$
- Determined optimal islet dose and density led to larger Cell Pouch

Cohort B

- 10 vs 8 chambers Cell Pouch
- Designed to evaluate varied immune suppression regimens
- Trial ongoing

Cohort C

Combined findings from A & B

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

INSULIN INDEPENDENCE ACHIEVED IN 6 OF 6 PATIENTS, COHORT A

Clinical POC that Cell Pouch supports the engraftment & therapeutic function of transplanted cells.



1. Islet dose required to achieve insulin independence has been determined

2. More islets administered via the Cell Pouch, the fewer required in the portal vein

POSITIVE GLUCOSE CONTROL IN THE NON-DIABETIC RANGE FOR ALL SUBJECTS

Sernova T1D Phase 1/2 Human Donor Islet Study - Cohort A

- 6 of 6 Patients Discontinued Insulin Therapy
- All Patients Achieved or Maintained HbA1c Values In The Non-diabetic Range (≤6.5%)



HbA1c – A Measure of Average Blood Glucose over Prior 90 Days

Epidemiologic Analysis Studies Demonstrate That Each 1% Reduction In A1C Was Associated With A 14% Reduced Risk Of Myocardial Infarction



PARTNERSHIPS & THE FUTURE







- Using Good Manufacturing Practices, the iPSCs are differentiated (developed) into the target pancreatic islet-like clusters.
- Controlled freezing (cryopreservation),
 essential for making cells commercially viable on a large scale.
 Extensive quality control.



- Thawing of cells to patient-ready form.
 Additional assurance that cells meet the rigorous standards set forth for cells to be transplanted into patient.
- - Storage or shipment of islet clusters (frozen).



5 Temperature-controlled shipping for patient transplant.

6 The patient



PARTNERING:

RESTORING THE BALANCE

Working in partnership with Evotec, we combine our Cell Pouch Bio-Hybrid Organ with induced pluripotent stem cells (iPSC) that have been converted from non-embryonic donor-derived cells to create islet-like clusters that closely mimic human pancreatic islet cells. The combination product is set to be the first treatment of its kind to reach clinical testing for T1D.

IPSC-DERIVED ISLET-LIKE CLUSTERS HAVE LONG-TERM NON-DIABETIC EFFICACY

Robust, Durable Normalization of Glycaemic Control in Diabetic Mice



- Evotec developed scalable, GMP-compatible process for ILC manufacturing from a GMP iPSC line
- Drug product with completed endocrine differentiation and optimized beta cell fraction
- IPSC's secrete Insulin, Glucagon and Somatostatin

Efficient Normalization of Random Fed Glucose



HIGH FRACTION OF INSULIN-PRODUCING BETA CELLS IN IPSC ISLETS

HISTOLOGICAL GRAFT ANALYSIS Preclinical murine model 32 weeks postimplantation

- Abundant endocrine cells with high beta cell fraction detectable
- Cell Pouch provides organ like environment for cell survival
- Excellent intra-graft vascularization, likely contributing to strong graft functionality



WE ENVISION A BETTER WAY FORWARD BY GIVING PATIENTS THEIR LIVES BACK!

Thank You

Cell Pouch + therapeutic islet cells = Bio-Hybrid Organ



Demonstrated long-term survival (over 5 years) of islets in an implanted Cell Pouch Bio-Hybrid Organ



Bio-Hybrid Organ has been shown to be well tolerated with a favorable safety profile



Insulin independence achieved in all patients in Cohort A

