



MIMEDX EPIFIX® Receives Reimbursement Approval in Japan

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Provides Favorable Access to a New \$500 Million Market for the Treatment of Refractory Diabetic and Venous Ulcers for EPIFIX – the First and Only Amniotic Tissue Product Approved for Use in Japan

MARIETTA, Ga., Sept. 12, 2022 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) (“MIMEDX” or the “Company”), a transformational placental biologics company, today announced that the Japanese Ministry of Health, Labour and Welfare (JMHLW) approved reimbursement of EPIFIX® to treat refractory or hard-to-heal lower extremity diabetic and venous ulcers. The Company is in the last stages of preparing for full product launch, anticipated in the fourth quarter. The Company estimates the Japanese total addressable market associated with the scope of the JMHLW reimbursement decision to be approximately \$500 million based on a recently completed third party market study. The study estimated that there are more than 400,000 hard-to-heal wounds that present each year in Japan that can be treated by EPIFIX and which qualify for reimbursement under the JMHLW’s decision.

“Achieving reimbursement was a key pre-requisite to launch EPIFIX in Japan, and we think the awarded rate of 35,100 Yen/cm² will be very favorable in supporting market adoption,” said Rohit Kashyap, Ph.D., MIMEDX President, Wound Care & Surgical. “We view the Japanese market as a meaningful new stream of future revenue. With this positive reimbursement decision now secured, we are moving quickly to finalize our launch sequence, which includes completing distributor agreements and training, gaining local patient experience, and building market awareness. We have been very encouraged by early physician interest and are well positioned to penetrate the market leveraging the strength of our clinical and economic data, established Key Opinion Leader relationships, and strong local society support.”

Dr. Hiroto Terashi, Chief Professor in the Department of Plastic Surgery at Kobe University, Chairman of the Japanese Society for Foot Care and Podiatric Medicine and Chairman of the Japan Society for Surgical Wound Care, said, “Physicians need products that are clinically effective in wound closure and that can prevent complications such as infection, wound recurrence, surgical intervention, and amputation. I am very excited to have reimbursement acceptance for EPIFIX in Japan, and I believe many patients and physicians will benefit from having a new treatment option for chronic wounds caused by lower extremity diabetic and venous ulcers. The clinical and scientific data that I have seen for EPIFIX shows strong support for use in difficult to heal wounds.”

Takanori Kuramoto, MIMEDX’s recently-appointed General Manager, Japan, added, “We are grateful for the involvement and collaboration of the Japanese Society for Foot Care and Podiatric Medicine and other societies to increase awareness of the proper use of EPIFIX within their physician communities. With over 250 physicians now trained, we will be efficient in making EPIFIX available to treat patients in need of the clinical outcomes that the product has been shown to deliver. Ongoing medical training and education will be a hallmark of our launch activity, and we appreciate the strong level of interest by local physicians and hospital staff for this new treatment option. The Japanese Society for Foot Care and Podiatric Medicine plans to conduct three additional EPIFIX training events for its members over the next six months.”

About EPIFIX

EPIFIX is a PURION® processed placental tissue allograft that supports the healing cascade by providing a protective barrier over wounds. 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 transformational placental biologics company, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental tissue engineering, we have both a commercial business, focused on addressing the needs of patients with acute and chronic non-healing wounds, and a promising late-stage pipeline targeted at decreasing pain and improving function for patients with degenerative musculoskeletal conditions. We derive our products from human placental tissues and process these tissues using our proprietary methods, including the PURION® 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 www.mimedx.com.

Contacts

Investors:

Jack Howarth
Investor Relations
404.360.5681
jhowarth@mimedx.com

Media:

Hilary Dixon
Corporate & Strategic Communications
404.323.4779
hdixon@mimedx.com

