MiMedx Reports Positive Pain And Foot Function Results From Phase 2B Clinical Trial Of AmnioFix® Injectable In The Treatment Of Plantar Fasciitis

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Patients Experienced Clinically Meaningful Reduction in Pain
AmnioFix Injectable Achieves Primary and Secondary Efficacy Endpoints
Statistically Significant Difference in Pain and Function Compared to Placebo

MARIETTA, Ga., March 26, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today announced positive pain and foot function results from its Phase 2B clinical trial of AmnioFix® Injectable in the treatment of Plantar Fasciitis.

The Phase 2B IND clinical trial evaluating the use of AmnioFix Injectable for the treatment of Plantar Fasciitis demonstrated a clinically and statistically significant difference compared to patients in the Control Group in their reduction in the visual analog scale (VAS) score for pain (p<0.0001) and Foot Function Index-Revised (FFI-R) scores (p=0.0004) at 3 months compared to baseline. Additionally, the safety of the product was demonstrated by the absence of serious, unanticipated, product-related adverse events and the relative absence of an elicited immune response post-injection demonstrated by the Treatment Group.

Plantar Fasciitis is the most common cause of chronic heel pain in adults, comprising 11–15% of the foot symptoms requiring professional care among adults, according to studies published in the*Journal of Research in Medical Sciences*. It is estimated that 1 in 10 people will develop Plantar Fasciitis during their lifetime, with approximately one million people per year seeking medical treatment. The Company believes 60% of these patients could be potential candidates to receive AmnioFix Injectable, which MiMedx estimates represents a $450 million annual market opportunity for the Company.

"As we noted in January 2018 when we initiated our Phase 3 trial to treat Plantar Fasciitis, we believe AmnioFix Injectable can become a new first-line therapy for the treatment of musculoskeletal degeneration pain," said Parker H. "Pete" Petit, Chairman and Chief Executive Officer. "We believe that our product will meet this need and quickly become a physician's product of choice for patients."

"These Phase 2B results clearly show that AmnioFix Injectable has the potential to provide safe, effective, and durable relief from pain associated with chronic Plantar Fasciitis," added Bill Taylor, President and COO. "We expect our Phase 3 study initiated in January 2018 to confirm these results as we move toward filing a Biologics License Application (BLA) in the second half of 2020 based on our current projections."

Clinical Study Design

The Phase 2B prospective, single-blinded, randomized, controlled trial studied a single injection of 40 mg of AmnioFix Injectable (micronized Dehydrated Human Amnion/Chorion Membrane (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.

The primary efficacy endpoint was the change in VAS score for pain for subjects between baseline and 3 months expressed as the difference in the mean scores between the AmnioFix Injectable Treatment Group versus placebo-treated Control Group. The principal secondary efficacy endpoint was the change in FFI-R score for patients between baseline and 3 months expressed as the difference in mean scores between the AmnioFix Injectable Group versus the Control Group.

Summary of Top-line AmnioFix Injectable Phase 2B Results

The Phase 2B IND clinical trial evaluating the use of AmnioFix Injectable for the treatment of Plantar Fasciitis demonstrated a clinically and statistically significant difference compared to patients in the Control Group in their reduction in VAS score for pain and FFI-R scores at 3 months compared to baseline. Additionally, the safety of the product has been demonstrated by the absence of serious, unanticipated, product-related adverse events and the relative absence of an elicited immune response post-injection demonstrated by the Test Group.

At three months, the Treatment Group (n=73) experienced a mean reduction of 54.1 points in their VAS score for pain compared to baseline. The Control Group (n=72) experienced a mean reduction of 31.9 points in their VAS score for pain at three months compared to baseline, a difference of 22.2 points between the two treatment groups (p<0.0001).

At three months, the Treatment Group experienced a mean reduction of 36 points in FFI-R score compared to baseline. The Control Group experienced a mean reduction of 22 points in FFI-R at three months compared to baseline, a difference of 14 points between the two treatment groups (p=0.0004).

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 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 that 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 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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