MIMEDX Reports Top-line Data from Two Late-Stage Musculoskeletal Trials with Proprietary Amniotic Tissue Technology

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Phase 2B Knee Osteoarthritis (KOA) Study Top-line Interim Results Demonstrate Varied Efficacy Signals between Patient Cohorts

Company to Pursue Phase 3 KOA Confirmatory Studies

Initial Review of Phase 3 Plantar Fasciitis Trial Data Does Not Support a Biologics License Application (BLA) Filing at This Time, Pending Further Analysis

MARIETTA, Ga., Sept. 13, 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 top-line results from two late-stage musculoskeletal clinical trials of the Company's micronized dehydrated Human Amnion Chorion Membrane (mdHACM): a Phase 2B clinical trial for the treatment of Knee Osteoarthritis (KOA) and a Phase 3 clinical trial for the treatment of Plantar Fasciitis (PF).

Top-line results from an interim analysis of the six-month efficacy data for the Phase 2B clinical trial for KOA did not meet primary endpoints, but did reveal varied efficacy signals between patient cohorts evaluated pre- and post- a blinded interim analysis performed in mid-2019, prompting the Company to plan for confirmatory efficacy studies for the KOA indication. The Phase 3 PF study did not meet its primary endpoint, and the Company will not pursue a BLA for this indication at this time. Throughout both studies, the mdHACM product was found safe and well-tolerated.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "These data, once examined thoroughly and reviewed with the U.S. Food and Drug Administration (FDA), will help guide our path forward, and merit additional clinical analysis as we pursue novel therapeutic solutions for patients with significant unmet needs. As a pioneer in amniotic tissue technology, our investigational studies further the science and our understanding of what is possible, and enable us to consider next-generation treatments for these painful and debilitating conditions. There is considerable market demand for safe and effective alternatives to reduce pain, improve function, and modify disease, and the potential positive signal within the KOA trial provides opportunity to build on these learnings and pursue additional studies. We look forward to further discussions with the FDA under the Regenerative Medicine Advanced Therapy (RMAT) process, and reviewing our next steps for continued clinical study of PURION® Processed mdHACM as a platform for regenerative medicine."

Top-line Interim Results: Phase 2B Knee Osteoarthritis (KOA)

The Phase 2B KOA trial formally ends in October 2021. An interim review of the 446 patients enrolled in the clinical trial showed that the study did not meet its two primary efficacy endpoints of a statistically significant change in the Visual Analog Scale (VAS) for Pain or in the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index. The top-line data indicate a potential positive clinical efficacy signal, but did not indicate a statistical difference between patients in the product treatment group and the placebo group, with all scores improving for both groups. Significant differences were observed between patients enrolled prior to the study's initial blinded interim analysis (the Pre-Interim Analysis Cohort), and those patients enrolled following the initial blinded interim analysis (the Post-Interim Analysis Cohort). Patients in the treatment group in the Pre-Interim Analysis Cohort demonstrated a greater improvement in WOMAC-Total, WOMAC-Pain and WOMAC-Function scores, with statistically significant separation between treatment and placebo-treated patients at both the three-month and six-month endpoints. The patients in the Post-Interim Analysis Cohort showed a positive response to both treatment and placebo. Additional analyses are planned to explore these differences.

Results for VAS did not indicate statistically significant differences between treatment and placebo-treated patients, or between the Pre-Interim Analysis Cohort and the Post-Interim Analysis Cohort at either the three-month or six-month endpoint, with a strong improvement in VAS observed across both cohorts.

Robert B. Stein, M.D., Ph.D., MIMEDX Executive Vice President, Research and Development, said, "The top-line interim results from the overall KOA study population are somewhat surprising given prior clinical experience and retrospective studies, and further examination will be required to determine the potential factors that may have contributed to the observed differences. The Phase 2B KOA trial provided important insights into our approach for the design of our future Phase 3 studies that could further elucidate the potential impact of mdHACM on the underlying disease process and cartilaginous tissues. In parallel, we are continuing to invest in research initiatives that broaden our understanding of the product's mechanism of action, disease modification potential, and long-term therapeutic utility."

The Company plans to meet with the FDA to thoroughly review the findings and determine the appropriate path forward toward the initiation of Phase 3 clinical trials in KOA. Based on the current analysis of the interim results for the Phase 2B clinical trial, the Company now believes that two Phase 3 studies in KOA will be required to file a BLA and intends to provide an update for the timing of the filing, previously tentatively planned for late-2024 or early-2025, following review and discussion with the FDA.

Top-line Results: Phase 3 Plantar Fasciitis (PF)

The Phase 3 PF study did not meet its primary endpoints. The product and placebo groups both improved during the treatment period, and demonstrated reduced VAS Pain and improved Foot Function Index-Revised (FFI-R) scores, without statistically significant separation between treatment groups. The Company plans on a complete review of the full study data, but does not intend to pursue a BLA filing for PF at this time, instead focusing resources on advancing confirmatory Phase 3 studies for KOA.

Both the Phase 2B KOA clinical trial and the Phase 3 PF clinical trial demonstrate strong safety results with no significant Adverse Events or Serious Adverse Events. The Company plans to review the full study results from both trials with investors at a future R&D Day, planned for later this year.

Mr. Wright added, “While the Plantar Fasciitis study results are disappointing, we continue to analyze these trial data from this trial to glean insights that may benefit our overall clinical pipeline. On behalf of MIMEDX, I extend our gratitude to all the patients, families, and physicians who participated in these important and informative trials.”

About the Intra-articular Micronized dHACM Versus Saline in the Treatment of Osteoarthritis of the Knee Trial
This study was a Phase 2B prospective, double-blinded, randomized controlled trial of PURION® Processed micronized dehydrated Human Amnion/Chorion Membrane (mdHACM) Injection, as compared to saline placebo injection in the treatment of osteoarthritis of the knee. Trial enrollment included 466 patients between the ages of 21 to 80 years, with a diagnosis of osteoarthritis defined as grade 1 to 3 on the Kellgren Lawrence grading scale and a Visual Analog Scale (VAS) for Pain score greater than 45. Due to a lower-than-expected number of study participant dropouts (3% in both arms) and with an adequate number of patients meeting the required time in study to assess the primary endpoint, the final number randomized was 446 patients.

The primary efficacy endpoints included change from baseline in VAS at 90 days and change from baseline in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at 90 days; the primary safety endpoint was incidence of related Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Adverse Events at 365 days. Secondary endpoints included: change from baseline in VAS at 180 days and change from baseline in WOMAC at 180 days. The WOMAC Index has become a standard study metric in KOA studies, and its use has been extensively validated. The 12-month safety visit follow up as requested by FDA is scheduled to be completed in October 2021.

About the Micronized dHACM Injectable for the Treatment of Plantar Fasciitis Trial
This study was a Phase 3 prospective, double-blinded, randomized controlled trial of a single injection of 40 mg of PURION® Processed micronized dehydrated Human Amnion/Chorion Membrane (mdHACM) into the plantar fascia, as compared to saline placebo injection in the treatment of plantar fasciitis. The trial enrolled 277 patients between the ages of 21 and 79 years, with an investigator-confirmed diagnosis of plantar fasciitis for greater than or equal to one month (30 days) and less than or equal to 18 months. Patients were required to have a Visual Analog Scale (VAS) Pain score of greater than or equal to 45 mm at randomization and to have received conservative treatment for greater than or equal to 1 month (30 days), including any of the following modalities: Rest, Ice, Compression, Elevation (RICE); stretching exercises; NSAIDs; or orthotics. The primary endpoints were change in VAS for Pain at 90 days and incidence of related adverse events at 180 days, serious adverse events and unanticipated events during the first 12 months post-injection. Secondary endpoints included self-reported responses to the Foot Function Index – Revised (FFI-R) at 90 days.

Important Cautionary Statement
This press release includes forward-looking statements. Statements regarding: (i) plans to conduct additional analyses of the clinical trial data and expectations regarding the results of such analyses, including expectations regarding safety and efficacy, and the value of safety data from the trials and these analyses; (ii) the Company’s expectations regarding mdHACM’s potential use as a safe and effective treatment option, and that it may be an effective treatment for persons battling inflammatory conditions; (iii) the Company’s plans for completing 12-month safety visit follow-up and its timing; (iv) plans for meetings with the FDA, and planned BLA submissions to the FDA, and their timing; and (v) plans for future clinical trials, including the Company’s decision to pursue or not pursue, and their timing; 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) the results of a clinical trial or trials may not demonstrate that the product is safe or effective, or may have little or no statistical value; (ii) the Company may change its plans due to unforeseen circumstances, and delay or alter the timeline for future trials, analyses, or public announcements; (iii) the timing of any meeting with the FDA depends on many factors and is outside of the Company’s control, and the results from any meeting are uncertain; (iv) a BLA submission requires a number of prerequisites, including favorable study results and statistical support, and completion of a satisfactory FDA inspection of the Company’s manufacturing facility or facilities; (v) plans for future clinical trials depend on the results of pending clinical trials, discussion with the FDA, and other factors; and (vi) conducting clinical trials is a time-consuming, expensive, and uncertain process. 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.

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