MiMedx Publishes Positive Results From Clinical Study Of Human Umbilical Cord For Diabetic Foot Ulcers

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Study Published in International Wound Journal Reported Statistically Significant Evidence of Healing Compared to Standardized Therapy (ST)

- Intent-To-Treat (ITT) EpiCord®-Treated Patients = 70% vs ST 48%, p=0.0089

- Per-Protocol EpiCord-Treated Patients = 81% vs ST 54%, p=0.0013

MARIETTA, Ga., Sept. 25, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today announced that a new clinical study has been published in the peer-reviewed *International Wound Journal*, which evaluated the safety and efficacy of using dehydrated human umbilical cord (dHUC - EpiCord) for chronic diabetic foot ulcers (DFUs).

The paper is entitled *"A multicentre prospective randomised controlled comparative parallel study of dehydrated human umbilical cord (EpiCord) allograft for the treatment of diabetic foot ulcers"* and was co-authored by: William Tettelbach, MD; Shawn Cazzell, DPM; Felix Sigal, DPM; Joseph M. Caporusso, DPM; Patrick S. Agnew, DPM; Jason Hanft, DPM; and Cyaandi Dove, DPM. The published article in the *International Wound Journal* can be found at https://onlinelibrary.wiley.com/doi/full/10.1111/iwj.13001.

This multicenter randomized and controlled trial was conducted at 11 centers in the United States and was led by William Tettelbach, MD, principal investigator and former Executive System Medical Director of Wound Care and Hyperbaric Medicine Services for Intermountain Healthcare. Dr. Tettelbach later became Associate Chief Medical Officer for MiMedx, a position that postdated the completion of the study.

Clinical Study Design and Results

This is the first published clinical study of dHUC tissue. The objective of the study was to determine the safety and effectiveness of dHUC as compared to standardized therapy with alginate wound dressings for chronic, non-healing DFUs.

The primary efficacy endpoint was the incidence of complete wound closure over a 12-week period. Data from 155 patients were analyzed in the Intent-to-Treat (ITT) cohort. Patients were randomized in a 2:1 ratio to receive weekly application of dHUC (n=101) or standardized therapy with alginate dressings (n=54). A total of 134 patients completed the study Per-Protocol (Per-Protocol cohort).

ITT analysis includes patients even if they did not fully adhere to the protocol. In comparison, in a Per-Protocol analysis, only patients who completed the entire clinical trial according to the protocol are included in the final analysis.

In the current study on an ITT basis, 70% of patients who received weekly dHUC had complete healing by 12 weeks versus 48% of patients only receiving weekly standardized therapy (p=0.0089).

For patients completing the study Per-Protocol, 81% of those who received weekly dHUC achieved complete healing by 12 weeks. In comparison, 54% of patients had complete healing in 12 weeks after receiving weekly standardized therapy (p=0.0013).

About dHUC

dHUC is a thick membrane derived from umbilical cord, the structure that protects the arteries and vein that carry essential nourishment and oxygenated blood to and from mother and fetus. dHUC is a minimally manipulated, dehydrated, non-viable cellular umbilical cord allograft intended for homologous use that provides a protective environment for the healing process.

Umbilical cord consists of amniotic epithelium and Wharton's jelly containing an extracellular matrix composed of collagen, proteoglycans and hyaluronic acid. MiMedx processes dHUC using the PURION® Plus process, an approach that provides an easy-to-use allograft stored at ambient conditions.

MiMedx currently markets dHUC as a Human Cellular and Tissue-based Product (HCT/P) under Section 361 of Food and Drug Administration regulations under the brand names EpiCord® and AmnioCord®. MiMedx manufactures its products according to current Good Tissue Practices (cGTP) standards, pursuant to 21 CFR 1271, an FDA regulation. The Company is also in compliance with the AATB's (American Association of Tissue Banks) 14th standard, of which MiMedx is a fully accredited member in good standing.

About MiMedx

MiMedx® is a leading biopharmaceutical company developing and marketing regenerative and therapeutic biologics utilizing human placental tissue allografts with patent-protected processes for multiple sectors of healthcare. "Innovations in Regenerative Medicine" is the framework behind the Company's mission to provide physicians products to help the body heal itself. The Company processes the human placental tissue utilizing its proprietary PURION® process methodology, among other processes, to produce allografts by employing aseptic processing techniques in addition to terminal sterilization. MiMedx has supplied over 1.3 million allografts to date for application in the Wound Care, Burn, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic, and Dental sectors of healthcare. For additional information, please visit www.mimedx.com.

Safe Harbor Statement

This press release includes forward-looking statements. Statements regarding the safety and efficacy of MiMedx dHUC for diabetic foot ulcers are forward-looking statements. Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will," "preliminary," and similar expressions, and are based on management's current beliefs and expectations. Forward-looking statements are subject to risks and uncertainties, and the Company cautions investors against placing undue reliance on such statements.

Actual results may differ materially from those set forth in the forward-looking statements. For more detailed information on the risks and uncertainties, please review the Risk Factors section of the Company's most recent annual report or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and the Company assumes no obligation to update any forward-looking statement.

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