MiMedx Announces Last Patients Last Visits in Three Late-Stage Musculoskeletal Trials with Proprietary Tissue Technology

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Advances Potential for Use of Micronized Dehydrated Human Amnion Chorion Membrane (mdHACM) as a Safe and Effective Treatment Option

On Track to Advance Planned Analyses and Announce Top-Line Data in Plantar Fasciitis, Achilles Tendonitis and Knee Osteoarthritis in Q3 2021

MARIETTA, Ga., April 19, 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 that the last patients have completed their last clinical visits in two late-stage Investigational New Drug (IND) trials: Phase 3 studies of AmnioFix® Injectable (micronized dehydrated Human Amnion Chorion Membrane (mdHACM)) as a potential treatment for Plantar Fasciitis and Achilles Tendonitis. In addition, all clinical effectiveness endpoint visits have been completed in a Phase 2B study of mdHACM as a potential treatment for Knee Osteoarthritis. With the completion of these patient visits, the Company will begin the planned review and statistical analyses of data from all three trials.

"Completion of the Phase 2B study for mdHACM as a treatment for Knee Osteoarthritis marks an extraordinary milestone," said Alfred Gellhorn, M.D., Adjunct Associate Professor of Clinical Rehabilitation and Director of Sports Medicine, Weill Cornell Medicine. "There is a tremendous unmet need for safe and effective treatment options for Knee Osteoarthritis. The osteoarthritis community has long recognized that current treatment options are painfully insufficient. The benefit of a novel therapeutic option in this setting for both patients and clinicians cannot be overstated."

"These studies are designed to prove the clinical efficacy and safety of AmnioFix Injectable in treating frustrating chronic conditions," said Stuart Miller, M.D., Principal Investigator, Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, and Assistant Professor, Department of Orthopaedic Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland. "The prior Phase 2B Plantar Fasciitis study has helped establish the product's safety profile, and I believe these further studies may demonstrate its effectiveness in battling inflammatory conditions. As a physician committed to advancing patient care, I would welcome having additional treatment options that could potentially address the pain and quality of life issues my patients face on a daily basis."

Timothy R. Wright, MiMedx Chief Executive Officer, added, "These trials play key roles in our late-stage AmnioFix Injectable pipeline, and with last patient visits complete across the three trials, we will now lock the databases, conduct the appropriate statistical analyses, and request meetings with the U.S. Food and Drug Administration (FDA) to review the findings. We anticipate announcing top-line results of all three trials this summer, have commenced planning efforts to initiate our Phase 3 clinical trial for Knee Osteoarthritis, and plan to file a Biologics License Application (BLA) for Plantar Fasciitis in the first half of 2022. Although we do not anticipate pursuing a BLA for Achilles Tendonitis, we expect to glean valuable safety data for the AmnioFix Injectable product from that trial. On behalf of MiMedx, I would like to express our sincere gratitude to all the patients, families and physicians who participated in these important studies critical to our submissions to FDA for approvals for the therapeutic use of amniotic tissues."

The typical steps for obtaining FDA approval of a BLA to market a biological product in the United States include performance of two adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication, along with the development of purity, potency and identity tests to demonstrate consistency and reliability of the manufacturing process through a chemistry, manufacturing and control program. Submission to the FDA of a BLA for marketing the product includes, among other things, reports of the outcomes and full data sets of the clinical trials, and proposed labeling and packaging for the product. In addition, the satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced is required to assess compliance with FDA's Current Good Manufacturing Practice (CGMP) regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, potency, quality and purity.

About the Micronized dHACM vs. Saline in the Treatment of Osteoarthritis of the Knee Trial
This trial, the first randomized clinical study of a micronized dehydrated Human Amnion/Chorion Membrane (mdHACM) Injection in the Treatment of Knee Osteoarthritis (KOA), is a Phase 2B, prospective, double-blinded, randomized controlled trial of the mdHACM injection as compared to saline placebo injection in the treatment of osteoarthritis of the knee. Trial enrollment was planned to include 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, and with an adequate number of patients meeting the required time in study to assess the primary endpoint, the final number randomized will be 447 patients.

The primary efficacy endpoints include change from baseline in VAS at 90 days, change from baseline in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at 90 days, and incidence of related Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Adverse Events at 365 days. Secondary endpoints include: 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 blinded efficacy visits for this study are complete, with the 12-month safety visit follow up as requested by FDA scheduled to compete in October 2021. The Company intends to initiate a Phase 3 study of mdHACM injection in the treatment of Knee Osteoarthritis in Q3 2021, after an end of Phase 2 meeting with FDA, and planning for this effort is underway.

About Knee Osteoarthritis
Osteoarthritis (OA) is by far the most common joint disease – millions of adults experience pain and decreased quality of life every day because of joint

destruction caused by osteoarthritis. Osteoarthritis is responsible for a staggering public health and economic impact: more than 242 million people worldwide currently suffer from symptomatic OA of the knee and hip; 45% of all people have a lifetime risk of developing OA of the knee; and OA is responsible for $71 billion in lost earnings annually in the U.S. Although knee replacement is an option for those with advanced knee arthritis, it carries significant risks, and current treatment algorithm, including oral anti-inflammatory medications, cortisone injections, and hyaluronic acid injections, are limited in the amount of relief it can provide. Anti-inflammatories have negative cardiovascular effects and injected steroids cause further joint degeneration.

About the Micronized dHACM Injectable for the Treatment of Plantar Fasciitis Trial
This study is a Phase 3, prospective, double-blinded, randomized controlled trial of micronized dehydrated Human Amnion Chorion Membrane (mdHACM) injection 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 scale of greater than or equal to 45 mm at randomization and be receiving 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 are 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 include self-reported responses to the Foot Function Index – Revised (FFI-R) at 90 days.

This study follows a Phase 2B prospective, single-blinded, randomized controlled trial of 145 patients, which demonstrated a statistically significant reduction in VAS score for pain and an improvement in Foot Function Index-Revised (FFI-R) score. 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 ($p<0.0001$). These effectiveness results were maintained at the six-month secondary endpoint.

About Plantar Fasciitis
More than two million people are treated for plantar fasciitis inflammation in the United States annually. In 10% of patients treated with traditional measures, the condition progresses to chronic plantar fasciitis-related pain – recovery from which is lengthy and recurrence of which is very common, with an estimated $284 million annual national economic burden. The current treatment algorithm aims to maintain arch shape, modify foot loading and/or improve shock absorbency of the heel through night splints and orthotics. While these measures may assist in reducing pain associated with plantar fasciitis, they do not address the root cause of the condition, which is thought to be both degenerative and inflammatory.

About the Micronized dHACM Injectable for the Treatment of Achilles Tendonitis Trial
This study is a Phase 3, prospective, double-blinded, randomized controlled trial of micronized dehydrated Human Amnion Chorion Membrane (mdHACM) injection as compared to saline placebo injection in the treatment of Achilles Tendonitis. The trial enrolled 158 patients between the ages of 21 and 80 years, with an investigator-confirmed diagnosis of plantar fasciitis for greater than or equal to 1 month (30 days) and less than or equal to 18 months. Patients were required to have a Visual Analog Scale (VAS) Pain scale of greater than or equal to 45 mm at randomization and be receiving conservative treatment for greater than or equal to one month (30 days), including any of the following modalities: Rest, Ice, Compression, Elevation (RICE); stretching exercises; NSAIDs or orthotics. The primary endpoints are 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 include self-reported responses to the Foot Function Index – Revised (FFI-R) at 90 days.

The Company does not anticipate pursuing a BLA for Achilles Tendonitis at this time, and plans to review options for this program after assessing the results of the Phase 3 study, including potentially exploring the efficacy of AmnioFix Injectable in a more well-defined subset of patients. The Company does expect to glean valuable safety data from the trial for the AmnioFix Injectable product, which can be used to supplement the data package for other clinical indications underway and inform future clinical indications under consideration.

About Achilles Tendonitis
Achilles tendonitis is a common condition that can occur at any time, but often results from years of overuse (long distance runners, sprinters) and is not typically related to a specific injury. Achilles tendonitis can result in pain and stiffness along the Achilles tendon; pain along the tendon or back of the heel that worsens with activity; severe pain the day after exercising; thickening of the tendon; bone spurs (insertional tendinitis); and chronic swelling. All may result in limited mobility and, potentially, a rupture or tear in the Achilles tendon. Current treatments include rest, icing, NSAIDs; exercise; orthotics; cortisone injections; and surgery. Moderate to severe post-surgical pain is noted in 20% to 30% of patients and is the most common complication. In addition, wound infection can occur, which is difficult to treat in this location.

Important Cautionary Statement
This press release includes forward-looking statements. Statements regarding: (i) expectations about the results of clinical trials, including expectations regarding safety and efficacy, and the value of safety data from the trials; (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 to review and analyze the results of its plantar fasciitis, Achilles tendonitis, and knee osteoarthritis clinical trials, and to announce top-line data from the plantar fasciitis, Achilles tendonitis, and knee osteoarthritis clinical trials in Q3 2021; (iv) plans for meetings with the FDA, and planned BLA submissions to the FDA, and their timing; and (v) plans for future clinical trials, 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 successful clinical trial results and is outside of the Company's control; (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; and (v) plans for future clinical trials depend on the results of pending clinical trials. 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.

Important Information
The Company intends to file a definitive proxy statement and associated WHITE proxy card in connection with the solicitation of proxies for the 2021 Annual Meeting with the Securities and Exchange Commission (the "SEC"). Details concerning the nominees of the Company's board of directors for election at the 2021 Annual Meeting will be included in the proxy statement. BEFORE MAKING ANY VOTING DECISION, SHAREHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and shareholders will be able to obtain a copy of the definitive proxy statement and other documents filed by the Company free of charge from the SEC's website at www.sec.gov. The Company's shareholders will also be able to obtain, without charge, a copy of the definitive proxy statement and other relevant filed documents from the "SEC Filings" section of the Company's website at www.mimedx.com.

Participants in the Solicitation
The Company, its directors, its director nominees and certain of its executive officers are participants in the solicitation of proxies from shareholders in respect of the 2021 Annual Meeting. Information regarding the names of the Company's directors and executive officers and certain other individuals and their respective interests in the Company by security holdings or otherwise is set forth in the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2020, filed with the SEC on March 8, 2021, and the Company's definitive proxy statement for the 2020 annual meeting of the Company's shareholders, filed with the SEC on October 15, 2020. To the extent holdings of such participants in the Company's securities have changed since the amounts described in the proxy statement for the 2020 annual meeting of the Company's shareholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of these participants in any proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in the Company's proxy statement and other relevant materials to be filed with the SEC, if and when they become available. Details regarding the nominees of the Company's Board of Directors for election at the 2021 Annual Meeting will be included in the Company's proxy statement, when available.

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 core 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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