



## **New Study Demonstrates Potential for MIMEDX Purion® Processed Dehydrated Human Amnion/Chorion Membrane to Modulate Pathological Scar Tissue Formation**

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*Proposed Mechanism Suggests Potential Path to Improve Outcomes in Clinical Applications where the Regulation of Excessive Fibrosis Can Promote a Normal Healing Response*

*Complex Nature of MIMEDX dHACM May Prove Useful in a Multitude of Applications Where Normal Healing Is Impaired*

MARIETTA, Ga., June 15, 2021 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company"), an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, today announced publication of its peer-reviewed [study](#) in the Journal of Investigative Dermatology (JID) Innovations, addressing the potential benefit of MIMEDX Purion processed dehydrated human amnion/chorion membrane (dHACM) to combat complications stemming from excessive fibrosis, a pathological process central to a number of serious unmet medical needs. It is estimated that worldwide more than 100 million people suffer from pathological scar formation annually, including hypertrophic and keloid scar formation, with long-term effects ranging in severity from minor cosmetic defects to significantly compromised tissue architecture and impaired function across a number of conditions.

MIMEDX Purion processed dHACM has been used extensively for the treatment of multiple acute and chronic conditions ranging from diabetic foot ulcers and significant burn injuries to musculoskeletal and sports medicine applications. Clinical evidence suggests that using these products in treatment regimens not only accelerates healing, but anecdotally, also improves the quality of the repair as evidenced by reduced scar tissue formation. Amniotic membrane has long been thought to possess anti-scarring properties; however, the mechanism to achieve a response is not fully understood. Therefore, this study, authored by Sarah Moreno, Michelle Masee, and Thomas J. Koob, Ph.D., was intended to explore the potential mechanism of action by which dHACM affects fibrotic pathways.

"Long-term effects of excessive fibrosis, or scarring, can range in clinical severity from minor cosmetic defects to significantly compromised tissue architecture and impaired function. While many distinct factors can trigger progressive fibrotic disease, a feature common to all fibrotic diseases is activation of Extracellular Matrix (ECM)-producing myofibroblasts, which are key mediators of fibrotic tissue remodeling," said Sarah E. Moreno, lead author and Manager of Research at MIMEDX. "We know that the ongoing presence of pro-fibrotic stimuli can impede the normal healing process, resulting in excessive fibrosis. Our goal was to examine whether, and how, MIMEDX amniotic tissue might disrupt this process. This study is a path to answer that question."

An *in vitro* model for fibrosis was developed through the stimulation of human dermal fibroblasts with Transforming Growth Factor beta (TGF- $\beta$ 1), a pro-fibrotic cytokine, to induce differentiation into myofibroblasts. The phenotypic shift was confirmed by the concomitant expression of alpha Smooth Muscle Actin ( $\alpha$ SMA) and increased extracellular matrix deposition. While this is a necessary step in the normal healing cascade, prolonged continuous TGF- $\beta$ 1 stimulus leads to persistent upregulation of fibrotic pathways and ultimately pathological scarring. Therefore, this model evaluated the potential of dHACM treatment in the sustained presence of TGF- $\beta$ 1 as a means to best recapitulate this environment *in vitro*. Introduction of dHACM into this model resulted in disruption of the TGF- $\beta$ 1 signaling pathway, reducing the elevated expression of fibrotic factors and ECM components, effectively regulating myofibroblast activity. The functional outcome of these effects was also observed in an *ex vivo* model for cellular contraction, where dHACM treatment reduced the contractile capacity of stimulated fibroblasts imbedded within a collagen matrix to near basal levels. The data demonstrate the ability of dHACM to regulate inherent molecular pathways and imply a possible mechanism of action for the prevention or treatment of pathological scar formation. Additional data or a relevant animal model will be necessary to confirm the findings and translate efficacy to a clinical outcome.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "Purion processed amniotic tissue has tremendous potential. We are investing heavily in research and development to increase our scientific understanding of its capabilities and facilitate its use in the treatment algorithm for patients suffering from debilitating diseases. The Company's early work characterized the core properties of our technology, including the identification of over 300 regulatory proteins and basic biological functions, such as cellular proliferation and migration. We are continuing to gain insights into the complexities of this tissue as exemplified by the work performed here on pathological scar formation, and are building on our existing library of peer-reviewed literature that provides MIMEDX with a critical advantage for the future development of novel therapeutics."

"This research provides data that clarify the molecular pathways targeted by dHACM to regulate aberrant fibroblast activity *in vitro*. The benefit of this finding could prove to be a significant advancement for the treatment of injuries where pathological scar formation is triggered," said Robert B. Stein, M.D., Ph.D., Executive Vice President, Research and Development at MIMEDX. "I commend our team for this contribution to expanding our understanding of placental tissue and their unwavering commitment to evaluating the utility of MIMEDX Purion processed human placental tissue as meaningful medicines promoting more effective healing."

### **Important Cautionary Statement**

This press release includes forward-looking statements. Statements regarding: (i) potential benefits from the use of MIMEDX Purion processed dHACM including the Company's expectation that it may regulate excessive fibrosis and reduce scarring, and (ii) expectations that the Company will develop novel therapeutics in the future, 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. Factors that could cause actual results to differ from expectations include: (i) Additional data or a relevant animal model will be necessary to confirm the findings and translate efficacy to a clinical outcome, and (ii) the Company may change its plans due future events and delay or alter its plans for future research and development. The Company describes additional risks and uncertainties in the Risk Factors section of its most recent annual report and quarterly reports 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.

#### **About MIMEDX**

MIMEDX is an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental biologics, we have both a base business, focused on addressing the needs of patients with acute and chronic non-healing wounds, and a promising late-stage pipeline targeted at decreasing pain and improving function for patients with degenerative musculoskeletal conditions. We derive our products from human placental tissues and process these tissues using our proprietary methods, including the PURION® process. We employ Current Good Tissue Practices, Current Good Manufacturing Practices, and terminal sterilization to produce our allografts. MIMEDX has supplied over two million allografts, through both direct and consignment shipments. For additional information, please visit [www.mimedx.com](http://www.mimedx.com).

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