TFF Pharmaceuticals Announces Positive Preclinical Results with Two Biodefense Countermeasures for the United States Army Medical Research Institute of Infectious Diseases (USAMRIID)

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Company's Thin Film Freezing maintained efficacy for two different biodefense countermeasures against Alphaviruses and Filoviruses

AUSTIN, Texas--(BUSINESS WIRE)--Feb. 19, 2021-- TFF Pharmaceuticals, Inc. (NASDAQ: TFFP), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented thin-film freeze-drying (TFFD) technology platform, today announced that, in collaboration with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the Company obtained positive preclinical *in vitro* efficacy data from TFF formulated biodefense countermeasures.

In April of 2020, TFF Pharmaceuticals and USAMRIID, part of the U.S. Army Medical Research and Development Command, the U.S. Army's premier institution and facility for defensive research into countermeasures against biological warfare, entered into a 3-year Cooperative Research and Development Agreement (CRADA) to investigate TFFD of various biodefense countermeasures to demonstrate the use of these formulations as needle-free, inhaled treatments that are temperature-insensitive. The first two countermeasures, a monoclonal antibody (mAbs) against Ebolavirus Zaire (EBOV) and a recombinant vesicular stomatitis virus (rVSV) vaccine candidate against Venezuelan equine encephalitis virus (VEEV), were TFFD formulated and tested for efficacy in a well-established *in vitro* neutralization assay. Data showed that the activity of the mAbs and rVSV vaccines were preserved after TFFD. Formulation optimization and long-term stability testing are ongoing. Next steps will be *in vivo* testing in appropriate animal models.

"This data utilizing our TFFD technology to reformulate currently developed and characterized medical countermeasures against EBOV and VEEV is an important milestone," said Glenn Mattes, CEO of TFF Pharmaceuticals. "Most countermeasures are parenterally delivered, require trained personnel for administration and are temperature sensitive. There is an urgent need to develop technologies to improve biodefense countermeasures to better protect the warfighter."

"Great strides have been made to develop licensed countermeasures against Department of Defense (DoD) select agents of interest, such as Ebolavirus Zaire (EBOV) and Venezuelan equine encephalitis (VEEV)," said John M. Dye, Jr., Viral Immunology branch chief, USAMRIID. "An alternate route of administration that bypasses the need for cold chain control and administration by specialized personnel could be critical in the protection of our defense forces in biologically hostile environments around the globe."

TFF continues to engage and collaborate with various government and defense contracting agencies in an effort to utilize the Company's TFFD technology platform to formulate dry powder vaccines and therapeutics for delivery via reconstitution, or for lung or nasal inhalation.

About the U.S. Army Medical Research Institute of Infectious Diseases:

For over 50 years, USAMRIID has provided leading edge medical capabilities to deter and defend against current and emerging biological threat agents. The Institute is the only laboratory in the Department of Defense equipped to safely study highly hazardous viruses requiring maximum containment at Biosafety Level 4. Research conducted at USAMRIID leads to medical solutions – vaccines, drugs, diagnostics, information, and training programs – that benefit both military personnel and civilians. Established in 1969, the Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Development Command. For more information, visit www.usamriid.army.mil. The information contained in this press release does not necessarily reflect the position or the policy of the Government and no official endorsement should be inferred.

About TFF Pharmaceuticals' Thin Film Freezing technology platform

TFF Pharmaceuticals' Thin Film Freezing (TFF) platform was designed to improve the solubility and absorption of poorly water-soluble drugs and is particularly suited to generate dry powder particles with properties targeted for inhalation delivery, especially to the deep lung, an area of extreme interest in respiratory medicine. The TFF process results in a "Brittle Matrix Particle," which possesses low bulk density, high surface area, and typically an amorphous morphology, allowing the particles to supersaturate when contacting the target site, such as lung tissue. Based upon laboratory experiments, the aerodynamic properties of the particles are such that the portion of a drug deposited to the deep lung has the potential to reach as high as 75 percent.

About TFF Pharmaceuticals

TFF Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented Thin Film Freezing, or TFF, technology platform. Early testing confirms that the TFF platform can significantly improve the solubility and absorption of poorly water-soluble drugs, a class of drugs that comprises approximately one-third of the major pharmaceuticals worldwide, thereby improving their pharmacokinetics. TFF Pharmaceuticals has two lead drug candidates: Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder. The Company plans to add to this pipeline by collaborating with large pharmaceutical partners. The TFF Platform is protected by 42 patents issued or pending in the US and internationally. To learn more about TFF Pharmaceuticals and its product candidates, visit the Company's website at https://tffpharma.com

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This press release contains forward-looking statements regarding TFF Pharmaceuticals, Inc., including the benefits of the Company's TFFD platform and its dry powder versions of voriconazole and the Company's plans to add to its existing pipeline of product candidates. Those forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual results to differ materially. Among those factors are: (i) the risk that the Company may not be able to successfully conclude preclinical testing of its EBOV mAbs or rVSV vaccine or obtain pre-market approval of either product candidate, (ii) no drug product incorporating the TFFD platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (iii) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFFD Platform, (iv) the risk that the Company will not be able to conclude a long-term commercial agreement with any third-party, and (v) those other risks disclosed in the section "Risk Factors" included in the Company's prospectus supplement filed with the SEC on December 8, 2020. TFF Pharmaceuticals cautions readers not to place undue reliance on any forward-looking statements. TFF Pharmaceuticals does not undertake, and specifically disclaims, any obligation to update or revise such statements to reflect new circumstances or unanticipated events as they occur, except as required by law.

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