InvestorRoom

Creative Medical Technology Holdings Announces IRB Approval for FDA Cleared Phase 1/2 Clinical Trial of Novel Cell Therapy for the Treatment of Type 1 Diabetes

Company reaches next clinical trial milestone for treatment of Type 1 Diabetes with the first novel allogenic cellular therapy in the dorsal artery of the pancreas in the United States

PHOENIX, Feb. 8, 2023 /PRNewswire/ -- **Creative Medical Technology Holdings, Inc.** (NASDAQ: CELZ), a biotechnology company working to revolutionize care through the development of potentially best-in-class regenerative therapeutics, today announced that it has received Institutional Review Board (IRB) approval to proceed with its Clinical Trial for the treatment of Type 1 Diabetes with its CELZ-201 cell therapy. The U.S. Food and Drug Administration (FDA) had previously cleared the Company's Investigational New Drug (IND) application within 30 days from submission.

The Company believes that CELZ-201 leverages a unique approach to harnessing the power of Perinatal Tissue Derived Cells® (PRDC) to multi-potentialities, including self-renewal ability, low antigenicity, reduced toxicity, and large-scale clinical expansion. The primary objective of the study is to evaluate CELZ-201 as a treatment for patients with newly diagnosed Type 1 Diabetes.

The company sponsored trial will be conducted at the University of Miami Health System in conjunction with the Diabetes Research Institute.

"The purpose of IRB review and approval is to assure that appropriate steps are taken to protect the rights and welfare of patients participating as subjects in the research and is an important milestone in proceeding with a clinical trial. We are pleased with achieving IRB approval expeditiously and look forward to moving forward with our Phase 1/2 clinical trial," Said Timothy Warbington, CEO of Creative Medical Technology Holdings, Inc.

"I am excited to proceed with the CELZ-201 perinatal cell product in this study, as I believe that if successful it could result in a promising treatment for many patients with Type 1 Diabetes," said Dr. Camillo Ricordi, Principal Investigator.

Safety and Efficacy of CELZ-201 in Patients With Recent Onset Type 1 Diabetes - Full Text View - ClinicalTrials.gov

About Type 1 Diabetes
As of 2019, there were 1.6 million adults aged 20 years or older diagnosed with Type 1 Diabetes (T1D) in the United States. The economic burden caused by T1D amounts to approximately $14.4 billion in medical costs and lost income, and there are currently limited treatment options beyond insulin. T1D results from the autoimmune destruction of insulin-producing islet cells in the pancreas, leading to loss of insulin production and impairment of blood glucose control. The absence of insulin leads to abnormalities in how the body processes nutrients, leading to high blood glucose levels. High blood glucose can lead to diabetic ketoacidosis and over time, to complications such as kidney disease/failure, eye disease (including vision loss), heart disease, stroke, nerve damage and even death. Due to the limitations and complexities of insulin delivery systems, it can be difficult to achieve and maintain balance in glucose control in patients with T1D. Hypoglycemia remains a critical limiting factor in glycemic management, and severe hypoglycemia can cause loss of consciousness, coma, seizures, injury, and can be fatal.

About Creative Medical Technology Holdings
Creative Medical Technology Holdings, Inc. is a biotechnology company dedicated to the advancement of identifying and translating novel biological therapeutics in the fields of immunotherapy, endocrinology, urology, neurology and orthopedics and is traded on NASDAQ under the ticker symbol CELZ. For further information about the Company, please visit www.creativemedicaltechnology.com.

Special Note Regarding Forward Looking Statements
NASDAQ Markets has not reviewed and does not accept responsibility for the adequacy or accuracy of this release. This news release may contain forward-looking statements including but not limited to comments regarding the timing and content of upcoming clinical trials and laboratory results, marketing efforts, funding, etc. Forward-looking statements address future events and conditions and, therefore, involve inherent risks and uncertainties. Actual results may differ materially from those currently anticipated in such statements. See the periodic and other reports filed by Creative Medical Technology Holdings, Inc. with the Securities and Exchange Commission and available on the Commission's website at www.sec.gov.

SOURCE Creative Medical Technology Holdings, Inc.

For further information: Company: Creative Medical Technology, IR@CreativeMedicalTechnology.com; Investor Relations, Devin Sullivan, SVP, The Equity Group Inc., dsullivan@equityny.com; David Shayne, Analyst, dshayne@equityny.com

---

https://creativemedicaltechnology.investorroom.com/2023-02-08-Creative-Medical-Technology-Holdings-Announces-IRB-Approval-for-FDA-Cleared-Phase-1-2-Clinical-Trial-of-Novel-Cell-Therapy-for-the-Treatment-of-Type-1-Diabetes