Innovations in Regenerative Biomaterials

MiMedx Enrolls First Patient In Its Phase 2B Clinical Trial Of RMAT Designated AmnioFix® Injectable For The Treatment Of Osteoarthritis Of The Knee

March 28, 2018

Initiation of Phase 2B Study Follows Quickly After FDA Grants RMAT Designation for Knee OA

MARIETTA, Ga., March 28, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today announced that the first patient has been enrolled in the Company's Phase 2B Investigational New Drug (IND) clinical trial to assess the safety and efficacy of AmnioFix® Injectable as a treatment for pain associated with Osteoarthritis (OA) of the knee.

OA of the knee is a degenerative and irreversible condition that is associated with pain, restricted mobility, and ultimately joint instability. For many, the disease significantly limits day-to-day function and can only be treated with joint replacement surgery. According to the National Institutes of Health'sUS National Library of Medicine, OA is the most common joint disorder in the United States and its prevalence increases with age. Approximately 20% of the U.S. population, or more than 60 million adults, is over the age of 60, and symptomatic knee OA occurs in 10% of men and 13% of women in that age group.

Parker H. "Pete" Petit, Chairman and Chief Executive Officer, said, "The enrollment of our first patient in this Phase 2B clinical study is another important milestone for MiMedx. This comes on the heels of the Regenerative Medicine Advanced Therapy (RMAT) designation, which highlights the need to advance promising therapies in areas of considerable unmet medical need, and reaffirms the significant potential for AmnioFix Injectable."

By granting the RMAT designation to AmnioFix Injectable for use in the treatment of OA of the knee, the FDA commits to taking specific actions to facilitate the development of the product. These actions may also include an accelerated and priority review.

"Given the lack of treatment options for patients with knee OA, and the high risks associated with using opioids to manage pain, AmnioFix Injectable has the opportunity to address a significant unmet clinical need by providing physicians and their patients with a new, safe, effective and durable front-line therapy for treating OA knee pain," added Bill Taylor, President and COO. "In addition, we believe AmnioFix Injectable has the potential to become a blockbuster therapeutic biologic, with long-term peak revenue potentially reaching $4 billion for musculoskeletal pain management within the more than $12 billion U.S. joint pain injection market."

Clinical Study Design

This Phase 2B, prospective, double blinded, randomized controlled trial will enroll approximately 318 patients at 20 centers. Patients will be randomized 1:1 into two treatment groups; a single injection of saline (placebo control) or a single injection of 40mg of AmnioFix® Injectable. The co-primary efficacy endpoints are the change in Visual Analog Scale (VAS) score and the change in Western Ontario and McMaster Universities (WOMAC) osteoarthritis index between baseline and day 90 expressed as the difference in means between each group. The primary safety endpoint is the incidence of adverse events, serious adverse events, and unanticipated adverse events during the first 12 months post injection in the AmnioFix Injectable group versus the placebo-controlled group.

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.

SOURCE MiMedx Group, Inc.

Robert P. Borchert, Vice President, Investor Relations, 770-651-9383, investorrelations@mimedx.com