InvestorRoom

# Creative Medical Technology Files Orphan Drug Designation Application with the U.S. FDA Using the ImmCelz® Platform for the Treatment of Brittle Type 1 Diabetes

PHOENIX, March 23, 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 filed an application with the U.S. Food and Drug Administration (FDA) to receive Orphan Drug Designation (ODD) for the treatment of Brittle Type 1 Diabetes using its ImmCelz®(CELZ-100) platform.

The ImmCelz® (CELZ-100) immunotherapy product utilizes the Company's cell-free system which has previously been validated to supercharge the patient's own cells to treat a number of immune disorders. Currently there is no FDA approved therapy for a definitive cure of Brittle Type 1 Diabetes. Human islet cell transplantation has been tried in Brittle Type 1 Diabetes patients and is currently under U.S. FDA review; however, it requires immunosuppression which has many potential concerns and complications.

The FDA's Office of Orphan Drug Products grants orphan status to support the development of medicines for rare disorders that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain benefits, including market exclusivity upon regulatory approval, if received, exemption of FDA application fees, and tax credits for qualified clinical trials.

"Human islet cell transplantation is a relatively new procedure used in people with difficult to control brittle diabetes. Patients who receive an islet transplant take medication that suppresses their immune system and prevents rejection of the islet tissue. In spite of the strengths of the current immunosuppression regimen, it has failed to enhance single-donor success rates, and the majority of patients require two or more islet transplants to achieve insulin independence. As such, there is an impetus to move away from the use of immunosuppressive therapy and instead shift toward developing immune therapies such as ImmCelz® to fight against transplant rejection and autoimmunity. The need for life-long, high-dose immunosuppression is also associated with substantial side effects, and continues to limit application of islet transplantation to manage brittle diabetes," said Courtney Bartlett, DNP – Director of Clinical Operations.

ImmCelz® therapy, when co-administered with islet cells (PHPI), is a promising approach to overcoming transplant rejection in patients with brittle diabetes. Regulatory T cells, or Tregs, play a critical role in maintaining immune tolerance and suppressing alloreactive T cells and innate immune cells that contribute to islet transplant rejection. Several preclinical and clinical studies have demonstrated the efficacy and safety of immune therapy in promoting islet transplant survival, and it offers several advantages over other immunosuppressive therapies.

"We are very excited with the possibility that our ImmCelz® platform can be utilized to help patients with Type 1 Brittle Diabetes. The filing of our ODD application further demonstrates our team's ability to accelerate development and implementation of our immune therapies. We look forward to working with our clinicians and new collaborators who want to make an impact on moving away from immunosuppression and its complications," said Timothy Warbington, CEO.

The use of the ImmCelz® platform with human Islet cell transplantation has been assigned its own designation as CELZ-101. This product within the ImmCelz® platform is unique in terms of production, scalability and efficacy.

**About ImmCelz**

ImmCelz®, which is protected by trade secrets and published U.S. patents, utilizes adult stem cells derived from qualified donors to endow specific properties to the patient's immune cells. After the patient's harvested cells are incubated with the Company's cell-free reprogramming "cocktail", the cells are re-injected back into the patient. These "supercharged" cells subsequently "educate" other cells of the immune system to stop attacking the body, while preserving the ability to attack foreign pathogens thus providing immune-optimization. The Company plans to advance multiple indications for ImmCelz® including for Type I diabetes, heart disease, liver disease, and kidney disease.

**Brittle Diabetes, An Orphan (Rare) Disease**

In 2022, the number of patients in the US with T1D (type 1 diabetes) is approximately 1.6 million as per the JDRF statistics (https://www.jdrf.org/t1d-resources/about/facts/). Awareness of hypoglycemia (low blood sugar) is impaired in 30% of patients with T1D and recurrent severe hypoglycemia is reported in 66% of these patients. Episodes of severe hypoglycemia place the patients' lives and the lives of others at risk (for example, a subject

driving a vehicle at the time of the hypoglycemic episode). Assuming there are 1.25 million people with T1D in the US, 375,000 are expected to have impaired awareness of hypoglycemia, 247,500 are expected to have recurrent severe hypoglycemia, and it is estimated that about 28% of them will fail to improve, despite access to a "Specialist Hypoglycemia Service". Thus, less than 74,250 people would not be responsive to interventions such as hypoglycemia-focused educational and behavioral programs and diabetes technologies.

**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, gynecology 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.

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