Innovations in Regenerative Biomaterials

AmnioFix® Injectable Granted Regenerative Medicine Advanced Therapy (RMAT) Designation by the FDA for the Treatment of Osteoarthritis of the Knee

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MARIETTA, Ga., March 9, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today announced that the U.S. Food and Drug Administration (FDA) has granted MiMedx's micronized amniotic tissue, AmnioFix® Injectable, the Regenerative Medicine Advanced Therapy (RMAT) designation for use in the treatment of Osteoarthritis (OA) of the knee.

In its letter to the Company, the FDA confirmed its determination that MiMedx Allogeneic Micronized Dehydrated Human Amnion/Chorion Membrane (micronized dHACM) for the treatment of OA of the knee meets the criteria for RMAT designation. The FDA further stated that MiMedx has provided clinical information to demonstrate preliminary clinical evidence to indicate that the drug has the potential to address unmet medical needs for this condition.

In granting the RMAT designation to MiMedx AmnioFix Injectable for use in the treatment of OA of the knee, the FDA committed to a multidisciplinary comprehensive discussion with MiMedx regarding the Company's development program, including planned clinical trials and plans for expediting the manufacturing development strategy.

"The FDA's RMAT designation for AmnioFix Injectable is an important milestone for MiMedx and highlights the importance of introducing promising therapies in areas of considerable unmet medical need. We are especially pleased that the FDA will meet to discuss expediting our development and manufacturing of this product to serve the needs of patients suffering from OA of the knee. We look forward to discussions with the FDA," said Parker H. "Pete" Petit, Chairman and Chief Executive Officer.

"AmnioFix Injectable has been shown to have the potential to reduce pain and improve function in patients with OA of the knee. Given the lack of treatment options for patients with this condition, 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 front-line therapy," 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 exceeding $4 billion for musculoskeletal pain management within the more than $12 billion addressable U.S. joint pain injection market."

An investigational regenerative medicine therapy is eligible for RMAT designation if it is intended to treat, modify, reverse, or cure a serious condition, and if preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition.

"Our clinical, scientific and regulatory team has done a superb job in the development of this product, and we are very fortunate to have such a talented and dedicated team in our organization," noted Taylor.

The FDA will also provide MiMedx with intensive guidance on efficient drug development, as well as an organizational commitment to involve senior management in facilitating the product's development program. The RMAT designation includes all of the benefits of the *Fast Track* and *BreakthroughTherapy* designation programs, including early interaction with sponsors, which may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

About Osteoarthritis of the Knee

Osteoarthritis of the knee is an irreversible and persistent condition, prevalent in adult populations and even more so in older populations, associated with pain, restricted mobility, swelling and ultimately joint instability that can significantly limit day-to-day functioning. Osteoarthritis affects an estimated 31 million Americans and is the leading cause of disability in American adults. Prevalence increases with age ranging from about 2% among persons under age 45 and more than 80% among those over 75. Symptomatic OA of the knee presents in 14 million Americans including 2 million under the age of 45, and more than 6 million between the ages of 45 and 64.

The disorder occurs when the joint surface cartilage (also called hyaline cartilage or articular cartilage) becomes worn away leaving the raw bone beneath exposed. The cartilage normally serves as a "pad" or a bearing in the joint. When the bearing wears away, the result is a roughed joint surface that causes the pain and stiffness associated with osteoarthritis.

Knee osteoarthritis is the leading cause of limitations in activities of daily living such as walking and climbing stairs. Knee osteoarthritis symptoms often develop slowly and may become markedly worse over time or with specific activities. Characteristic signs and symptoms of osteoarthritis include stiffness, pain, soreness, inflexibility, swelling, grating/creaking, bone spurs and deformity. While knee osteoarthritis is often a progressive and irreversible degenerative process, functional improvement and pain control are the most common treatments used to treat this condition.

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