



TFF Pharmaceuticals Announces Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for use of its Thin Film Freezing Technology Platform

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USAMRIID to study use of TFF technology to formulate dry powder neutralizing antibodies and vaccines against national priority biodefense threats for pulmonary delivery

AUSTIN, Texas--(BUSINESS WIRE)--Apr. 15, 2020-- TFF Pharmaceuticals, Inc. (NASDAQ: TFFP), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative drug products based on its patented Thin Film Freezing (TFF) technology platform, has entered into a Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), part of the U.S. Army Medical Research and Development Command and the U.S Army's premier institution and facility for defensive research into countermeasures against biological warfare, located on Fort Detrick, Maryland.

Under the terms of the CRADA, TFF Pharma and the USAMRIID will collaborate over a 3-year period to investigate Thin Film Freezing to formulate two different countermeasures, a monoclonal antibody against Alphaviruses (e.g. Venezuelan, Western, and Eastern equine encephalitis viruses) and a vesicular stomatitis virus vaccine against Filoviruses (e.g. Ebola, Marburg). USAMRIID will evaluate the immune responses induced by the dry powder formulations given by the pulmonary or intranasal route in a rodent model, as compared to the traditional routes of administration.

"Biodefense threats and emerging infectious diseases such as COVID-19 continue to be a major concern to our military and civilian populations," said Glenn Mattes, CEO of TFF Pharmaceuticals. "There is a critical unmet need for the development of more effective vaccines, therapeutics and drug formulations to meet this threat."

"We believe our Thin Film Freezing technology approach can produce efficacious biodefense and emerging disease countermeasure powder formulations that are highly suitable for the respiratory route of administration; highly absorbable and effectively distributed; and physiochemically stable for an extended period," continued Mattes. "This CRADA, with the world's preeminent biodefense research organization, is another validation of Thin Film Freezing's potential as an important, disruptive platform technology."

The Company's testing confirms that Thin Film Freezing maintains a potential vaccine's particle size distribution and immunogenicity, is robust for extended periods at room temperature, and withstands unintentional freezing. It can be stored and shipped free of cold-chain handling, displays extended stability for stockpiling (dry powder storage vs. liquid), and provides for needle-free vaccination (nasal or inhalation administration).

"Our warfighters - and our scientists - are frequently deployed to some of the world's most environmentally hostile climates," said Dr. John M. Dye, Jr., Viral Immunology branch chief, USAMRIID. "Having biodefense countermeasures that are potentially more easily administered via a pulmonary or intranasal route, and are temperature stable, could be an important advantage in these types of environments."

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

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 39 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 TFF platform and its dry powder versions of countermeasure vaccines. 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: (1) there can be no assurance that the Company's research collaboration with USAMRIID will lead to a commercial dry powder version of a countermeasure vaccine, (2) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (3) the Company has no current agreements or understandings with any large pharmaceutical companies or others for the development of a drug product or vaccine incorporating the TFF Platform and (4) those other risks disclosed in the section "Risk Factors" included in the Company's 2019 Annual Report on Form 10-K filed with the SEC on March 27, 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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