MIMEDX Provides AXIOFILL® Update & Reiterates 2023 Full Year Net Sales and Fourth Quarter Adjusted EBITDA Margin Outlook

December 29, 2023

Receipt of FDA Warning Letter for AXIOFILL Classification; Not Related to Safety

Request for Designation for AXIOFILL Submitted to FDA and Currently Under Review

Reiterates Expectations for 2023 Net Sales Growth in the High Teens and Fourth Quarter Adjusted EBITDA Margin of Above 20%

MARIETTA, Ga., Dec. 29, 2023 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) (“MIMEDX” or the “Company”) today provided the following update regarding AXIOFILL and reiterated its outlook for 2023 full year net sales growth and fourth quarter adjusted EBITDA margin.

AXIOFILL Update

Following a routine inspection earlier in the year, the United States Food and Drug Administration (“FDA”) took the position that one of the Company’s recently-launched placental-derived tissue products – AXIOFILL – does not meet the requirements as a Section 361 product and is therefore subject to enforcement as a Section 351 product. Specifically, FDA asserts that the production of AXIOFILL involves more than “minimal manipulation.” The Company does not agree with FDA’s position and has been actively engaged with the agency through its “Request For Designation” (“RFD”) process. However, on December 21, 2023, MIMEDX received a Warning Letter from FDA reiterating the agency’s position on AXIOFILL. The Warning Letter does not relate to any of the Company’s other products, nor does it assert any product safety claims or adverse events related to AXIOFILL. AXIOFILL has been on the market since September 2022 and has a strong safety record.

The Company believes that AXIOFILL, which is expected to generate less than 5% of MIMEDX’s total net sales anticipated for 2023, was developed and is manufactured to comply with the requirements for a Human Cell, Tissue or Cellular or Tissue-based Product (“HCT/P”) under Section 361 of the Public Health Service Act. Specifically,

- AXIOFILL is composed solely of human placental disc extracellular matrix (ECM)
- AXIOFILL is used to “replace or supplement damaged or inadequate integumental tissue” which is consistent with ECM homologous use.

AXIOFILL’s product characteristics can be reasonably considered directly comparable to at least one other commercially available HCT/P on the market that the FDA regulates under Section 361 and, as a result, the Company believes FDA is not consistently applying the rules for permitted use.

Joseph H. Capper, MIMEDX Chief Executive Officer commented, “In the course of developing our products, we go to great lengths to ensure that they comply with all relevant regulatory requirements. We believe that AXIOFILL has been incorrectly characterized by the agency, particularly in light of the existence of other Section 361 products currently available on the market. While AXIOFILL sales are not material to our overall performance, we will, nonetheless, continue to work with FDA and explore all available options to ensure physicians and patients have continued access to this incredibly safe and important product. Importantly, we are permitted to continue selling the product until this matter has been fully adjudicated.”

The Company will respond to the Warning Letter within the required 15-day period. The Company is also currently engaged with FDA in the RFD process regarding AXIOFILL. MIMEDX plans to provide commentary about this matter during its upcoming fourth quarter and year end 2023 conference call in late-February.

Mr. Capper concluded, “We remain on track to cap off a fantastic year, with strong top line growth and profitability. As such, we are also reiterating our expectations for full year 2023 net sales in the high-teens and fourth quarter adjusted EBITDA margin above 20%. With clear strategic direction and excellent performance from across the entire enterprise, 2023 has turned out to be quite the turning point for MIMEDX. We plan to carry this momentum into 2024 and could not be more excited about the numerous prospects for our growing Company.”

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.

Forward Looking Statements

This press release may contain statements which constitute forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the future operating performance of MIMEDX and MIMEDX’s pursuit of growth and innovation. 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. Investors are cautioned that any such forward looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the

forward looking statements as a result of various factors. Important factors that could cause such differences are described in MIMEDX's periodic filings with the Securities and Exchange Commission. Any forward looking statements speak only as of the date of this press release and MIMEDX assumes no obligation to update any forward looking statement.

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