MIMEDX Provides Update on AXIOFILL® Request for Designation ("RFD") from FDA

March 27, 2024

Receives Determination Letter from FDA Stating AXIOFILL Does Not Qualify for Classification as an HCT/P Under Section 361

MIMEDX Continues to Pursue All Available Options to Keep AXIOFILL on the Market

Reiterates Expectations for 2024 Net Sales Percentage Growth in the Low Double Digits and 2024 Adjusted EBITDA[1] Margin Above 20%

MARIETTA, Ga., March 27, 2024 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company") today announced that the U.S. Food and Drug Administration ("FDA") has issued a determination letter in connection with the RFD process related to AXIOFILL, a human-derived particulate wound dressing. In the letter, FDA reaffirmed its position that AXIOFILL does not meet the regulatory classification requirements of a Human Cell, Tissue or Cellular or Tissue-based Product ("HCT/P") under Section 361 of the Public Health Service Act ("PHSA").

Joseph H. Capper, MIMEDX Chief Executive Officer, commented: "We are disappointed that the FDA, through the RFD process, has reached a conclusion that continues an inconsistent approach to regulating AXIOFILL and other human-derived particulate products. As I stated on our February conference call, we intend to exhaust all of our legal and regulatory options in an attempt to ensure continued access to this incredibly safe and effective product. Since the FDA has issued a final agency decision, we are taking steps to assert our position in court."

In response to the RFD determination letter, the Company has filed suit in the U.S. District Court for the Northern District of Georgia and intends to exhaust all legal options available, given the arbitrary and capricious manner in which FDA is regulating like-kind products. Notably, while these proceedings are taking place, the Company plans to continue marketing AXIOFILL.

Today, there are at least three nearly identical products, including AXIOFILL, that are treated differently by FDA. The first of these products received an RFD designation classifying it as a 361 product, consistent with other HCT/Ps. Based on this precedent, MIMEDX introduced AXIOFILL in September 2022, also as a 361 product. As we now know, the FDA has taken a position that AXIOFILL is designated as a 351 biologic product, requiring the most time-consuming and expensive path to approval. Further confusing the matter, a third human-derived particulate product recently received 510(k) clearance, a regulatory pathway typically used for medical devices, including xenografts and synthetic products.

Mr. Capper continued, "We have been working diligently to mitigate the impact of any potential disruption related to AXIOFILL, including through our recent acquisition of exclusive rights to a bovine-derived collagen particulate from Regenity Biosciences. With the introduction of this new product later in the year and with our efforts to keep AXIOFILL on the market long-term, we look forward to continuing to address a variety of patient care needs with our best-in-class portfolio of healing solutions. Finally, we do not currently anticipate the ongoing matter related to AXIOFILL will require us to change our full year 2024 financial guidance, which we issued on our February 28, 2024 earnings conference call."

Important Cautionary Statement

This press release includes forward-looking statements. Statements regarding: (i) future sales or sales growth; (ii) our 2024 financial guidance issued on February 28, 2024; (iii) the impact of the FDA's determination letter and our lawsuit against the FDA on our 2024 financial goals and expectations for future financial results; and (iv) our ability to classify AXIOFILL as a HCT/P under Section 361 and the legal and regulatory options available to us regarding such classification. Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "goal," "outlook," "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) future sales are uncertain and are affected by competition, access to customers, patient access to healthcare providers, the reimbursement environment and many other factors; (ii) the Company may change its plans due to unforeseen circumstances; (iii) the results of scientific research are uncertain and may have little or no value; (iv) our ability to sell our products in other countries depends on a number of factors including adequate levels of reimbursement, market acceptance of novel therapies, and our ability to build and manage a direct sales force or third party distribution relationship; (v) the effectiveness of amniotic tissue as a therapy for particular indications or conditions is the subject of further scientific and clinical studies; and (vi) we may alter the timing and amount of planned expenditures for research and development based on regulatory developments. 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 a pioneer and leader focused on helping humans heal. With more than a decade of helping clinicians manage chronic and other hard-to-heal wounds, MIMEDX is dedicated to providing a leading portfolio of products for applications in the wound care, burn, and surgical sectors of healthcare. The Company's vision is to be the leading global provider of healing solutions through relentless innovation to restore quality of life. For additional information, please visit www.mimedx.com.

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[1] Adjusted EBITDA and related margins are non-GAAP financial measures. Please refer to the Company's web site and most recent annual report and quarterly reports filed with the Securities and Exchange Commission for a reconciliation of Adjusted EBITDA and related margins to the most directly comparable GAAP measures.