

# MIMEDX Announces Commercial Launch of EPIFIX® in Japan with Exclusive Distribution Agreement with GUNZE MEDICAL LIMITED

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MIMEDX aligns with a leading distributor of wound care products in Japan to capitalize on first-mover advantage for EPIFIX

MARIETTA, Ga. and OSAKA, Japan, Jan. 04, 2023 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company"), a pioneer and leader in placental biologics, today announced that it has entered into an exclusive distribution agreement with GUNZE MEDICAL LIMITED ("Gunze Medical"), a subsidiary of Gunze Limited, for sales of EPIFIX in Japan. Gunze Medical is a leading distributor of products used in a wide range of wound and surgical settings, including bioabsorbable devices and materials, such as sutures and sheet products. The company has a team of over 90 sales representatives and clinical support staff nationwide, as well as strong existing clinician relationships. MIMEDX and the Gunze Medical team will collaborate to continue physician education activities and drive further key opinion leader ("KOL") engagement in the country.

"We are delighted to join forces with the Gunze Medical team to bring EPIFIX to Japan," stated Todd Newton, MIMEDX interim Chief Executive Officer. "Following the receipt of regulatory approval in 2021 and a favorable reimbursement rate decision just back in September 2022, we believe this partnership with Gunze will position EPIFIX for long-term success in this important market."

Since receiving regulatory approval, the Company has collaborated with local physician societies, including the Japanese Society for Foot Care and Podiatric Medicine, and approximately 20 national KOLs to drive initial awareness of EPIFIX in the market. In that time, over 250 physicians have been trained, several of whom have also treated their first patients with EPIFIX.

"We have been working to create commercial momentum in Japan for over a year, and Gunze Medical provides us with a strong, local commercial presence that shares our market vision and patient commitment," continued Mr. Newton. "We are mutually committed to delivering the sales and clinical support necessary to demonstrate the value of EPIFIX for patients in Japan suffering from hard-to-heal wounds each year."

"EPIFIX offers a proven treatment option for patients dealing with chronic wounds, and we are proud to partner with MIMEDX to make this product widely available to healthcare professionals in Japan," stated Shojiro Matsuda, General Manager, Medical Division, Gunze Limited. "With our dedicated commercial team and complementary sales call point for this product, we believe we are well-positioned to capitalize on the first-mover advantage EPIFIX has in Japan as the first and only amniotic tissue product approved for use in the country."

# **About EPIFIX**

EPIFIX is a PURION® processed placental tissue allograft that supports the healing cascade by providing a semi-permeable, protective barrier over wounds. The product protects the wound bed to aid in the development of granulation tissue and provides a human biocompatible extracellular matrix that retains 300+ regulatory proteins.

MIMEDX received regulatory approval for EPIFIX from the Japanese Ministry of Health, Labour and Welfare (JMHLW) in June 2021 and reimbursement approval at a rate of JPY35,100/cm<sup>2</sup> in September 2022. EPIFIX is classified as a Class IV Medical Device and "Specified Biological Product" under JMHLW guidelines, and approved for the treatment of refractory ulcers, such as diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) that do not respond to conventional therapy. It is the first and only amniotic tissue product approved for use in Japan.

### About MIMEDX

MIMEDX is a pioneer and leader in placental biologics, developing and distributing placental tissue allografts to help address unmet clinical needs in multiple sectors of healthcare, including the Advanced Wound Care market as well as in surgical recovery settings. MIMEDX is also focused on advancing a promising late-stage pipeline opportunity targeted at decreasing pain and improving function for patients with knee osteoarthritis. Our products are derived from human placental tissues and processed using our proprietary methods, including the Company's own PURION <sup>®</sup> process. We employ Current Good Tissue Practices, Current Good Manufacturing Practices, and terminal sterilization to produce our allografts. MIMEDX has supplied over two million allografts, through both direct and consignment shipments. For additional information, please visit <a href="https://www.mimedx.com">www.mimedx.com</a>.

## **About Gunze Limited**

Gunze was founded in Kyoto, Japan in 1896, and today operates diverse businesses as a leading developer and manufacturer of Medical Devices, Plastic Films, Engineering Plastics, Electronic Components, Apparel, and various other segments. Gunze employs more than 5,600 people worldwide throughout 10 countries.

The Medical Device business, established in 1985, has a substantial footprint in over 35 countries. Its head office and manufacturing facility are located in Kyoto, Japan, and has subsidiaries in the U.S., EU, and China. By applying innovative fiber and polymer processing technologies, Gunze manufactures a comprehensive range of medical products focused on bioabsorbable and biocompatible materials such as skin substitutes, tissue reinforcement felt, bone fixation devices, dural substitutes, and suture thread. Gunze's mission will continue to be centered on advancing the quality of life of patients by providing innovative solutions to improve clinical outcomes.

# MIMEDX Safe Harbor Statement

Some of the information and statements contained in this press release and certain oral statements made from time to time by representatives of MIMEDX constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that do not directly or

exclusively relate to historical facts. Forward-looking statements include statements regarding: (i) our belief that our partnership with Gunze will position EPIFIX for long-term success in the Japan market; and (ii) our belief that we are well positioned to take advantage of the first-mover advantage EPIFIX has in Japan as the first and only amniotic tissue product approved for use in the country. 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. These statements are based on numerous assumptions and involve known and unknown risks, uncertainties and other factors that could significantly affect our operations and may cause our actual actions, results, financial condition, performance or achievements to differ materially from any future actions, results, financial condition, performance or achievements expressed or implied by any such forward-looking statements. Factors that may cause such a difference include, without limitation, those discussed in the Risk Factors section of the Company's 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.

#### Contact:

Matt Notarianni Investor Relations 470-304-7291 mnotarianni@mimedx.com