

Creative Medical Technology Holdings Receives FDA Clearance to Initiate a Phase 1/2 Clinical Trial of StemSpine® using AlloStem™ (CELZ-201-DDT) for the Treatment of Chronic Lower Back Pain

PHOENIX, Sept. 19, 2023 /PRNewswire/ -- **Creative Medical Technology Holdings, Inc. ("Creative Medical Technology" or the "Company")** (NASDAQ: CELZ), a biotechnology company focused on a regenerative approach to immunotherapy, endocrinology, urology, gynecology, and orthopedics, today announced that the U.S. Food and Drug Administration ("FDA") has cleared the Company to proceed with a Phase 1/2 clinical trial of StemSpine® using AlloStem™ ("CELZ-201-DDT").

The study is designed to evaluate the safety, efficacy, and tolerability of CELZ-201-DDT. The study will enroll 30 individuals suffering from chronic lower back pain. CELZ-201-DDT is a patented procedure that utilizes an "off the shelf, ready-to-use" universal and proprietary allogenic (donor) cell line developed by the Company and trademarked as AlloStem™. Using an ultrasound guided, non-surgical procedure AlloStem™ is injected in areas surrounding the diseased disc(s), thereby potentially repairing, remodeling, and improving the blood supply around the disc and lower back area, without exposing the patient to radiation as with other cell-based procedures. CELZ-201-DDT distinguishes itself by using a unique immunomodulatory formula derived from allogeneic perinatal cells, which in preliminary studies have shown potential for tissue repair and changing cytokine profiles.

"The FDA's clearance allowing us to pursue this clinical trial is a milestone event for Creative Medical Technology and a validation of our commitment to developing and advancing novel regenerative therapeutics that can improve patient lives," said Timothy Warbington, CEO of Creative Medical Technology. "An estimated 20% of Americans suffer from chronic lower back pain, with many of these individuals relying on opioids as the standard of care for relief. With an opioid crisis in the United States, we believe that CELZ-201-DDT is potentially a more effective, sustainable, and safer non-surgical pain management option compared to opioids, and we look forward to advancing these studies."

"Chronic lower back pain is an increasing cause of disability globally," noted Courtney Bartlett, Director of Clinical Development. "This clinical trial sets the foundation to potentially help patients with a safer alternative therapy for chronic lower back pain as the procedure can be performed in the outpatient setting under direct ultrasound guidance, without any radiation exposure."

About Creative Medical Technology Holdings, Inc.

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.

About StemSpine Inc.

StemSpine Inc. is a wholly owned subsidiary of Creative Medical Technology Holdings Inc., concentrating on Orthopedic Medicine, including spine, knees, shoulders and joints.

Forward Looking Statements

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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