In light of the concerns related to the Coronavirus (COVID-19), the Company is reiterating its long standing processing safety standards, and providing information regarding the impact of MiMedx's terminal sterilization process on the inactivation of enveloped viruses, such as COVID-19. MiMedx employs rigorous safety methods and practices in the processing of its products, adheres to all industry standards for the screening of placenta donors, and the Company's proprietary PURION® process has continually used terminal sterilization as an essential part of the process. MiMedx has the appropriate controls in place to continue to provide safe products with the emergence of the COVID-19 virus.

COVID-19 Background Information and Regulatory Guidance

According to the Centers for Disease Control ("CDC"), "coronavirus disease 2019" (abbreviated "COVID-19") is a respiratory disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 100 locations internationally, including in the United States. The COVID-19 virus is a coronavirus in the family *Coronaviridae*. This family of viruses share similar properties and molecular structure as the viral family *Flaviviridae*, comprising viruses such as Zika (ZIKV) and Bovine Viral Diarrhea Virus (BVDV).

COVID-19 is continuing to spread and there is expectation for additional dispersion of the virus. While the transmission and impact of this novel virus are rapidly evolving, the virus is thought to spread mainly between people who are in close contact with one another (within about 6 feet) through respiratory droplets produced when an infected person coughs or sneezes. It also may be possible that a person can get COVID-19 by touching a surface on which the virus is present and then transferring it to their own mouth, nose, or possibly eyes. Current symptoms reported for patients with COVID-19 have included mild to severe respiratory illness with fever, cough, and difficulty breathing. Symptoms may appear 2-14 days after exposure.

The 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 COVID-19 via human tissues. MiMedx continues to monitor these updates and implement any additional recommendations.

Product Safety

Processing

The Company's proprietary processing technology imparts MiMedx placental allografts with their unique properties, in which the factors that are critical for clinical efficacy are preserved while providing a product that may be stored at ambient conditions with a five year shelf life. The Company's terminal sterilization further contributes to the differentiation of the MiMedx product portfolio.

Terminal Sterilization

The terminal sterilization conducted by MiMedx is a validated process in conformance with the International Organization for Standardization ("ISO") standard ISO 11137-1 and ISO 11137-2. Conformance with this standard requires a demanding Sterility Assurance Level ("SAL") of 10^{-6}, meaning the probability of a non-sterile unit is less than 1 in 1 million. Only a validated process can provide this level of assurance. MiMedx's terminal radiation sterilization processes (e-beam and gamma) were developed and validated following the maximal verification dose method as defined in ISO 11137-1 and ISO 11137-2. MiMedx uses the parametric release process for sterility, as defined in the *FDA Guidance for Industry on Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes*. This guidance enables the use of defined critical process controls to demonstrate control of the sterilization process in accordance with regulations for product testing and release.

The guideline requires verification that the dose range received for all products in any given lot meets the established specifications of 17.5-30.0 kGy. The results of the sterilization validation established that the lower end of the specified dose range (17.5 kGy) achieves a sterility assurance level of 10^{-6}, i.e. from a microbial standpoint, the probability of a non-sterile product is less than 1 in 1 million. The same parametric release process also ensures that the log reduction values (LRV) are achieved for each lot released.

In previous testing conducted in 2017, MiMedx showed viral inactivation of BVDV, which shares similar properties and molecular structure as viruses in the family *Coronaviridae*. The study was executed per FDA Guidance Document *Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin*. This viral inactivation study characterized the effect of terminal sterilization on BVDV. The study determined that:

- BVDV was reduced to non-detectable levels (complete inactivation) at all 3 radiation doses tested, i.e. 8.8 kGy, 17.5 kGy, and 30.0 kGy. The radiation doses tested encompassed the validated range used in the Company's process, including exposure to only one half of the minimum radiation dose required for MiMedx products (8.8 kGy compared to 17.5 kGy).
- The results indicated that there's a 95% confidence that BVDV exhibits a 5.0 Log reduction (or 10^{-5}) when exposed to the minimum sterilization dose required for MiMedx products. Of importance, in normal operation, MiMedx products receive a dose greater than the minimum sterilization dose; therefore suggesting that the true log reduction may be greater than indicated in the report.
- In addition, the study reported levels of inactivation attributable to both interaction with the test articles as well as shipping conditions. Based on this data, the report estimated inactivation results for the overall sterilization process (irradiation, interaction with product, and shipping) at 7.2 Logs (or $10^{-7.2}$).

Additional controls in place include donor screening and processing steps such as rinses, chemical treatments, dehydration and supply/equipment sterilization/disinfection that contribute to viral inactivation and the safety of MiMedx products in addition to the terminal sterilization. To further mitigate risks, MiMedx intends to implement additional criteria as recommended by the AATB and the FDA for determining donor eligibility once available.

Donor Screening

Neither an effective treatment nor a vaccine is currently available for COVID-19; therefore, the public health response focuses on preventing infection and further transmission. The regulatory response has primarily focused on screening potentially infected donors.

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 an attending physician, which includes a blood draw for serology testing. This includes screening for travel history, potential exposure, and any symptoms that may be consistent with COVID-19. Additionally, tissue cultures taken at the time of 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 guidance and donor screening criteria, and continues to be in compliance with all requirements, including all AATB recommendations on donor eligibility for COVID-19 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.

In summary, MiMedx has the appropriate controls in place between donor screening (i.e. evaluation of donor travel), contributing processing steps, and the terminal sterilization process to continue to provide safe products with the emergence of the COVID-19 virus.

FOR MORE INFORMATION

- **AATB Screening Bulletins**
    - https://www.aatb.org/content/bulletin-20-9
    - https://www.aatb.org/content/bulletin-20-8
    - https://www.aatb.org/content/bulletin-20-7
    - https://www.aatb.org/content/bulletin-20-3

- **Symptoms***:* Refer to the CDC website - https://www.cdc.gov/coronavirus/2019-ncov/about/symptoms.html

- **Person under Investigation** (PUI): Refer to CDC Criteria to Guide Evaluation of PUI for COVID-19 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

- **Close Contact***:* Refer to the CDC website - https://www.cdc.gov/coronavirus/2019-ncov/faq.html

- **CDC:** Due to the dynamically changing outbreak geography, please refer to the CDC on countries at risk for transmission and community spread and the latest travel advisories.