MIMEDX AMNIOTIC ALLOGRAFTS ARE TERMINALLY STERILIZED TO ENHANCE SAFETY RELATED TO MICROBIOLOGICAL AND VIRAL TRANSMISSION

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Introduction

In light of the media attention and in the wake of concerns related to the Zika virus, the Company is reiterating its long standing processing safety standards for the **terminal sterilization** of MiMedx amniotic allografts. The MiMedx flagship **amniotic allografts have always been terminally sterilized,** and the Company's proprietary PURION® Process has continually used terminal sterilization as an essential part of the process. To address potential questions related to the Zika virus, MiMedx is reconfirming the rigorous product safety methods and practices followed by the Company in the processing of its amniotic allografts as well as restating its precise standards for screening of placenta donors.

It should be noted that aseptic processes, which many tissue companies utilize, are usually validated to claim a less than 1 in 1,000 probability of a non-sterile unit per FDA Guidance and ISO standards. The probability of an occurrence of a non-sterile unit in products produced by MiMedx is significantly lower, however. Specifically, MiMedx's process and terminal sterilization validations provide a less than 1 in 1 million probability of a non-sterile unit, which is at least a 1,000 times higher safety margin than typical aseptically processed tissue products.

Zika Virus Background Information and Regulatory Guidance

According to the Centers for Disease Control ("CDC"), the Zika virus is an emerging mosquito-borne Flavivirus that was initially limited to sporadic cases in Africa and Asia. In 2007, it was detected in French Polynesia, and then later detected in other Pacific islands, South America and certain Caribbean Islands. Zika is continuing to spread and the first U. S. mosquito generated cases have now been reported in Florida. The latest data reported by the CDC lists more than 55 countries and territories with active, local Zika virus transmissions. There is an expectation for additional dispersion of the virus. The Zika virus' potential adverse effects on pregnancy are an area of greatest concern, and knowledge of the impact of Zika and its transmission is rapidly evolving. Although most Zika virus infections are characterized by mild influenza-like illness, severe manifestations have been described, including microcephaly in babies born to infected mothers. The primary way a pregnant woman (or any other individual) gets the Zika virus is through the bite of an infected *Aedes* species mosquito; however, the Zika virus can be sexually transmitted to a pregnant female by a man infected with the Zika virus as well.

The Food and Drug Administration ("FDA") and the American Association of Tissue Banks ("AATB") have issued guidance on donor eligibility and screening recommendations to reduce the risk of transmission of Zika virus via human tissues. MiMedx has been processing its amniotic allografts based on those recommendations since they were published.

Product Safety

Processing

The terminal sterilization conducted by MiMedx is a validated process in conformance with the International Organization of Standardization ("ISO") standard ISO 11137 "Sterilization of Healthcare Products." Conformance with this ISO standard requires a demanding Sterility Assurance Level ("SAL") of 10^{-6}, which is the probability of 1 in 1,000,000 units being non-sterile. To further enhance the safety of its amniotic products, the **MiMedx proprietary processing methodology employs aseptic processing techniques in addition to terminal sterilization**.

Not only does terminal sterilization enhance safety and prevention of infectious disease transmission, it also is a critical component in the Company's proprietary processing technologies. The Company's proprietary processing technologies provide the MiMedx amniotic allografts with their unique capabilities to retain the proteins and growth factors that are critical for clinical efficacy, provide ease of use by the physician and offer the capacity to be stored at ambient temperature with a five year shelf life. The Company's terminal sterilization further contributes to the differentiation of the MiMedx amniotic allografts.

Neither an effective treatment nor a vaccine is currently available for the Zika virus; therefore, the public health response focuses on preventing infection, particularly in pregnant women. The regulatory response has primarily focused on screening potentially infected placenta donors. While these responses are prudent, MiMedx believes its sector of the healthcare industry and especially processors of placental tissue products, have a responsibility to take even more stringent measures to ensure the product safety of their respective allografts. **MiMedx has taken those rigorous measures and safeguards into account in its proprietary processing methodologies to help ensure the safety of the Company's amniotic allografts.** MiMedx hopes that this degree of uncompromising insistence on product safety is demanded and practiced by all who process placenta-based products.

With the emergence and propagation of the Zika virus, MiMedx has anticipated that questions would soon arise. In advance of questions, MiMedx is reconfirming the Company's established safety processes to reassure patients and physicians of the exacting terminal sterilization methodology and the standards MiMedx employs to assure the sterility of the Company's amniotic allografts for potential microbiological and viral transmissions. With the heightened concerns related to the Zika virus, the Company expects that the detailed steps taken by all other tissue processors of placenta-based products will be reviewed to ensure their product safety and the processes utilized do adequately reduce the potential for microbiological and viral transmissions. MiMedx has continuously made assessments and implemented modifications to the Company's original processes in both the donor screening and the processing functions to maximize product safety. MiMedx has recently introduced its new lyophilized version of OrthoFlo which is also terminally sterilized to the same standards as the other MiMedx amniotic allografts.

At a recent CDC conference, it was reported that four patients receiving amniotic tissue products contracted infections that were most likely transmitted by a common donor. MiMedx learned through further discussion with the CDC that these tissue products were not terminally sterilized. Additionally, the FDA has taken action against this small, Texas-based manufacturer by issuing a warning letter. If any provider of amniotic and placental tissue does not currently have adequate processes in place, it is critical that all of these providers commit to implementing the adequate level of sterilization that inactivates viruses to the degree necessary to result in a sterile product. In addition, all providers of amniotic and placental tissue must further commit to a validation process which confirms that the assured degree of inactivation is met and sustained. MiMedx undertakes these meticulous and laborious measures and wishes that all others would take similar safety measures. There are a number of amniotic allografts currently on the market that are attempting to replicate the MiMedx technologies, but these allografts are not necessarily produced on par with the MiMedx processing and sterilization techniques.

Adding the Company's strict terminal sterilization processes to its proprietary processing methodologies does not affect the cytokines, growth factors, regulatory proteins, chemokines and other critical factors that optimize the performance of the MiMedx allografts. These factors contained in the MiMedx allografts and their inherent benefits, along with the Company's rigorous safety standards, are the critical advantage and differentiation of the MiMedx products.

Donor Screening

Each MiMedx placenta donor completes a series of questions to ensure that the donor has not engaged in behaviors that place her at an increased risk for the transmission of infectious disease, and undergoes a physical examination by a healthcare professional which includes a blood draw for serology testing. Additionally, tissue cultures taken following recovery are analyzed to detect the presence of bacterial contaminants. All test results for serology, bacteriology and infectious disease are reviewed prior to the release of the donor tissue. Only tissue from donors with acceptable test results in conformance with MiMedx standards as well as the standards of all state and federal regulatory bodies is released to be processed.

MiMedx has thoroughly reviewed the FDA Zika Guidance and has made updates to the Company's donor eligibility process to continue to be in compliance with all requirements. The Company also includes all AATB recommendations on donor eligibility for Zika transmission risks in the MiMedx Quality System. The Company has devoted numerous resources and energy to assuring that placenta donors are fully screened for any risk of infectious disease. Also, the Company's amniotic allografts are specifically processed to ensure the dual goals of maximizing patient safety and retaining the native characteristics of the placental tissues and amniotic membrane.