MiMedx Announces Publication Of Phase 2B Clinical Trial Efficacy Data For Micronized dHACM In The Treatment Of Plantar Fasciitis In Foot & Ankle International

August 2, 2018
- Publication in Peer-Reviewed Journal Underscores Statistically Significant Difference Seen in Pain and Foot Function Compared to Control Group
- Mean Visual Analog Scale (VAS) Score for Pain Was Reduced by 76% at Three Months in Treatment Group Compared with a 45% Reduction in Control Group

MARYIETTA, Ga., Aug. 2, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today announced that the positive pain and foot function results from its Phase 2B clinical trial of micronized dHACM (dehydrated Human Amnion/Chorion Membrane) in the treatment of Plantar Fasciitis have been published in the peer-reviewed journal, *Foot & Ankle International*. The publication of this data follows the Company’s late-March announcement (3/28/18 Positive Pain and Foot Function Results) that it achieved the primary and secondary efficacy endpoints in this Phase 2B study.

The paper entitled “Randomized Controlled Trial of Micronized Dehydrated Human Amnion/Chorion Membrane (dHACM) Injection Compared to Placebo for the Treatment of Plantar Fasciitis,” was authored by: Shawn Cazzell, DPM¹; Jordan Stewart, DPM²; Patrick S. Agnew, DPM³; John Senatore, DPM⁴; Jody Walters, DPM⁵; Douglas Murdoch, DPM⁶; Alex Reyzelman, DPM⁷; and Stuart Miller, MD⁸. The article in *Foot & Ankle International* can be found online at [http://journals.sagepub.com/doi/full/10.1177/1071100718788549](http://journals.sagepub.com/doi/full/10.1177/1071100718788549).

The Phase 2B prospective, single-blinded, randomized, controlled trial (RCT) studied a single injection of 40 mg of micronized dHACM injection as compared to a single injection of saline (placebo control) in the treatment of Plantar Fasciitis. The trial enrolled and treated 145 patients at 14 study sites.

Stuart Miller, MD, principal investigator of the most recently published clinical trial, said, ”We are encouraged by the results of this Phase 2B clinical study, and look forward to the completion of the Phase 3 clinical trial, expected in 2019.”

The primary efficacy endpoint was the mean change in VAS score for pain between baseline and the 3-month follow-up visit. The secondary efficacy endpoint was the mean change in Foot Function Index - Revised (FFI-R) score between baseline and 3 months. The baseline VAS and FFI-R scores were similar between groups. At the 3-month follow-up, the mean VAS score was reduced by 76% for patients in the Treatment Group compared with a 45% reduction for the Control Group (p<0.0001), and the mean FFI-R score was reduced by 60% for patients in the Treatment Group, while the Control Group had mean reduction of 40% versus baseline (p=0.0004).

Overall, at the three-month study follow-up visit, 60 (82.2%) patients in the treatment group, and 34 (47.2%) patients in the control group reported at least a 50% reduction in VAS score from baseline (p<0.0001).

**Biologics License Application (BLA) Progress**

Based on its Phase 2B interim study results, in January 2018 the Company announced that it had initiated the pivotal Phase 3 clinical trial to assess the safety and efficacy of micronized dHACM injection to treat patients with recalcitrant Plantar Fasciitis pain. Top-line results from the Phase 3 study are expected in the second half of 2019. Following the conclusion of this trial, MiMedx currently anticipates filing a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for micronized dHACM injection to treat Plantar Fasciitis in the second half of 2020.

“This is a positive step towards a BLA filing and helping patients with painful plantar fasciitis conditions,” noted David Coles, Interim Chief Executive Officer.

**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 give 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 safe and effective 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](http://www.mimedx.com).

**Safe Harbor Statement**

This press release includes forward-looking statements. Statements regarding expectations of further favorable study results, the timing of study results, and the expected timing of a BLA filing are forward-looking. 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. 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.
Footnotes for Study Authors' Institutions:
1Limb Preservation Platform, Inc., Fresno, CA; 2Timonium Foot & Ankle Center, Timonium, MD; 3Coastal Podiatry Center, Virginia Beach, VA; 4Union Memorial Hospital, Baltimore, MD; 5University of Arizona Medical Center, Tuscon, AZ; 6Baylor / Scott & White Podiatry Center, Temple, TX; 7Center for Clinical Research, Inc., Castro Valley, CA; 8MedStar Union Memorial Hospital, Baltimore, MD.

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