MiMedx Announces Statistically Significant Results In New Multicenter Clinical Study Of Healing Of Diabetic Foot Ulcers Using EpiFix®

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- Study Published in International Wound Journal Reported Statistically Significant Evidence of Healing Compared to Control Group

- Intent-To-Treat EpiFix Treated Patients = 70% vs Control 50%, p=0.0338

- Per-Protocol EpiFix Treated Patients = 81% vs Control 55%, p=0.0093

MARIETTA, Ga., Aug. 24, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today announced that a new study regarding the use of EpiFix® in the treatment of diabetic foot ulcers (DFUs) has been published in the peer-reviewed journal, *International Wound Journal*.

The paper is entitled *"A Confirmatory Study on the Efficacy of Dehydrated Human Amnion/Chorion Membrane dHACM Allograft in the Management of Diabetic Foot Ulcers: A Prospective, Multicenter, Randomized, Controlled Study of 110 Patients from 14 Wound Clinics."* The paper was authored by: William Tettelbach, MD; Shawn Cazzell, DPM; Alexander M. Reyzelman, DPM; Felix Sigal, DPM; Joseph M Caporusso, DPM; and Patrick S. Agnew, DPM. The electronic publication of the article in *International Wound Journal* can be found at https://onlinelibrary.wiley.com/doi/full/10.1111/iwj.12976.

This multi-center randomized and controlled trial 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 is now Associate Chief Medical Officer for MiMedx, a position that postdated the completion of the study.

Clinical Study Design and Results

The objective of the study was to determine the safety and effectiveness of EpiFix as compared to standard of care (SOC) therapy for the treatment of non-healing DFUs. The primary efficacy endpoint was the incidence of complete wound closure over a 12-week period. Data from 110 patients meeting study inclusion and exclusion criteria were analyzed in the Intent-to-Treat (ITT) cohort. A total of 98 patients completed the study Per Protocol (Per-Protocol cohort).

ITT analysis requires patients to be included 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 counted towards the final results.

In the current study on an ITT basis, 70% of patients who received weekly EpiFix had complete healing by 12 weeks versus 50% of patients only receiving weekly SOC (EpiFix 70% vs. SOC 50%, p=0.0338).

For patients completing the study per protocol, 81% of those who received weekly EpiFix treatments achieved complete healing by 12 weeks. In comparison, 55% of patients had complete healing in 12 weeks after receiving weekly SOC alone (EpiFix + SOC 81% vs. SOC 55%, p=0.0093).

In the ITT cohort, adjusting for co-variates associated with healing, Cox regression analysis showed patients treated with EpiFix were more than twice as likely to heal completely within 12 weeks as those not receiving EpiFix (HR: 2.15, 95% confidence interval 1.30-3.57, p=0.003).

Mechanism of Action

EpiFix® is a tissue matrix allograft composed of dehydrated human amnion/chorion membrane (dHACM). The Company's published scientific work indicates that MiMedx dHACM retains a diverse array of regulatory proteins including essential growth factors, cytokines and chemokines, which are regulators in inflammation, wound repair and tissue regeneration.

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 and tissues 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 EpiFix 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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