TFF Pharmaceuticals Announces Topline Results of Voriconazole Inhalation Powder Phase 1 Clinical Trial

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Phase 1 Dosing of Voriconazole Inhalation Powder up to 80 mg/dose in healthy subjects for direct-to-lung delivery of voriconazole for Invasive Pulmonary Aspergillosis (IPA)

Phase 2 studies to commence, assessing the efficacy of the dry powder formulation for the treatment of IPA

Company is investigating potential treatment or prevention of COVID-19 Associated Pulmonary Aspergillosis (CAPA) and other pulmonary fungal infections

AUSTIN, Texas--(BUSINESS WIRE)--Sep. 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, today announced topline safety data from its Phase 1 clinical trial of Voriconazole Inhalation Powder, a next-generation, direct-to-lung, inhaled dry powder version of voriconazole. Voriconazole is generally considered to be the most effective antifungal drug for treating Invasive Pulmonary Aspergillosis (IPA).

The recently completed Phase 1 trial was a randomized, double-blind, placebo-controlled study with an inhalation route of administration to 64 healthy adult volunteers that was designed with single ascending dose (SAD) and multiple ascending dose (MAD) phases. In the SAD portion, single doses of 10, 20, 40 or 80 mg were delivered to healthy normal volunteers. During the MAD portion of the trial, healthy normal volunteers received doses of 10, 20, 40 or 80 mg that were delivered twice daily for a total of 13 doses over 7 days. Thirty-two healthy subjects were enrolled in each part to evaluate the safety, tolerability and pharmacokinetic profile of Voriconazole Inhalation Powder.

“The Voriconazole Inhalation Powder when dosed up to 80 mg twice daily showed no signs of the clinically significant hepatic or visual toxicities that were previously reported for the oral or intravenous forms of voriconazole,” stated Dr. Peter Couroux, Global Senior Medical Director at Cliantha Research, who served as the Principle Investigator of the study. “We also saw no changes in pulmonary function, including FEV_1, during the trial, suggesting that the drug is extremely well tolerated and is suitable to move forward in the clinical development process.” [1]

An independent Data Safety Monitoring Board (DSMB) reviewed all of the clinical safety data and reported that there were, “no clinically significant adverse events, laboratory test results, electrocardiograms, or ECGs, or vital signs. Further, DSMB reported that there were no clinically meaningful relationships or trends observed for differences between vital signs, liver function tests, spirometry, visual examinations, pulse oximetry and ECGs as a function of dose or treatment.”

“The results of this trial with TFF Voriconazole Inhalation Powder at doses up to 80 mg twice daily represent a significant milestone in the development of this product since the oral or intravenous form of voriconazole, which represent the current standard of care, demonstrate significant rates of adverse events, which did not occur in our study,” said Glenn Mattes, President and CEO of TFF Pharmaceuticals.

“In addition to a better safety profile, delivery of TFF Voriconazole should produce an efficacious method of treating IPA and associated fungal infections with fewer drug-drug interaction issues when administering oral voriconazole directly to the lungs with our thin film freezing dry powder,” said Mattes.

Dosing of the Voriconazole Inhalation Powder resulted in plasma levels greater than drug levels achieved in published reports for dose levels that were efficacious in IPA patients. The Company believes this demonstrates that the TFF Voriconazole Inhalation Powder can be safely and effectively delivered to the lung, where it is needed to fight IPA infections.

TFF Pharmaceuticals will now advance the Voriconazole Inhalation Powder into Phase 2 studies to assess the efficacy of the dry powder formulation for the treatment of IPA. Voriconazole is recommended as the first line treatment for IPA according to the Infectious Disease Society (IDSA) - Practice Guidelines for the Diagnosis and Management of Aspergillosis (2016), but voriconazole is associated with significant drug-drug interactions and toxicities.

COVID-19 Associated Pulmonary Aspergillosis (CAPA)

TFF Pharmaceuticals is also exploring the use of the product for the treatment or prevention of COVID-19 Associated Pulmonary Aspergillosis (CAPA) and other pulmonary fungal infections. These pulmonary fungal infections are increasing due to the use of corticosteroids for treatment of COVID-19. Treatment with corticosteroids predispose patients to *Aspergillus* infections and reports are emerging demonstrating that severe COVID-19 patients are increasingly being affected by these fungal co-infections.

“TFF is aware of the increasing prevalence of IPA in COVID-19 patients,” said Glenn Mattes. “We are working with our clinical and regulatory teams to quickly determine the best path forward to validate TFF Voriconazole’s role in treatment of this serious fungal infection.”

TFF Pharmaceuticals’ proprietary Thin Film Freezing technology platform allows the reformulation of voriconazole into dry powder particles with properties believed to be ideally suited for inhalation delivery. In addition to voriconazole, TFF is also developing dry powder formulations of tacrolimus to prevent lung transplant rejection and niclosamide to treat COVID-19 (SARS-CoV2) infections.

[1.] FEV_1: Forced Expiratory Volume in the first second. The volume of air that can be forced out in one second after taking a deep breath, an important measure of pulmonary function.

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 Tac-Lac 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 TFF platform and its dry powder versions of voriconazole and tacrolimus 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 clinical testing or obtain pre-market approval of its dry powder versions of voriconazole and tacrolimus, (ii) no drug product incorporating the TFF 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 TFF 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 2019 Annual Report on Form 10-K filed with the SEC on March 26, 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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