



#### **Sernova and Evotec**

Partnership and Licensing Option Agreement iPSC-Based Beta Cell Replacement Therapy for Insulin-Dependent Diabetes





SERNOVA FORWARD-LOOKING

#### **STATEMENTS**

This presentation contains forward-looking statements within the meaning of applicable Canadian securities laws. Forward-looking statements in this presentation are statements that are not historical facts and are generally, but not always, identified by the words "expects", "plans", "anticipates", "believes", "intends", "estimates", "projects", "potential" and similar expressions, or that events or conditions "will", "would", "may", "could" or "should" occur. Forward-looking statements include statements about subsequent clinical activity, including enrolment of patients and continuing results therefrom, and the potential benefits, safety and efficacy of the Cell Pouch for various indications, including type 1 diabetes (T1D).

While Sernova considers these assumptions to be reasonable, these assumptions are inherently subject to significant scientific, business, economic, competitive, market and social uncertainties and contingencies. Additionally, there are known and unknown risk factors that could cause Sernova's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained in this presentation. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. Readers should not place undue reliance on these statements, or the scientific data presented and should refer to the risk factors identified in the company's continuous disclosure filed on SEDAR.com. Sernova expressly disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.





**EVOTEC FORWARD-LOOKING** 

#### **STATEMENTS**

Information set forth in this presentation contains forward-looking statements, which involve a number of risks and uncertainties. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate", "believe", "could", "estimate", "expect", "goal", "intend", "look forward to", "may", "plan", "potential", "predict", "project", "should", "will", "would" and similar expressions. The forward-looking statements contained herein represent the judgement of Evotec as of the date of this presentation. Such forward-looking statements are neither promises nor guarantees but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based. Given these risks, uncertainties, and other factors, you should not place undue reliance on these forward-looking statements.



#### **Partnership Highlights and Terms**



- Sernova has acquired an option for an exclusive global license to Evotec's Induced Pluripotent Stem Cell (iPSC)-based human beta cells for use with its Cell Pouch System to treat insulin-dependent diabetes
- Provides Sernova access to unlimited supply of insulin-producing islet cells, removing the major obstacle
  to commercialization of Cell Pouch given current supply constraints of human donor islets
- Evotec making €20M / CAD \$27M equity investment in Sernova
  - €15M / CAD \$20M at CAD \$1.57 per share (closing price on May 16, 2022)
  - €5M / CAD \$7M by August 31, 2022 at CAD \$2.50 per share, or earlier if 5-day VWAP hits CAD \$2.50
  - Equates to ~6% equity position in Sernova
- Preclinical development program(s) will be co-developed until IND
- Evotec will manufacture the cells through commercialization
- IND anticipated in early 2024
  - Sernova has right to exercise its option for an exclusive global license upon IND filing
  - Sernova will owe undisclosed milestone payments upon license option exercise and upon first patient dosed
- Evotec has an option for joint funding of clinical development with a profit-sharing participation upon commercialization



#### Strong Strategic Fit to Advance Potential 'Functional Cure' for Diabetes



Partnership and licensing option agreement to enable a potential 'functional cure' for insulin-dependent diabetes without supply constraints

#### Cell Pouch System<sup>™</sup>

- Implantable medical device / immune protected cells
- Provides vascularized environment for cells
- Survive for long periods of time

   creating an organ-like
   environment
- Strong patent portfolio and IP
- Scalable, retrievable
- Phase 1 / 2 clinical data in-hand



- iPSC-based islet-like clusters mimicking human islet cells
- Includes insulin producing beta cells but also other hormone producing cell types (e.g. glucagon, somatostatin)
- Long-term function in rodent models of diabetes demonstrated
- Scalable manufacturing

Creating an off-the-shelf iPSC-based beta cell replacement therapy as a potential 'functional cure' for insulindependent diabetes



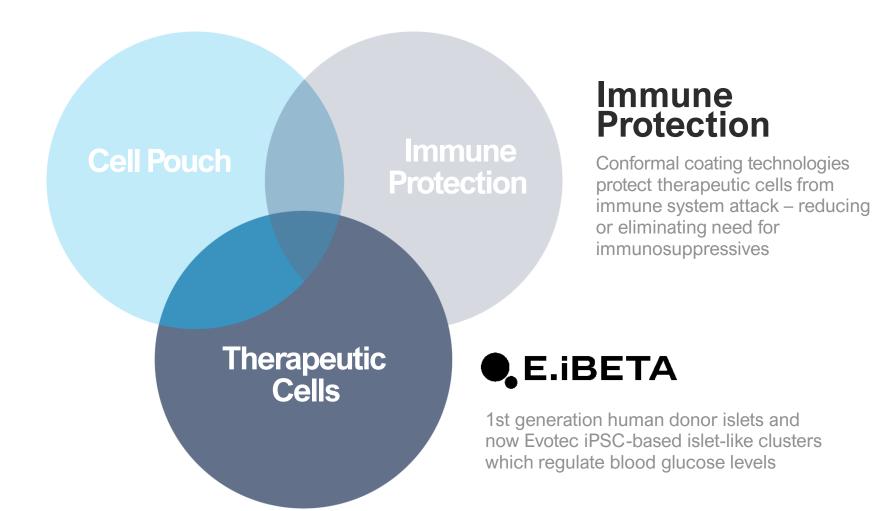
### Platform Approach: Finding 'Functional Cure' for Chronic Diseases



Integrated Regenerative Medicine Solution for Treatment of Chronic Diseases

#### **Cell Pouch**

Proprietary scalable, implantable medical device that provides vascularized environment for therapeutic cells to survive for long periods of time – creating an organ-like environment

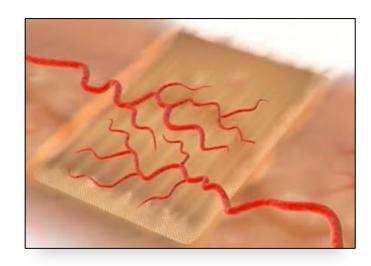




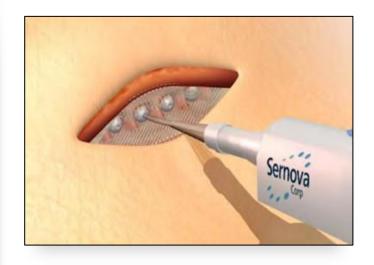


#### **Cell Pouch Containing Therapeutic Cells**

#### Biologically compatible delivery process – allows natural vascularization



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



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



Therapeutic cells are responsive to endogenous regulation and release missing proteins or hormones into the bloodstream to correct biological dysfunction



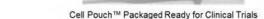
Manufactured GMP in a clean

#### **Cell Pouch GMP Manufacturing**

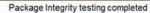


- GMP manufacturing of Cell Pouch is performed by an FDA-inspected US-based contract manufacturer
- All Cell Pouch configurations are produced in a Class VII Clean Room
- Product and process development is conducted in accordance with manufacturer's inspected and certified **Quality System** 
  - Established 2-year shelf-life based on real-time stability testing
  - Package integrity and ship testing completed











ISO 13485



**EU Medical Devices Regulation MDR 2017/745** 

**Canadian Medical Device Regulation (CMDR)** 

US FDA Quality System Regulations (QSR) 21 CFR 820





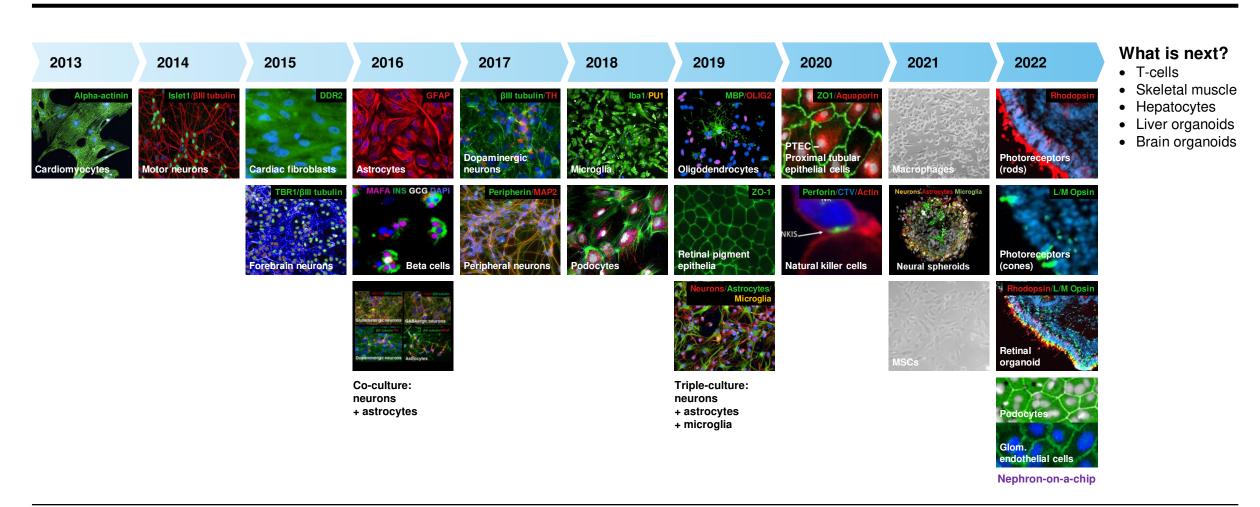
## Best-in-class, off-the-shelf human beta cells replacement therapy

iPSC-based human beta cells in unlimited supply



#### World-leader in industrialized production of iPSC-based cells

>15 cell types, co-cultures and organoids established





#### Proprietary production processes for human iPSC

Industrialized and scalable iPSC differentiation

# Generation of E.iBeta Pluripotent Endoderm Pancreatic endoderm progenitor Alb1 Cdx2 Sox9 Ptf1a Sst δ-cells Ppy PP-cells Endocrine progenitor Acinar Fraction of E.iBeta Ins β-cells Fraction progenitor Gcg α-cells Fraction for E.iBeta

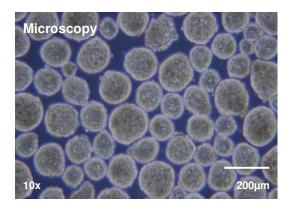
- Cell therapies can deliver 'functional cures' to patients
- Supplying an unlimited quantity of high-quality cells at low cost are the major obstacles to bring cell therapies to market
- Evotec is a leader in producing iPSC-based cell types and organoids at highest quality and industrial scale
- One of the largest iPSC groups in the industry with >100 people dedicated to developing iPSC-based cells for drug discovery and cell therapy
- Intricate know-how of developmental biology
- Focus on industrialization, robustness, scalability, GMP compatibility and QC

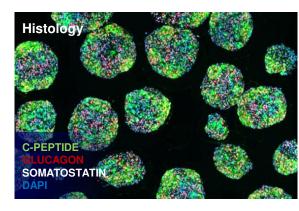


#### E.iBETA deliver long-term efficacy in preclinical models

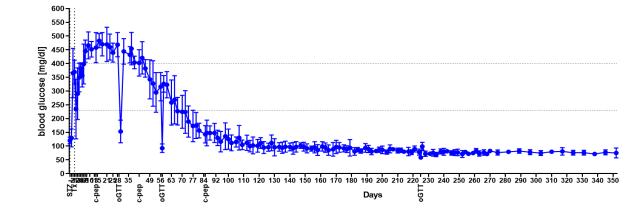
Cell composition and quality coupled with process robustness is key for success

#### E.iBeta generated from a GMP iPSC line in bioreactor





Long-term normalization of blood glucose in diabetic mice following **E.iBeta** transplantation



- Optimal cell composition
- Pharmaceutical quality
- Translation into GMP manufacturing

- Long-term stable glucose control demonstrated in diabetic mice for almost 1-year post-transplantation
- Equipotent to human primary islets (data not shown)
- Physiological regulation no hypoglycemia observed



#### Delivering off-the-shelf cell therapy products to patients

EVOcells – A world-class end-to-end infrastructure

**iPSC Platform** 

iPSC-based cell types gene editing

QC & upscaling oncology expertise

Pre-clinical development & CMC

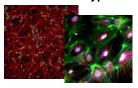
**Clinical manufacturing** 

Marked supply

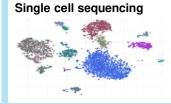
Clinical development

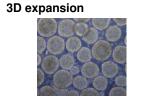
Marketing and sales

iPSC-based cell types

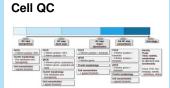


ArrayCGH, karyotyping, WGS











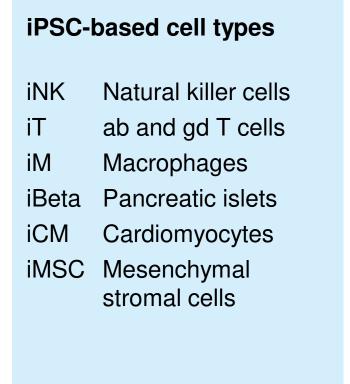
- E.iBeta on the way to clinical testing
- Highly skilled teams working on all aspects of developing IPSC-based beta cells for clinical application
- Reproducible and GMP-compatible production of **E.iBeta** batches derived from GMP-grade iPSCs



#### Building a pipeline in iPSC-based cell therapies

Evotec's internal off-the-shelf cell therapy programs

Field	Program / Project	Disease area	Exploratory	Pre-clinical research	Pre-clinical development	IND / Phase 1
Anti-tumour cell therapy	iNK	IO <sup>1</sup>				
	iM	Ю				
	γδ iT	Ю				
	αβ iΤ	Ю				
Regenerative therapy	<b>●, E.iBETA</b> Sernova Cell Pouch™	Diabetes				
	iCM	Heart failure				
Immune-modulation	iMSCs, iMSC exosomes	Various				
	iNK, iTreg	Anti-fibrotic, auto-immune				







#### Highlights of Sernova-Evotec Licensing Transaction

- Combining Evotec's iPSC technology with Sernova's Cell Pouch System<sup>™</sup> will immediately put Sernova at the forefront to find a 'functional cure' for insulin-dependent diabetes
- E.iBeta + Cell Pouch System = Best-in-Class beta cell therapy for insulin-dependent diabetes
  - Supply of E.iBeta removes limitations of using human donor islets
  - Cost sharing arrangement for development up to IND
  - Evotec has an option for joint funding of clinical development with profit-sharing participation upon commercialization
- Sernova now has an unlimited supply of highly ethical E.iBeta, which can be transplanted into patients using the Sernova Cell Pouch System
- Evotec equity investment of CAD \$27M / € 20M
  - Evotec and Sernova become strategic partners in regenerative medicine cell therapy
  - Potential to expand beyond diabetes





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