InvestorRoom

Creative Medical Technology Holdings Announces IRB Approval for FDA Cleared Phase 1/2 Clinical Trial of StemSpine® using AlloStem™ ("CELZ-201-DDT") Novel Cell Therapy to Treat Chronic Lower Back Pain

Company reaches next clinical trial milestone for the intramuscular treatment of Chronic Lower Back Pain with the first novel allogenic cellular therapy in the United States

PHOENIX, Oct. 10, 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 it has received Institutional Review Board ("IRB") approval to proceed with its clinical trial for the treatment of chronic lower back pain with its StemSpine® procedure using AlloStem™ ("CELZ-201-DDT") cell therapy.

The receipt of IRB approval is a necessary step that will allow Creative Medical Technology to move forward with recruitment of its recently FDA approved Phase 1 /2 randomized, double blind, placebo controlled clinical trial to evaluate the safety, efficacy, and tolerability of CELZ-201-DDT. The study will enroll 30 individuals suffering from chronic lower back pain caused by Degenerative Disc Disease.

An IRB is an FDA-registered consortium that has been formally designated to review and monitor biomedical research involving human subjects. IRB approval is a critical and necessary prerequisite to commencing human clinical trials and serves an important role in the protection of the rights and welfare of human research subjects.

"We are pleased to announce the expeditious receipt of this vital next step in commencing the clinical trial for CELZ-201-DDT," said Timothy Warbington, CEO of Creative Medical Technology. "Studies show that 8% of all adults in the United States, approximately 16 million people, experience chronic lower back pain. The economic impact is also significant, as a report from the National Library of Medicine estimates that $200 billion is spent annually on the management of back pain. In addition to limiting their daily activities and negatively impacting their quality of life, many of those suffering rely on opioids as the standard of care which carry their own side effects, not the least of which is addiction. We are hopeful that the outcome of this clinical trial will validate the efficacy, safety, and endurance of CELZ-201-DDT as a non-surgical treatment option for chronic lower back pain."

About CELZ-201-DDT

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.

Details on the clinical trial may be found here: NCT06053242.

About Creative Medical Technology Holdings

Creative Medical Technology Holdings, Inc. is a biotechnology company dedicated to the advancement of identifying and translating novel immediately deployable FDA registered 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.

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.

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