

Creative Medical Technology Holdings Files Investigational New Drug Application (IND) with FDA for Treatment of Stroke using ImmCelz® Regenerative Immunotherapy

Company to Start Clinical Trial to Address 30 Billion Dollar Stroke Market Using Novel Cell Therapy

PHOENIX, Jan. 12, 2021 /PRNewswire/ -- **(OTC - CELZ)** Creative Medical Technology Holdings Inc. announced today filing of an Investigational New Drug (IND) application with the Food and Drug Administration (FDA) requesting clearance to initiate the first clinical trial using cellular immunotherapy for treatment of stroke. The proposed study will involve treatment of 4 groups of 8 patients per group. Treated patients will receive one intravenous injection of ImmCelz® product at 0.5 X10(6) cells per kilogram; the second arm 1 X10(6) cells per kilogram; the third arm 2X10(6) cells per kilogram; and the fourth arm will serve as a control. Patients will be followed for a total of 6 months with both safety and efficacy being examined.

"The uniqueness of the ImmCelz® approach is that the immunological cells used are derived from the same patient to which they are administered." Said Dr. Amit Patel, board member of the Company and co-inventor of the technology. "We have previously reported potent reduction of stroke infarct volume, as well as post-stroke behavioral improvements in animals treated with ImmCelz®. We are enthusiastic to move this treatment into patients, with stroke being the first indication."

The ImmCelz® treatment involves utilization of stem cells outside of the body to "reprogram" the patient's own immune cells so as to endow upon the immune cells regenerative activities. In contrast to other stem cell based approaches, the immune cells are significantly smaller in size than stem cells and are believed to more effectively penetrate areas of the damaged brain and induce regeneration.

"Utilization of ex vivo manipulation of immune cells to induce biologically relevant therapeutic cascades was originally performed by experiments 17 years ago with our colleague Dr. Wei-Ping Min, in which we utilized dendritic cells to induce a population of T cells that would protect organ transplant regeneration¹." Said Dr. Thomas Ichim, co-inventor of ImmCelz®. "We are enthusiastic that these technologies are now maturing to the point of entering clinical trials and actually helping patients."

"According to the National Institute of Health (NIH), Stroke affects approximately 800,000 people in the United States annually alone. Very little treatments are available subsequent to initiation of brain damage." Said Timothy Warbington, President and CEO of the Company. "Based on our previous experiences with the FDA, we anticipate a smooth review process given the fact that the active ingredient in ImmCelz® are cells from the same patient. Subsequent to the first IND clearance, we plan to file IND's on other indications, which appear promising based on preclinical data."

About Creative Medical Technology Holdings

Creative Medical Technology Holdings, Inc. is a commercial stage biotechnology company specializing in Regenerative Medicine in the fields of immunotherapy, urology, neurology and orthopedics and is quoted on the OTC under the ticker symbol CELZ. For further information about the company, please visit www.creativemedicaltechnology.com.

Forward Looking Statements

OTC 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.

Creativemedicaltechnology.com

www.StemSpine.com

www.Caverstem.com

www.Femcelz.com

¹ [Inhibitory Feedback Loop Between Tolerogenic Dendritic Cells and Regulatory T Cells in Transplant Tolerance | The Journal of Immunology \(jimmunol.org\)](http://Inhibitory%20Feedback%20Loop%20Between%20Tolerogenic%20Dendritic%20Cells%20and%20Regulatory%20T%20Cells%20in%20Transplant%20Tolerance%20|%20The%20Journal%20of%20Immunology%20(jimmunol.org))

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