MIMEDX Receives Regulatory Approval to Commercialize EPIFIX® in Japan

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Availability of EPIFIX Allografts Expected Early 2022

Approval Makes it Possible to Bring EPIFIX's Healing Properties to as Many as 100,000 New Patients Annually

MARIETTA, Ga., June 08, 2021 (GLOBE NEWSWIRE) -- MIMEDX Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company"), an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, today announced successful regulatory approval by the Japanese Ministry of Health, Labour and Welfare (JMHLW) to market EPIFIX® in Japan.

EPIFIX - a bioabsorbable, human amniotic membrane allograft, is applied to affected areas for wound healing. The product uses proprietary methods, including the PURION® process, to provide a semi-permeable, protective barrier that supports the healing cascade. EPIFIX protects the wound bed to aid in the development of granulation tissue and delivers a human biocompatible extracellular matrix that retains 300+ regulatory proteins.

MIMEDX submitted a Shonin (pre-market approval) to the JMHLW, Japan's primary regulatory body for creating and implementing safety standards for drugs and medical devices, and the Pharmaceutical and Medical Device Agency (PMDA), an independent administrative agency that works with JMHLW to ensure the safety and quality of drugs and medical devices, in mid-2020. EPIFIX was approved for hard-to-heal chronic wounds, such as diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), which do not respond to conventional therapy. EPIFIX will be classified as a Class IV Medical Device and "Specified Biological Product" under JMHLW guidelines.

Dr. Hiroto Terashi, Chief Professor in Department of Plastic Surgery at Kobe University, Chairman of the Japanese Society for Foot Care and Podiatric Medicine (JFCPM), and Chairman of the Japan Society for Surgical Wound Care (JSSWC) said, "As a plastic surgeon and wound care physician for my entire career, I am delighted with EPIFIX's approval in Japan. EPIFIX will greatly expand treatment options for chronic wounds caused by lower extremity venous and diabetic ulcers in patients in Japan, providing opportunities for increased limb salvage."

"Diabetic foot ulcers and venous leg ulcers that are unable to heal on their own pose a serious long-term health risk to people around the world. Our vision is to provide access to EPIFIX technology that can change people's lives, no matter where they live," said Stan Micek, MIMEDX Senior Vice President, Business Development and International. "We are extremely pleased with JMHLW's decision to grant Shonin approval for EPIFIX, and we are glad to be one step closer to bringing EPIFIX to market in Japan. Our focus will now shift toward obtaining appropriate reimbursement and establishing logistical and distribution networks for commercialization, which we hope will result in full availability of EPIFIX in the Japanese market in early 2022."

The Company is currently working with JMHLW to establish reimbursement pricing, a process expected to take up to six months. Once a reimbursement pricing policy is approved and the reimbursement rate is listed, the Company can begin offering EPIFIX to patients and providers in Japan.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "EPIFIX can only benefit patients with hard-to-heal wounds if they can access its life-improving properties, and regulatory approval is a significant milestone in addressing unmet need for people in Japan. With today's announcement, EPIFIX now has the potential to reach as many as 100,000 additional patients each year. This critical step helps us fulfil our mission of bringing advanced regenerative medicine to suffering patient populations and is important in the Company's global expansion."

Important Cautionary Statement

This press release includes forward-looking statements, including among other things, statements regarding: (i) expectations about the classification of EPIFIX as a Class IV Medical Device and "Specified Biological Product" under JMHLW guidelines; (ii) expectation that EPIFIX will greatly expand treatment options for chronic wounds caused by lower extremity venous and diabetic ulcers in patients in Japan; and (iii) the Company's expectations regarding the approval of a reimbursement pricing policy for EPIFIX in Japan and the timeline for availability of EPIFIX in the Japanese market. 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. Factors that could cause actual results to differ from expectations include: (i) the Company may change its plans due to unforeseen circumstances, and delay or alter the timeline for future trials, analyses, or public announcements; (ii) the timing of any meeting with or decision by JMHLW depends on many factors and the availability and timing of such a meeting or decision is outside of the Company's control; and (iii) reimbursement pricing approval requires the satisfaction of various conditions; is often subject to detailed rules; and the timing, amount, and final approval decision rests with the JMHLW. 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 an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, developing and distributing placental tissue allografts

with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental biologics, we have both a core 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.

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