



MiMedx Provides Additional Information and Context to Wall Street Journal Article

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MARIETTA, Ga., Aug. 15, 2018 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), a leading developer and marketer of regenerative and therapeutic biologics, today provided additional background and context to certain points, including third party statements, in an article published by *The Wall Street Journal* ("WSJ") on August 14, 2018:

MiMedx products are manufactured according to current Good Tissue Practices (cGTP) standards, pursuant to the Food and Drug Administration ("FDA") regulations specified in 21 CFR 1271, which are the requirements and guidelines the Company must follow. MiMedx is also in compliance with the American Association of Tissue Banks' 14th standard, of which the Company is a fully accredited member in good standing.

In addition, certain MiMedx products are marketed as cellular and tissue based products ("HCT/Ps") under Section 361 of the Public Health Service Act until either a biologics license application ("BLA") by the Company is approved or the FDA's enforcement discretion under the November 2017 guidance document¹ ends. Since the 2016 inspection report from the FDA referenced by the WSJ, MiMedx has continued its transition to cGMP compliance for certain products as it conducts clinical trials to seek approval for certain indications under a BLA filing for its micronized dehydrated Amnion/Chorion Membrane ("dHACM") injection (AmnioFix® Injectable).

In terms of the clinical evidence supporting the Company's products, MiMedx continues to build its compendium of clinical studies, including numerous randomized controlled studies, to support the use of EpiFix®. In addition, the Company has three ongoing investigational new drug programs with the FDA covering clinical studies intended to support an eventual BLA for micronized dHACM injection. As an example, interim results from a Phase 2B multicenter, randomized controlled trial evaluating the use of micronized dHACM injection as a treatment for Plantar Fasciitis were recently published in *Foot and Ankle International*. The interim results reflected statistically significant improvement in pain and foot function compared to the placebo control group. MiMedx also began enrolling patients into its Phase 3 Plantar Fasciitis trial in January 2018.

Selling micronized amniotic tissue-based products is a broad industry matter now covered by a finalized guidance document¹ from the FDA on homologous use and minimal manipulation of HCT/Ps. The guidance stated that all micronized amniotic products would require a biologics license to be lawfully marketed in the United States, and that FDA would use its enforcement discretion to provide a 36-month transition period. MiMedx is committed to the transition process as described in the November 2017 guidance. In the meantime, and until the end of the transition period, MiMedx continues to sell its micronized allograft products as HCT/Ps in the United States.

MiMedx continues to make progress on its market expansion objectives and clinical trial programs while continuing to maintain positive operating cash flow with no outstanding long-term debt. The Board and management team remain focused on positioning MiMedx to capitalize on the full array of opportunities presented by the Company's processing capabilities, clinical science, customer relationships and scale.

As previously disclosed, the MiMedx Audit Committee is conducting an independent internal investigation into current and prior-period matters concerning sales and distribution practices and other matters. The Audit Committee is working diligently with its advisors to complete the investigation, and the Company is also working to prepare its financial statements for audit and regain compliance with Securities and Exchange Commission reporting obligations as soon as practicable.

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 provide 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 1.3 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. 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. 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.

1. See FDA, *Guidance for Industry and Staff: Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use* (Nov. 2017).

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