



MiMedx Receives Certificate From FDA Allowing The Export Of MiMedx Allografts

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COMPANY'S SHEET HCT/P PRODUCTS CERTIFIED TO BE MARKETED IN, AND LEGALLY EXPORTED FROM, THE U.S.

MARIETTA, Ga., Jan. 6, 2016 /PRNewswire/ -- MiMedx Group, Inc. (NASDAQ: MDXG), the leading regenerative medicine company utilizing human amniotic tissue and patent-protected processes to develop and market advanced products and therapies for the Wound Care, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic, and Dental sectors of healthcare, announced that it has recently posted an updated "Certificate to Foreign Government" on its website that describes all of the MiMedx sheet form allografts and the Food and Drug Administration FDA's certification that the listed products are HCT/P's.

The company's AmnioFix® and EpiFix® are among the products listed. Specifically, the FDA stated "It is certified that the MiMedx Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) listed in the Certificate to Foreign Government may be marketed in, and legally exported from, the United States of America". Further the document states, "The last inspection showed that the plant(s) at that time appeared to be in compliance with the FDA regulation Title 21, Code of Federal Regulations Part 1271."

Parker H. "Pete" Petit, Chairman and CEO, said "There has been some measure of confusion in the market related to FDA's position regarding our sheet allografts, particularly EpiFix and AmnioFix. We have stated all along that while we are in discussion with the FDA regarding our micronized allografts, the FDA has indicated that they have no issues with our sheet allografts and that they do, in fact, qualify as HCT/P's.

Petit continued, "As we continue to expand our International efforts, many foreign governments require a CFG, or Certificate to Foreign Government. Companies request these documents from the FDA, and the FDA generated the certificate. We recently received our updated certificate and felt it was appropriate to put it on our website and resolve any confusion that may exist. The statement in the certificate referenced above is very clear that the FDA considers the MiMedx sheet allografts to be regulated as HCT/P's."

About MiMedx

MiMedx® is an integrated developer, processor and marketer of patent protected and proprietary regenerative biomaterial products and bioimplants processed from human amniotic membrane and other birth tissues. **"Innovations in Regenerative Biomaterials"** is the framework behind our mission to give physicians products and tissues to help the body heal itself. Our biomaterial platform technologies are AmnioFix®, EpiFix®, CollaFix™ and OrthoFlo. AmnioFix and EpiFix are our tissue technologies processed from human amniotic membrane derived from donated placentas. Elected in advance of delivery through our donor program, a mother delivering a healthy baby via scheduled full-term Caesarean section birth may donate the placenta in lieu of having it discarded as medical waste. We process the human amniotic membrane utilizing our proprietary PURION® Process, to produce a safe and effective implant. MiMedx is the leading supplier of amniotic tissue, having supplied over 500,000 allografts to date for application in the Wound Care, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic and Dental sectors of healthcare. The Company has recently introduced OrthoFlo, an amniotic fluid derived allograft for homologous use. Amniotic fluid is donated by consenting mothers delivering a healthy baby by scheduled full-term Caesarean section births. CollaFix™, our next technology platform we plan to commercialize, is our collagen fiber technology, developed with our patented cross-linking polymers, designed to mimic the natural composition, structure and mechanical properties of musculoskeletal tissues in order to augment their repair. CollaFix™ is the only biological, biodegradable, biomimetic technology that matches human tendon in strength and stiffness. The Company distinguished its revenue in two primary regenerative medicine specialties of "Wound Care" and "SSO." The Company defines SSO as surgical, sports medicine and orthopedics with spinal procedures included in orthopedics and abdominal and lower pelvic procedures included in surgical.

Safe Harbor Statement

This press release includes statements that look forward in time or that express management's beliefs, expectations or hopes. Such statements are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, the certificate issued by the FDA's should clarify any questions related to the regulatory status of the Company's amniotic membrane allografts. These statements are based on current information and belief, and are not guarantees of future performance. Among the risks and uncertainties that could cause actual results to differ materially from those indicated by such forward-looking statements include that the certificate issued by the FDA's should may not clarify any questions related to the regulatory status of the Company's amniotic membrane allografts, and the risk factors detailed from time to time in the Company's periodic Securities and Exchange Commission filings, including, without limitation, its 10-K filing for the fiscal year ended December 31, 2014, and its most recent Form 10Q filing. By making these forward-looking statements, the Company does not undertake to update them in any manner except as may be required by the Company's disclosure obligations in filings it makes with the Securities and Exchange Commission under the federal securities laws.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mimedx-receives-certificate-from-fda-allowing-the-export-of-mimedx-allografts-300200269.html>

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