

## AltuCell Therapeutics Announces Proof-of-Concept in Lead Programs in Type 1 Diabetes in Human Subjects; Phase 1 Pilot in Humans Has IND Approval & Trial to Begin Shortly

AltuCell Therapeutics, Inc., AltuCell announced today the achievement of approval of IND in Italy after pre-clinical proof-of-concept based on data from its two lead programs for type 1 diabetes testing of cadaver stem cell-derived islets in both human and non-human subjects. Their capsules have been implanted in people with diabetes for 5 year, demonstrating long-term safety, with no toxicity or tissue necrosis, and no rejection in any of the patients treated.

Deer Park, NY, January 15, 2021 -- (PR.com)--- Micro-Encapsulation are gel microspheres that serve as micro-containers for a variety cells including highly specialized cells such as pancreatic islet beta cells secreting insulin

- Stem cell-derived islets have successfully reduce insulin requirements in diabetic human and non-human subjects.
- Islet cells can be encapsulated with full retention of the entrapped cells viability and function without immunosuppression or anti-rejection therapy
- AltuCell plans to initiate two clinical trials in 2021 IND approved in Italy for cadaver islets cell in human recipient transplants
- AltuCell and team has received All Government Regulatory approval needed for trial execution
- Patented AltuCaps® for Microencapsulation of stem cells for Diabetes, autoimmune diseases and inflammatory diseases: Partnering and investment opportunities available
- One Comparable deal recently announced is the purchase of Semma Therapeutics by Vertex Pharmaceuticals for almost a Billion dollars

AltuCell Releases Evidence in Support of Microencapsulated Sertoli Cells for Reversal of Diabetes

<u>AltuCell Therapeutics</u>, Inc. is a biotechnology company leading in molecular and regenerative therapy use of stem cells for Diabetes and other autoimmune and neurodegenerative diseases. AltuCell announced today the achievement of approval of IND in Italy after pre-clinical proof-of-concept based on data from its two lead programs for type 1 diabetes testing of cadaver stem cell-derived islets in both human and non-human subjects. Their capsules have been implanted in people with diabetes for 5 years, demonstrating clear, long-term safety, with no toxicity or tissue necrosis, and no rejection in any of the patients treated.

Gary Harlem, ALTuCELL's President & Chief Executive Officer commented, "Dr. Riccardo Calafiore, M.D. Endocrinology (Chief Science Officer AltuCell) Dr. Giovanni Luca, M.D. Endocrinology (Co-Director R&D) and Dr. Giuseppe Basta, M.D. Endocrinology (Co-Director of R&D) from the University of Perugia Department of Medicine to perfect the technology for cellular implantation. Our patented process ensures that our microcapsules are pure and virtually endotoxin free and maintain their immunoisolatory properties in vivo, with no toxicities nor immune rejection. The benefits of Altsulin/Altustem result in a superior product that is safe. Our encapsulated stem cells approach is a new modality that allows us to create programmable and controllable systems to deliver therapeutics with



greater precision than those technologies that rely on manipulating a patient's own genome. We are very excited to begin U.S. trials."

## Cell Therapy in Human Subjects

ALTuCELL is presently engaged in a human proof of concept study designed to evaluate the ability of Altsulin to increase serum levels of Insulin-Like Growth Factor-1 (IGF1) in patients with Laron Syndrome (aka Laron-type dwarfism), an autosomal recessive disorder characterized by an insensitivity to growth hormone (GH), usually caused by a mutant growth hormone receptor. Patients with Laron Syndrome, a pediatric orphan disease, have the lowest level IGF1 values seen in any disease. Altsulin has demonstrated significant effectiveness in increasing serum levels IGF1 in all pre-clinical animal models tested to date, providing the pharmacologic basis for the implanted Sertoli Cell therapy.

In animal models, ALTuCELL's microencapsulated cell technology have been proven safe and effective not only in the treatment of T1D, but also of other chronic diseases, including neurodegenerative diseases such as Huntington's disease and lethal neuromuscular disorders like Muscular Dystrophy. As for the latter, pre-clinical data look very strong toward clinical application.

The ALTuCELL microencapsulation technology has also demonstrated effective implantation of numerous cell types including Mesenchymal Stem Cells extracted from the post-partum human umbilical cord (Wharton's Jelly) for the treatment of early onset type 1 diabetes and other regenerative medicine applications.

AltuCell holds over 40 Patents worldwide.

For additional information please visit the ALTuCELL website: <a href="https://altucell.com/home">https://altucell.com/home</a> <a href="https://altucell.com/home">www.altucell.com/home</a>

About AltuCell

Altucell, Inc. is a cellular engineering and biotech company backed by sound research and science focused on fulfilling a large "unmet need" in cell, molecular and regenerative therapy for treatment of Diabetes and other autoimmune and neurodegenerative diseases. The company's proprietary and unique technology overcomes the major barriers to transplantation by a novel strategy utilizing patented micro-encapsulation technology, enabling a transplantable, cell-based therapy that avoids detection and rejection by the immune system.

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