Innovations in Regenerative Biomaterials

## MiMedx Announces the Enrollment of the First Patients in the Phase 3 Clinical Trial of AmnioFix® Injectable for Achilles Tendonitis

January 17, 2018

MARIETTA, Ga., Jan. 17, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), the leading biopharmaceutical company developing and marketing regenerative and therapeutic biologics utilizing human placental tissue allografts with patent-protected processes for multiple sectors of healthcare, today announced that the first patients have been randomized and enrolled in the Company's Phase 3 Investigational New Drug (IND) clinical trial for MiMedx's micronized amniotic tissue, AmnioFix® Injectable, in the treatment of Achilles Tendonitis.

The Phase 3 Achilles Tendonitis clinical trial is studying MiMedx's AmnioFix® Injectable in a prospective, double blinded, randomized controlled trial of the Micronized dHACM (dehydrated Human Amnion Chorion Membrane) Injection as compared to saline placebo injection.

The design of the Phase 3 Achilles Tendonitis study will include approximately 158 patients. The primary efficacy endpoint of this study will be the change in Visual Analog Scale (VAS) score for patients between baseline and Day 90 between the AmnioFix Injectable group versus placebo-treated group. The primary safety endpoint will be the proportion of product-related adverse events, serious adverse events, and unanticipated adverse events during the first twelve months post injection in the AmnioFix Injectable group versus the placebo-treated group.

Parker H. "Pete" Petit, Chairman and CEO, said, "We are pleased to enroll our first patients in this important Phase 3 IND study in the Orthopedic/Sports Medicine area. Clearly, there is an unmet need in the market for this type of treatment, and we believe the efficacy and safety profile of AmnioFix Injectable meets that need. Available treatments such as corticosteroids or platelet rich plasma have not been consistently shown to be effective as a first-line therapy for this condition. This is our second Phase 3 clinical trial that has commenced patient enrollment. Yesterday, we announced the start of patient enrollment on our Phase 3 Plantar Fasciitis clinical trial."

Bill Taylor, President and COO, said, "Following the completion of this Achilles Tendonitis Phase 3 trial and the Company's other ongoing Phase 3 trial for the use of AmnioFix Injectable in the treatment of Plantar Fasciitis, MiMedx plans to submit a Biologic License Application (BLA) to the FDA for tendonitis. With the ineffectiveness of available treatments, the lack of other safe and effective treatment options, and the high risks associated with pain management by opioids, the unmet need for a safe and effective first-line regenerative medicine therapy to treat pain and function symptoms for tendonitis, such as AmnioFix Injectable, is clear. Beginning Phase 3 enrollment so close together in our Achilles Tendonitis and our Plantar Fasciitis studies, should also allow both trials to complete around the same time and fit very well into our timing for the BLA submission for an overall tendonitis indication."

**About MiMedx**

MiMedx® is the 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 our mission to give physicians products and tissues to help the body heal itself. We process the human placental tissue utilizing our proprietary PURION® Process among other processes, to produce safe and effective allografts. MiMedx proprietary processing methodology employs aseptic processing techniques in addition to terminal sterilization. MiMedx is the leading supplier of placental tissue, having 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, including statements regarding the Company's intention and timing of the filing of its Biologic License Application with the FDA, the belief that AmnioFix Injectable meets a market need, and that the start of enrollments in both Phase 3 studies so close to each other should allow both trials to complete around the same time and fit into the Company's timing for its planned BLA submission. These statements also may be identified by words such as "believe," "except," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. Forward-looking statements are subject to significant risks and uncertainties, and we caution investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Among the risks and uncertainties that could cause actual results to differ materially from those indicated by such forward-looking statements include the risk that unexpected results or concerns may arise from additional data or analysis from our clinical trials; regulatory submissions may take longer or be more difficult to complete than expected; that regulatory authorities may require additional information or further studies or may fail to approve or may delay approval or grant marketing approval that is different than anticipated; and the market may not adopt the utilization of AmnioFix Injectable as anticipated. For more detailed information on the risks and uncertainties, please review the Risk Factors section of our 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 we assume no obligation to update any forward-looking statement.

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