Creative Medical Technology Holdings Announces FDA Clearance of Investigational New Drug (IND) Application for AlloStem™, a Novel Cell Therapy for the Treatment of Type 1 Diabetes

AlloStem™ represents the first novel allogenic cellular therapy in the dorsal artery of the pancreas in the United States

PHOENIX, Nov. 3, 2022 /PRNewswire/ -- Creative Medical Technology Holdings, Inc. (NASDAQ: CELZ), an immuno-endocrine company working to revolutionize care through the development of potentially best-in-class regenerative therapeutics, today announced that the U.S. Food and Drug Administration has cleared the Company's Investigational New Drug (IND) application, enabling the Company to proceed with initiating a clinical trial for Type 1 Diabetes using AlloStem™.

AlloStem™ 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 (CELZ-201) is to evaluate AlloStem™ in patients with newly diagnosed Type 1 Diabetes. Patient recruitment is expected to begin in Q1 2023 with trial commencement updates to follow.

The national principal investigator of the study is Camillo Ricordi, M.D. Dr. Ricordi is the Stacy Joy Goodman Professor of Surgery, Distinguished Professor of Medicine, Professor of Biomedical Engineering, and Microbiology and Immunology at the University of Miami in Florida, where he serves as the Director of the Diabetes Research Institute and the Cell Transplant Program.

Dr. Ricordi will give an update on the study today at the 8th Perinatal Stem Cell Society Congress/Workshop at 9:00am EST.

"This is a milestone event for Creative Medical Technology Holdings as it marks the Company's first IND clearance from the FDA," said Timothy Warbington, CEO. "We are excited to commence this trial under the guidance of one of the world's most respected diabetes clinical researchers and at a renowned research institute."

Mr. Warbington continued, "We are also excited to announce the use of our proprietary AlloStem™ product in this study, as we believe it validates our efforts in creating assets that support our approach to developing immunotherapies. With this IND clearance, we are accelerating our efforts to identify novel biologics and develop therapies with the potential to effectively treat unmet needs of patients. I wish to acknowledge our team and collaborators for their hard work and dedication to this program."

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.

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.

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https://creativemedicaltechnology.investorroom.com/2022-11-03-Creative-Medical-Technology-Holdings-Announces-FDA-Clearance-of-Investigational-New-Drug-IND-Application-for-AlloStem-TM-,-a-Novel-Cell-Therapy-for-the-Treatment-of-Type-1-Diabetes