

Creative Medical Technology Holdings Provides Corporate Update

Continued Advancements in Developing Regenerative Therapeutics While Maintaining Strong Financial Position

PHOENIX, June 12, 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 provided an update on recent business activities.

"As we approach the mid-point of the year, we wanted to take this opportunity to summarize recent clinical, regulatory, and business developments," said Timothy Warbington, Chief Executive Officer of Creative Medical Technology. "Although we provided a similar update in April, we believe that these incremental advancements further validate our business model of pursuing the development of best-in-class regenerative therapeutics that address multiple indications and growing end markets. None of this would have been possible without the hard work and dedication of our team, an extensive IP portfolio with significant potential commercial applications, and a strong financial position."

2023 Developments

Type 1 Diabetes

As previously announced, in November 2022 the U.S. Food and Drug Administration cleared the Company's Investigational New Drug (IND) application, enabling the Company to proceed with initiating a first in country Phase 1/2 clinical trial for Type 1 Diabetes using CELZ-201 (AlloStem™). The Company received Institutional Review Board (IRB) approval to proceed with its clinical trial in February 2023, announced the engagement of Syneos Health as the contract research organization for this trial in March 2023, and has the updated recruiting trial status at [ClinicalTrials.gov](#).

In March, the Company announced the FDA filing for an Orphan Drug Designation (ODD) treatment of Type 1 Brittle Diabetes utilizing our ImmCelz® product in conjunction with islet transplantation. In discussions with FDA we are fortified in our belief that the ImmCelz® Program in addition to T1D islet transplantations, has the ability to expand to multiple other cell and organ transplants to treat or reduce rejection. Such discussions have led to the acceleration of the ImmCelz® program with the intent to file an ImmCelz® IND in the latter part of 2023, while continuing with the ODD for Brittle Diabetes.

Type 2 Diabetes

In April 2023, the Company announced positive follow-up data and significant efficacy using CELZ-001 cells to treat patients with Type 2 Diabetes.

At a six-month follow up, there were no safety concerns related to CELZ-001 utilizing the same infusion procedure as in the current U.S. FDA cleared CELZ-201 clinical trial for Type 1 Diabetes, and an overall efficacy of 93% was reported in the treated patients demonstrating at least a 50% reduction in insulin requirement.

Chronic Lower Back Pain

In May, the Company announced positive top line pilot study results for the StemSpine® procedure using AlloStem™ to treat chronic lower back pain. This patented procedure utilizes AlloStem™, an "off the shelf, ready-to-use" universal and proprietary allogenic (donor) cell developed by the Company.

The data demonstrated a greater than 90% reduction in narcotic usage, greater than 80% reduction in pain score, and greater than 50% reduction in the Oswestry Score in the treated patients. No patients required re-dosage or surgical intervention at the primary end point of six months and there were no safety related concerns. To the Company's knowledge, this pilot study is the first to demonstrate safety and clinical efficacy of injecting donor cells in areas surrounding the disc, thereby potentially repairing, remodeling, and improving the blood supply around the disc and lower back area. Further translation of the StemSpine procedure may help to alleviate the current opioid crisis by offering additional, non-surgical options to patients who suffer from chronic lower back pain.

Next Milestone Achievement in ImmCelz® Platform Development

In May, the Company announced significant advancements in the ongoing development of its ImmCelz® (CELZ-100) platform, a cell-free system which has previously been validated to supercharge a patient's own cells to

treat a number of immune disorders.

Independent studies confirmed that the ImmCelz® platform: required 75% fewer donor patient cells compared to industry standard; possessed purity of greater than 95% compared to the industry standard of greater than 80%; and demonstrated a greater than 200% reduction in functional suppression of effector T cells, which are a critical concern for patients with autoimmune issues, while still possessing a high number of functional T regulatory cells.

The Company believes that the ability to reduce the number of required donor patient cells while simultaneously producing a more effective product allows for the ability to reach a greater number of potentially sicker patients. It may also potentially allow the Company to offer and treat even a wider variety of immune disorders that require multiple dosing strategies while maintaining patient safety.

Next Generation iPSC Pipeline for ImmCelz® Immunotherapy Platform

In May 2023, the Company announced that it had received confirmation that Greenstone Biosciences Inc. has successfully developed a human induced pluripotent stem cell (iPSC) pipeline for the Company's ImmCelz® platform. In June 2022, the Company announced its collaboration with Greenstone Biosciences Inc. on this project, called the iPScelz™ program.

This collaboration and the associated development of this cell line is expected to enable the Company to increase the scalability for the ImmCelz® Immunotherapy Platform, save two to three years in research and development time along with associated expenses, and accelerate its drug discovery program using artificial intelligence.

Reverse Stock Split

As previously announced, the Company's Board of Directors approved a 1 for 10 reverse stock split of its shares of common stock that becomes effective at 9:00 a.m. Eastern time on June 12, 2023.

Mr. Warbington commented, "We wish to emphasize that this action was undertaken for the sole purpose of bringing the Company into compliance with The Nasdaq Capital Market's \$1.00 minimum price requirement. We believe that maintaining our listing on Nasdaq is an important component of our business development and makes our equity more attractive to a broader range of investors. We continue to look forward to our future with confidence and optimism."

Financial Position

On March 31, 2023, the Company reported cash and certificates of deposit of \$14.6 million, working capital of \$14.4 million, and no long-term debt. The Company calculates that it has more than sufficient funds to meet its anticipated operating costs and capital expenditure requirements through 2024, therefore no additional capital will be sought at this time. Our number of shares of common stock outstanding following the effect of the reverse stock split is approximately 1.4 million.

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

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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