MiMedx Provides Update On Its Reimbursement Coverage

November 21, 2017

MARIETTA, Ga., Nov. 21, 2017 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), the leading biopharmaceutical company developing and marketing regenerative and therapeutic biologics utilizing human placental tissue allografts and patent-protected processes for multiple sectors of healthcare, provided a reimbursement update today.

Parker H. "Pete" Petit, Chairman and Chief Executive Officer, said "With the publication of the Venous Leg Ulcer (VLU) study earlier this quarter, one of the nation's largest not-for-profit health plans serving more than 3 million people recently decided to add EpiFix® coverage for Diabetic Foot Ulcers (DFUs), VLUs and burns. We also added another state Medicaid with nearly 2 million lives adding EpiFix coverage for DFUs, VLUs and burns. We expect many more health plans to follow suit with this type of decision in the future."

The Company also provided a reimbursement update in light of the recently issued Food and Drug Administration (FDA) Final and Draft Guidance documents related to human tissue titled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use" (the "HCT/P Guidance").

Over the years, the Centers for Medicare and Medicaid Services (CMS), through its sub-committee, the Healthcare Common Procedure Coding System (HCPCS) Committee, has assigned Q Codes for numerous products. These Q codes are assigned based on the Committee's review and are maintained by the HCPCS national panel, composed of representatives from Blue Cross/Blue Shield Association, the Health Insurance Association of America and CMS. Once assigned, payers typically then determine whether to reimburse those Q Codes. The payers further develop coding decisions based on the product's efficacy. Since MiMedx's EpiFix was introduced to the market in 2011, this is the process that payers have followed regarding EpiFix payment policy. Based on the clearly demonstrated efficacy of EpiFix in the numerous Randomized Controlled Trials (RCTs) in which EpiFix was the focus, the reimbursement coverage of EpiFix for the treatment of wounds has continued to grow over the years.

Petit added, "With the issuance of the final HCT/P Guidance document by the FDA, we believe the payer coverage for EpiFix will further improve. The only changes we anticipate from the final HCT/P Guidance are the addition of more payers covering EpiFix. Our recently published landmark multicenter VLU clinical trial and completed DFU study, along with the rest of our compendium of clinical data including an EpiFix comparative RCT, should further solidify MiMedx's leadership position in the wound care market. Payers have long stated they want products that help to close wounds faster thereby reducing reduce hospital days and other expenses. It is important to note that the HCPCS Committee has assigned Q codes for product indications as a 'cover' as well as 'wound healing' with similar reimbursement rates. Based on product efficacy, the payers have traditionally utilized both 'cover' and 'wound healing' codes for their coverage decisions. We expect this traditional practice will be fully continued by the payers with the issuance of the final HCT/P guidance."

Bill Taylor, President and Chief Operating Officer, commented, "With the recent publication of the VLU study, which is the first large scale successful VLU study completed in nearly 20 years, and the first large RCT of this quality on an amniotic membrane, we announce that we anticipate a robust increase in the level of reimbursement coverage for VLU procedures from commercial payers. Please recall that we have Medicare reimbursement coverage for both VLUs and DFUs; however, the breadth of our reimbursement coverage with commercial payers is primarily for DFUs. With the publication of the VLU study and the outstanding results in VLU healing rates, we are expecting a significant revenue opportunity to develop as commercial payers add EpiFix coverage for treatment of VLUs. On a very conservative basis, we have communicated that we could obtain VLU coverage for approximately 133 million additional commercial lives."

"We view the impact of the final HCT/P Guidance as having a very positive effect on not only sustaining our current levels of EpiFix reimbursement coverage, but also being highly complementary to our on-going initiative with commercial payers in the adoption of coverage for the treatment of VLUs. The body of evidence demonstrating the clinical efficacy of EpiFix in the treatment of DFUs and VLUs is overwhelming," concluded Petit.

About MiMedx
MiMedx® is the leading biopharmaceutical company developing and marketing regenerative and therapeutic biologics utilizing human placental tissue allografts with patent-protected processes for multiple sectors of healthcare. "***Innovations in Regenerative Medicine"*** is the framework behind our mission to give physicians products and tissues to help the body heal itself. We process the human placental tissue utilizing our proprietary PURION® Process among other processes, to produce safe and effective allografts. MiMedx proprietary processing methodology employs aseptic processing techniques in addition to terminal sterilization. MiMedx is the leading supplier of placental tissue, having supplied over 1 million allografts to date for application in the Wound Care, Burn, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic and Dental sectors of healthcare. For additional information, please visit www.mimedx.com.

Important Cautionary Statement
This press release includes forward-looking statements, including statements regarding the Company's belief that EpiFix RCTs are responsible for the growth in reimbursement coverage over the years and that this coverage will continue to improve, that the final HCT/P Guidance will have a positive effect on the Company and the only change anticipated is the addition of more payers covering EpiFix for DFU's and VLUs, that the combination of the VLU and DFU studies and the Company's compendium of clinical data should solidify the Company's position in the wound care market, and the Company's belief that it could obtain VLU coverage for approximately 133 million more commercial lives. These statements also may be identified by words such as "believe," "except," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. Forward-looking statements are subject to significant risks and uncertainties, and we caution investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Among the risks and uncertainties that could

cause actual results to differ materially from those indicated by such forward-looking statements include that the guidance documents may not be implemented as expected; payers may decide not to add reimbursement coverage notwithstanding the clinical data and the guidance documents available; unexpected results or concerns may arise from data or analysis from our clinical trials; EpiFix RCTs may not have been responsible for the growth in reimbursement coverage over the years and therefore this coverage may not continue to improve with further clinical data; additional reimbursement coverage may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies or may fail to approve or may delay approvals; and the Company's clinical trial successes may not translate to commercial advantages. For more detailed information on the risks and uncertainties, please review the Risk Factors section of our most recent annual report or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statement.

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