SVA.TO

Giving Patients Their Lives Back!

Approaching Regenerative Medicine From a New Angle

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PIONEERING FUNCTIONAL CURES FOR CHRONIC DISEASES

Cell Pouch™ Transplant System

- A flexible, implantable cell containment system filled with therapeutic cells
  - Human Donor Cells
  - iPSC Islet Clusters with partner Evotec
- Creates a vascularized, organ-like environment
- Cells sustainably produce missing therapeutic proteins or hormones

Product Portfolio

- Lead program: Phase I/II insulin-dependent diabetes (T1D) ongoing
  - Insulin-producing cells in-implanted Cell Pouch™
  - A potential Functional Cure for Type 1 diabetes
- Pre-clinical programs in thyroid disease and hemophilia

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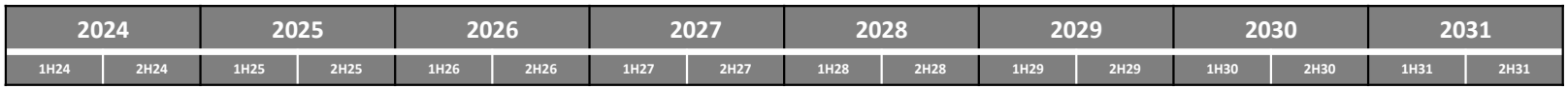
CELL POUCH TRANSPLANT SYSTEM™ PIPELINE

PMA – Premarket Authorization (US)
BLA – Biologics License Application (US)
MAA – Market Authorization Application (EU, CA)

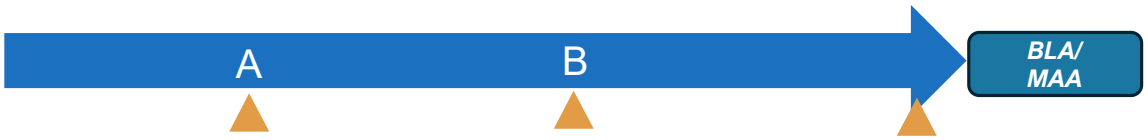


Cell Pouch + HDIs
(Donor Islets + Systemic Immunosuppression)

Cell Pouch + EVT3101
(iPSC-derived islets + Systemic Immunosuppression)

evotec

Cell Pouch + Thyroid
(Autotransplant during thyroidectomy)



1	2	3	4	5	6	7	8	9	10
Initiate COHORT C	Complete COHORT B	Complete COHORT C	Phase III (Optional)	Cell Pouch PMA (Optional)	Process Lock iPSC-ILC Mfg	Complete Preclinical	Initiate PI/II iPSC-ILC Trial	Interim Phase I/II Data	Initiate PIII iPSC-ILC Trial

A	B
Initiate PI/II Thyroid Trial	Initiate PIII Thyroid Trial

▲ Value Inflection and Financing Opportunity

Ongoing engagement with potential M&A

LEAD PROGRAM TYPE 1 DIABETES

Let's be Honest - The Clinical Need is Nowhere Near Met!

- **HEART DISEASE**:
Including coronary artery disease, heart failure, and cardiomyopathy.

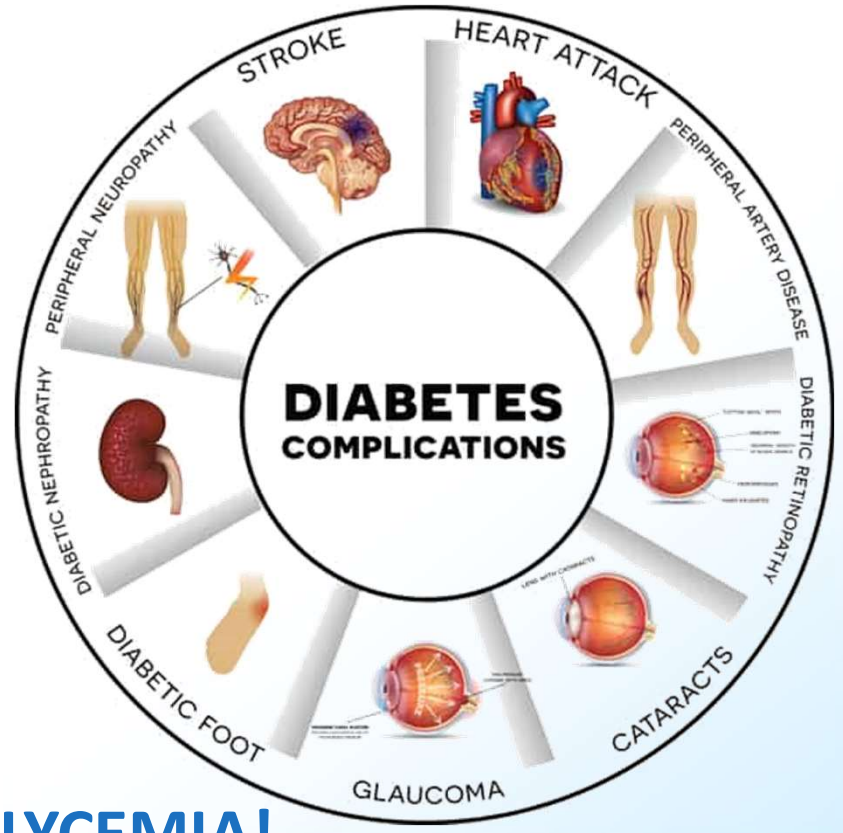
- **KIDNEY DISEASE**:
damage to kidneys, leading to end-stage renal disease (ESRD) and transplantation or dialysis

- **NEUROPATHY:**
damage nerves over time, leading to peripheral diabetic neuropathy (PDN).

- **EYE PROBLEMS**:
retinopathy, macular edema, and cataracts.

- **FOOT PROBLEMS:**
diabetic foot diseases, including foot ulcers and amputations.

- **STROKE**:
Increase the risk of stroke.



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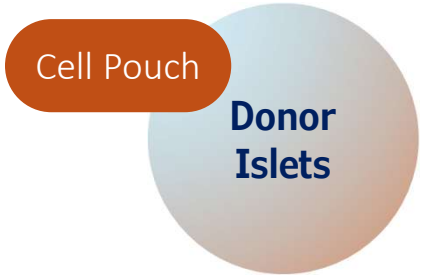
1 IN 10 DIE OF SEVERE HYPOGLYCEMIA!

DEVELOPING A FUNCTIONAL CURE FOR TYPE 1 DIABETES

Evolution of program built to expand the treatable patient population

1 Cell Pouch + Donor Islets
Phase 1/2 Ongoing



- Insulin-dependent T1D patients with history of severe hypoglycemic episodes
- Insulin independence observed
- Cohort A complete, Cohort B ongoing, optimized dose, islet density and immune suppression. Cohort C initiate Q4 2024

2 Cell Pouch + iPSC ILC's
Phase 1/2 Planning Underway

- Broad T1D population
- ILCs in unlimited and consistent supply
- Pre-clinical performance in animal models (donor islets =/≈ ILCs) complete
- ILCs are cryopreserved for improved commercial logistics, providing competitive advantage

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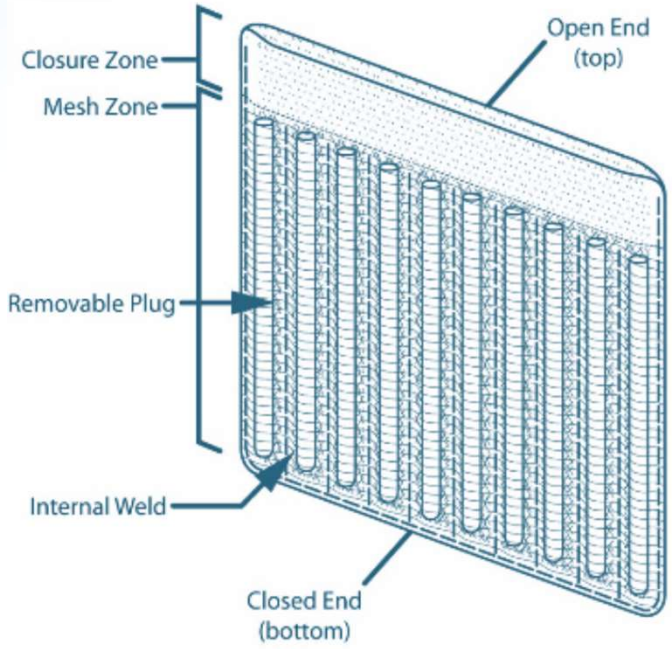
CELL POUCH

A Cell Transplant Delivery System

POSITIVE CLINICAL OUTCOMES PAIRED WITH PRECLINICAL SAFETY AND EFFICACY IN ESTABLISHED MODELS OF CHRONIC DISEASES



SAFETY & EFFICACY

Preclinical and Clinical studies of cell and tissue transplantation have demonstrated safety and efficacy in multiple chronic diseases

FUNCTIONAL SUPPORT FOR ISLET GRAFTS

Facilitates islet vascularization and tissue matrix essential for islet function and glucose homeostasis in patients with type 1 diabetes

COMPLETE CONTAINMENT & RETRIEVABILITY

Provides complete containment *and* retrievability of therapeutic cells in the event of a quality or safety issue with the cell product

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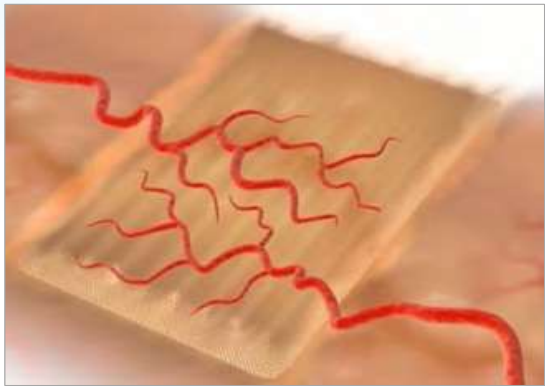
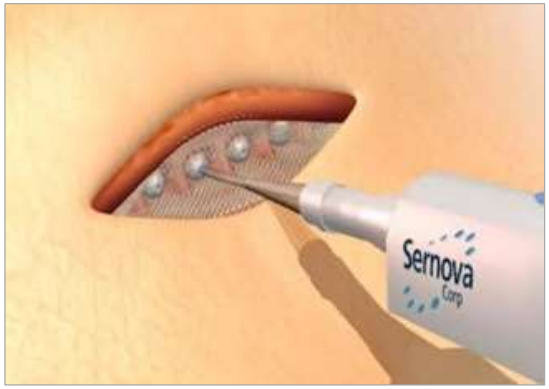
HOW IT WORKS CELL POUCH PROVIDES AN ORGAN-LIKE ENVIRONMENT FOR FUNCTIONAL CELLS

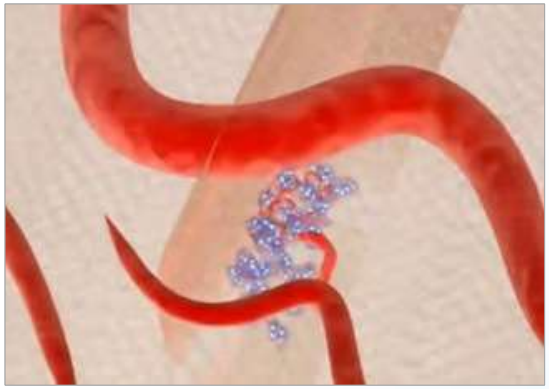
THE VASCULARIZED TISSUE CHAMBERS ALLOW OPTIMAL ENGRAFTMENT AND SUPPORT THE LONG-TERM SURVIVAL AND FUNCTION OF TRANSPLANTED THERAPEUTIC CELLS



Cell Pouch placed deep under the skin, promoting development of vascularized tissue chambers that support long-term survival and function of therapeutic cells



Therapeutic cells introduced into the vascularized tissue chambers enabling effective engraftment within the native tissue matrix



Therapeutic cells responsive to endogenous regulation to correct biological dysfunctions by producing missing proteins or hormones

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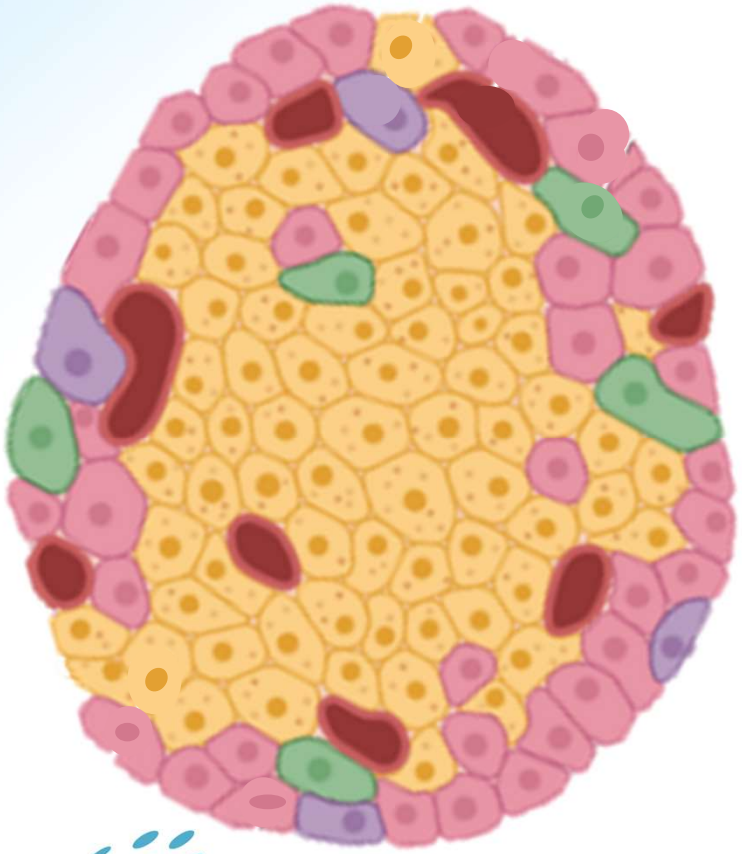
PANCREATIC ISLET OF LANGERHANS CELLS non-diabetic



Islet cells of the pancreas are composed of various cells, including beta, alpha, and delta. These cells produce hormones (e.g., insulin and glucagon) that are secreted into the bloodstream and help control the level of glucose (sugar) in the blood.

Alpha Cells
(20- 30%)

Secrete **glucagon** to raise blood glucose.

Beta Cells
(50 -70%)

Secrete **insulin** to lower blood glucose.

Delta Cells
(10%)

Secrete **somatostatin** to lower insulin and glucagon

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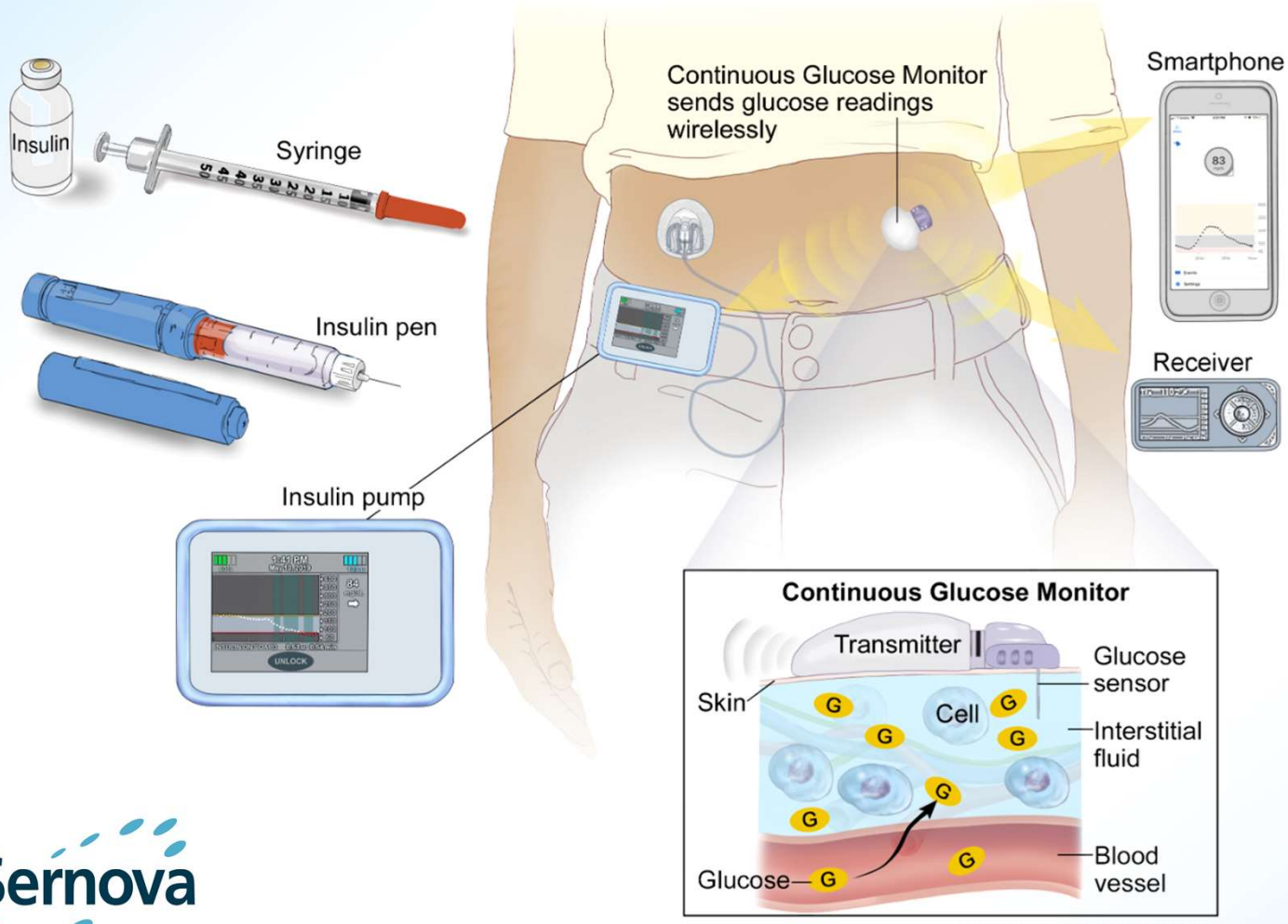
CURRENT TREATMENT Lacks Hormonal Control Cycle



- ✓ Insulin
- ✗ Glucagon
- ✗ Somatostatin

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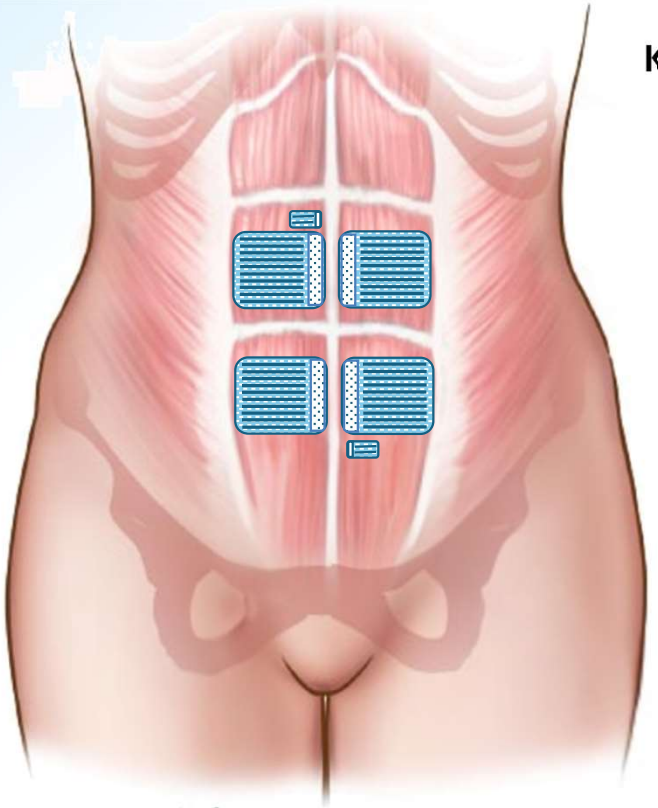
PHASE 1/2 T1D MULTI-COHORT TRIAL DESIGN



Key Patient Inclusion Criteria

1. Type 1 diabetes
2. Onset <40 years of age
   a) Insulin dependent ≥5 years
3. Recent history of severe hypoglycemic episodes
4. Impaired awareness of hypoglycemia
5. No stimulated C-peptide in response to mixed meal tolerance test (MMTT)
6. Undergoing intensive diabetes management
   a) Self-monitoring of glucose values ≥3 times per day
   b) Insulin administration ≥3 times per day or insulin pump
   c) Under care of endocrinologist, diabetologist or diabetes specialist

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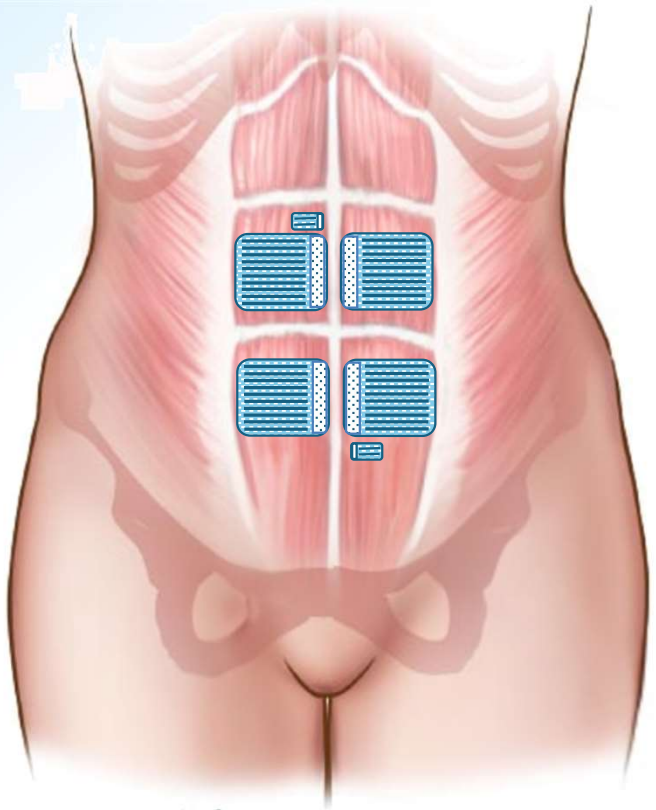
PHASE 1/2 T1D MULTI-COHORT TRIAL DESIGN



COHORT A (n=6)

- **Enrollment Completed**
- 8-Channel Cell Pouch
- Cell Pouch Placement - Subfascial
  - Below umbilicus (4)
- 180-day post-Tx1 evaluation
- Immunosuppression

COHORT B (n=10)

- **7 of 10 Recruited**
- 10-Channel Cell Pouch (>50% greater capacity vs. 8-channel)
- Cell Pouch Placement - Subfascial
  - Above (2) & below (2) umbilicus
- 90-day post-Tx1 evaluation
- Immunosuppression

Day 0	Week 3	Week 6	Months 5 to 6	Month 12
Cell Pouch Implants	Immunosuppression Initiation	Purified Islets Transplanted into Cell Pouch (Tx1)	Purified Islets Transplanted into Cell Pouch (Tx2)	Supplemental dose if required
Day 0	Week 3	Week 6	90 Days Post-Tx1	180 days Post-Tx2

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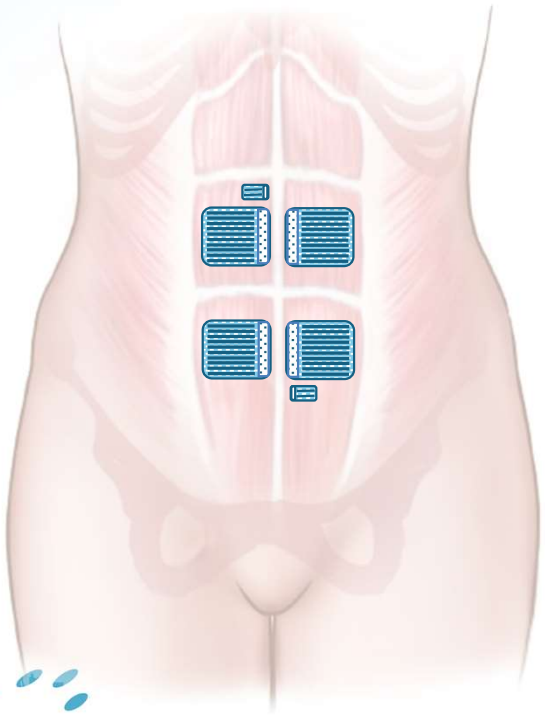
COHORT A - ADAPTIVE TRIAL

INSULIN INDEPENDENCE HAS BEEN ACHIEVED!



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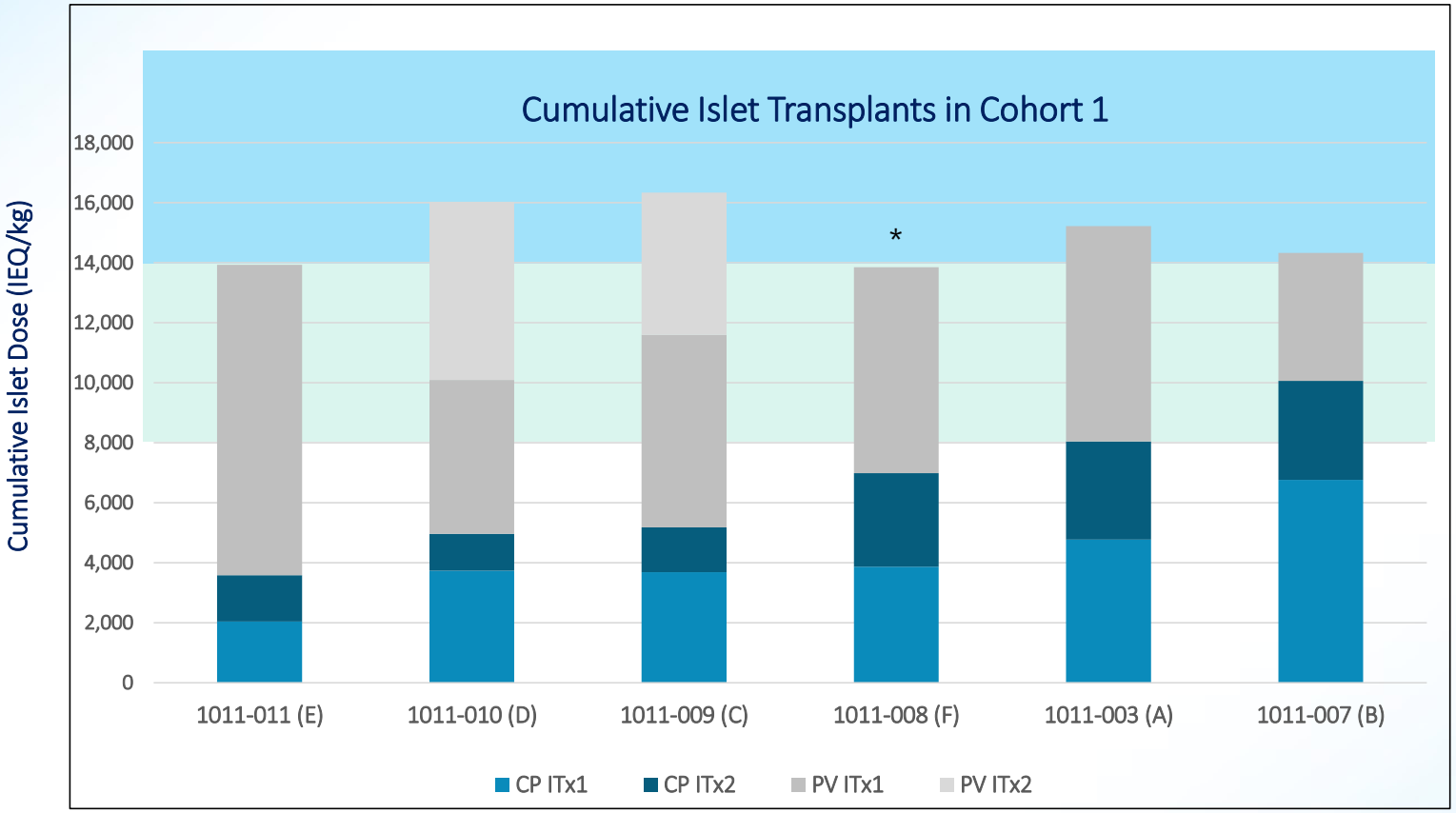
RESULTS

- **5 of 6 patients** receiving 2 islet Txs to Cell Pouch + IP Txs achieved **insulin independence with durations ranging from 9 months to more than 4 years**
- Determined **optimal islet dose and density** for Cell Pouch
- **Positive stimulated serum C-peptide** in 3/6 patients, but
- **Antibody Mediated Rejection (AMR)** in remaining 3
- De novo DSA/AMR drove **adjustments in maintenance immunosuppression**

Insulin Independence Achieved in 5 of 6 Patients, Cohort A

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

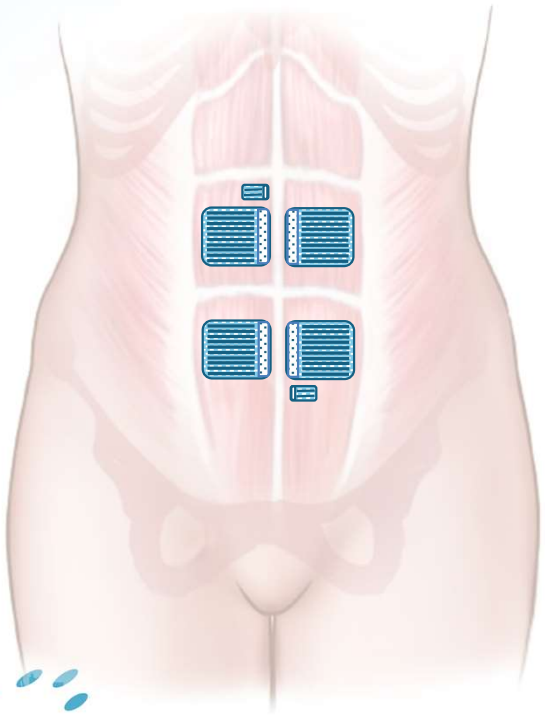


1. **Islet dose required to achieve insulin independence has been determined**
2. **More islets administered via the Cell Pouch, the fewer required in the portal vein**

*Following portal vein islet transplant, graft function remains sub-optimal for Patient "F", only - Insulin therapy reduced but ongoing

CP – Cell Pouch PV – Portal Vein ITx – Islet Transplant

COHORT B - ADAPTIVE TRIAL



INSULIN INDEPENDENCE
HAS BEEN ACHIEVED!

RESULTS

Pts With Target Immunosuppression Regimen:

- **Patient A:** - Severe neutropenia
  - Reduced -> D/C'd immunosuppression
- **Patient B:** - **Positive fasting c-peptide**
  - **Insulin independent with 1 Tx to Cell Pouch and <4900 IEQ/kg IP Tx**

Pts With Reduced Immunosuppression Regimen:

- **Patient C, D, E & F:** no detectable c-peptide
- **Patient E:** DSA

Pts With Optimized Immunosuppression Regimen:

- **Patient G:** - **Recently enrolled**
  - **Awaiting pancreas for 1st Tx to Cell Pouch**

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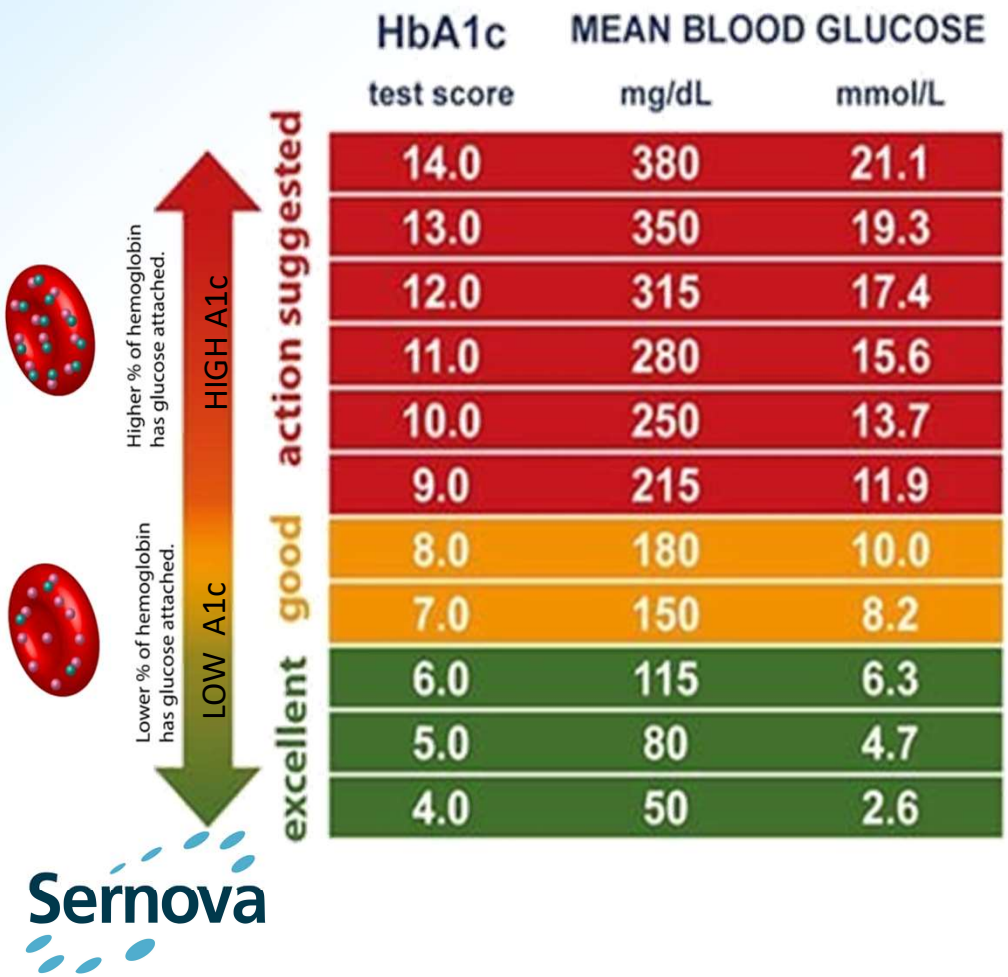
HEMOGLOBIN A1C (HbA1c)

Amount of sugar attached to hemoglobin protein in red blood cells. The more sugar that sticks to the hemoglobin, the higher the A1c.



HbA1c test score	MEAN BLOOD GLUCOSE mg/dL	mmol/L
14.0	380	21.1
13.0	350	19.3
12.0	315	17.4
11.0	280	15.6
10.0	250	13.7
9.0	215	11.9
8.0	180	10.0
7.0	150	8.2
6.0	115	6.3
5.0	80	4.7
4.0	50	2.6

High A1c level higher risk of developing diabetes-related complications like heart disease, stroke, nerve damage and kidney disease.

Good blood glucose control and reducing the A1c (even by one percent) are directly related to lowering the risk of complications associated with diabetes.

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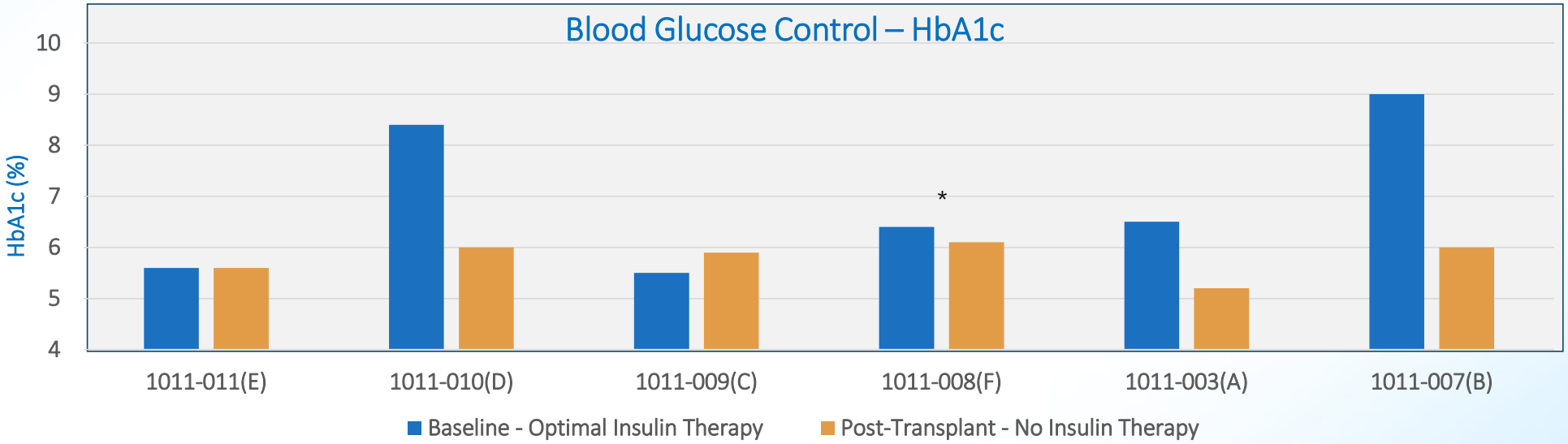
GLUCOSE CONTROL IN THE NON-DIABETIC RANGE FOR ALL SUBJECTS

Sernova T1D Phase 1/2 human donor islet study - Cohort A

- 5 Of 6 Patients Discontinued Insulin Therapy
- All Patients Achieved Hba1c Values In The Non-diabetic Range (≤6.5%)[1]



Epidemiologic Analysis Of The UK Prospective Diabetes Study (UKPDS) Data Demonstrates That Each 1% Reduction In A1C Was Associated With A 14% Reduced Risk Of Myocardial Infarction

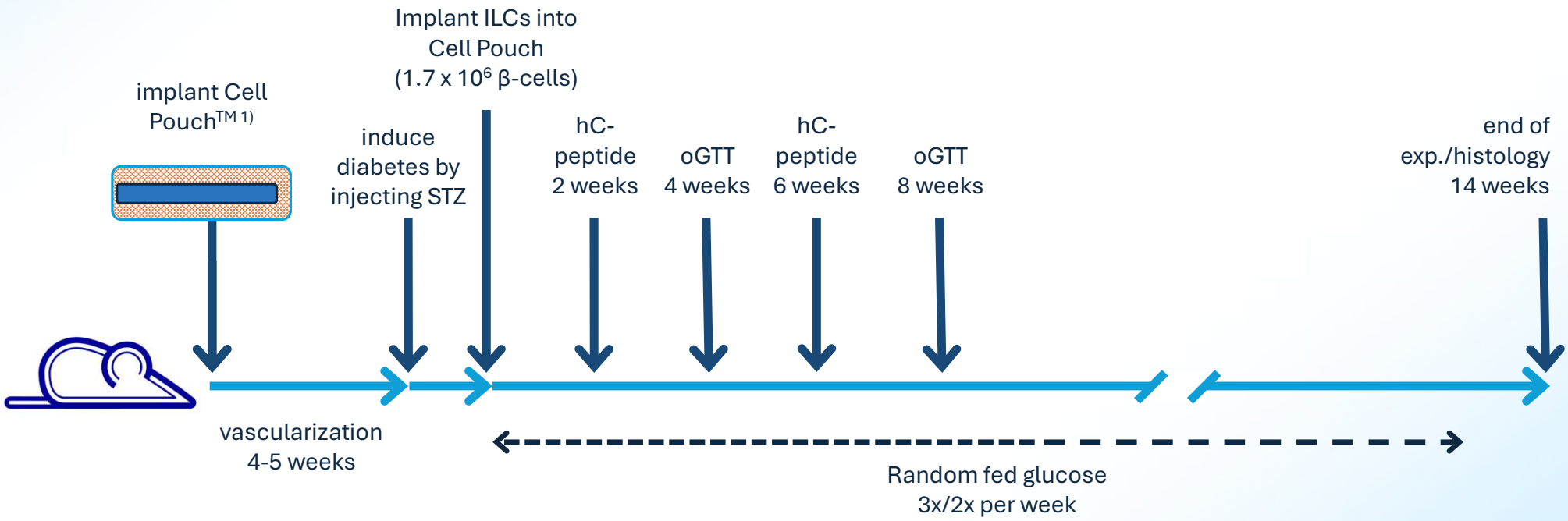
*Following portal vein islet transplant, graft function remains sub-optimal for Patient "F", only - Insulin therapy reduced but ongoing

[1]American Diabetes Association https://diabetes.org/about-diabetes/

Partnering to Give Patients Their Lives Back!

Developed iPSC Derived Islet like Clusters (ILCs)

TESTING ILC + CELL POUCH™ COMBINATION IN DIABETIC MICE



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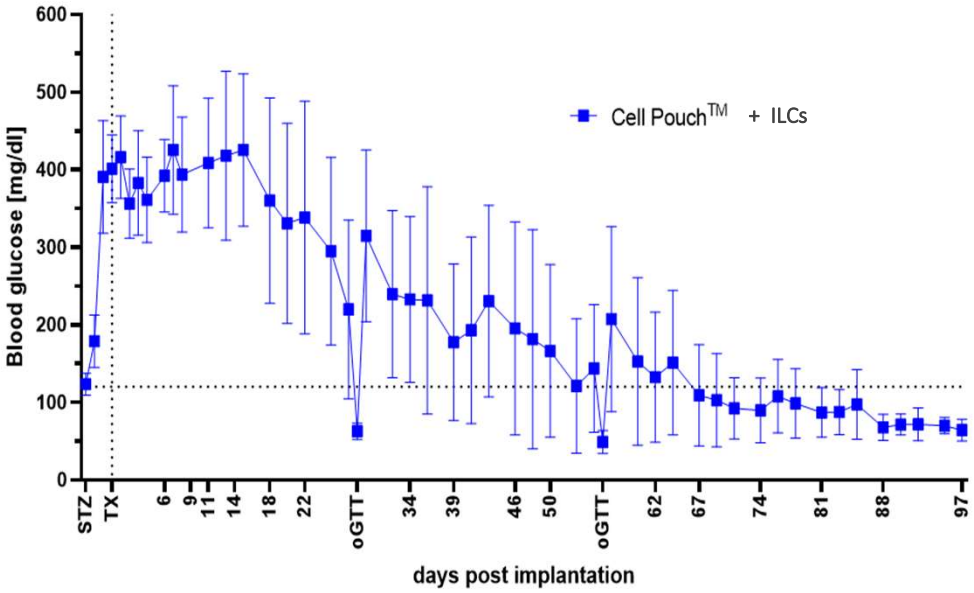
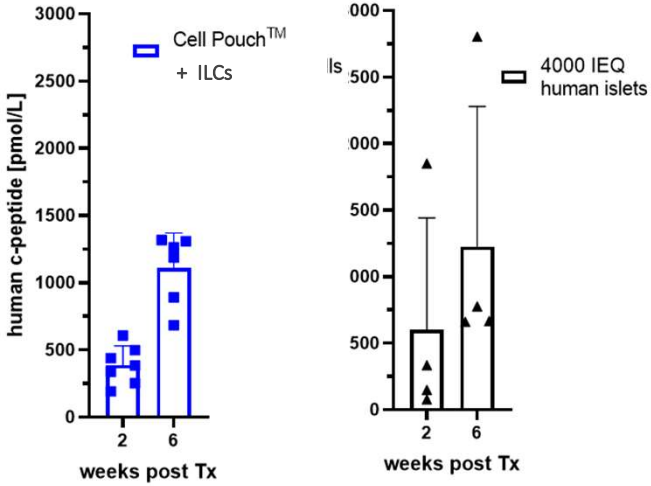
EXCELLENT ANTI-DIABETIC ACTIVITY OF ILCS IN THE CELL POUCH

Rapid normalization of glycaemic control with human islet-like

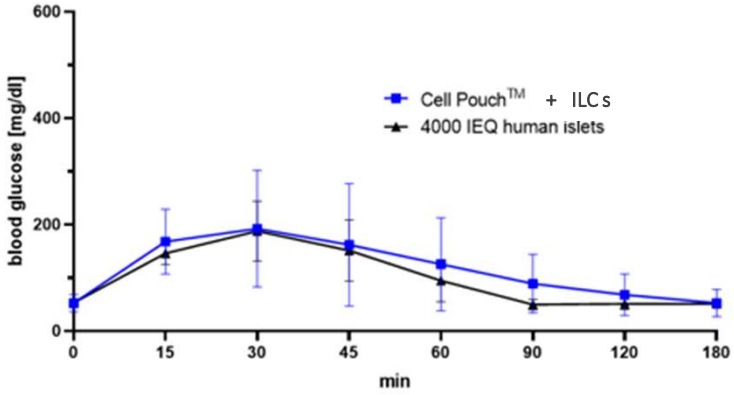
Efficient normalization of random fed glucose



Robust circulating hC-peptide levels



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



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1 https://sernova.com/

T1D COHORT A PATIENT – *Giving Patients their Lives Back!*

*"After entering the safety, tolerability and efficacy study of Sernova's Cell Pouch for clinical islet transplantation and as the first transplant candidate, I can easily state how **absolutely wonderful** life is, to be free of always thinking of how to manage my diabetes.*

After having T1D for 47 years with approximately 21,535 injections of various cow/pig, synthetic insulins, 34,310 finger sticks, 1,460 urine tests, 15 years on the pump, carbohydrate counting, blood tests, low blood sugar reactions, and doctors…doctors and more doctors' visits, I have now been free of the need for injectable insulin for 15 months.*

My only wish is that it could have been done sooner."

*Cohort A, Patient 1 – June 2021, went on to be **Insulin Independent for >4 Years***

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*Insulin independent for 4 years as of April 2024
Note: Above quote is from a single patient and may not be indicative of the experience of all patients now or in the future.