TFF Pharmaceuticals Announces Presentation of Patient Data with Voriconazole Inhalation Powder (TFF VORI) at the 15th International Congress on Lung Transplantation

September 8, 2022

Dr. Bradley Gardiner from the Royal Alfred Hospital in Melbourne, Australia presented results from compassionate use of treating pulmonary fungal infections in a lung transplant patient

Patient previously intolerant to oral voriconazole therapy successfully treated with TFF VORI

FORT WORTH, Texas, Sept. 08, 2022 (GLOBE NEWSWIRE) -- 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 that Dr. Bradley Gardiner of the Royal Alfred Hospital in Melbourne, Australia shared a podium presentation on the compassionate use of TFF's Voriconazole Inhalation Powder (TFF VORI) as part of the 15 th International Congress on Lung Transplantation, which is being held in Paris on September 8-9, 2022.

Presentation details are as follows:

Title: **Inhaled voriconazole: an effective novel antifungal delivery method which reduces systemic absorption and toxicity**
Date/Time: Thursday, September 8 at 10:49a.m. CET (4:49a.m. ET)
Presenter: Dr. Bradley Gardiner - Infectious Diseases Physician, Royal Alfred Hospital

TFF VORI is a next-generation, direct-to-lung, inhaled dry powder formulation of voriconazole for the treatment and prevention of Invasive Pulmonary Aspergillosis (IPA). TFF's proprietary Thin Film Freezing technology platform allows the reformulation of voriconazole into a dry powder with properties ideally suited for inhalation. The inhaled formulation increases the local concentration of therapy in the lung, where it is needed most, potentially improving efficacy while also reducing systemic toxicities and drug-drug interactions seen with orally administered voriconazole. TFF previously announced data from its Phase 1b study of TFF VORI showing the therapy was well tolerated in asthma patients and could provide a differentiating benefit to a broad population of patients with IPA and other pulmonary fungal infections.

As part of TFF's ongoing compassionate use program, a lung transplant patient with pulmonary fungal infections in Australia was treated with TFF VORI beginning in February 2022 and has continued on chronic daily therapy (80mg BID) for the past 6 months. This patient was not able to continue with oral voriconazole or other azole antifungals due to preexisting melanoma and significant toxicities when previously administered oral voriconazole. The patient had also been experiencing a meaningful loss of pulmonary function prior to initiation of the TFF VORI treatment. Notably, upon initiation of TFF VORI, the patient's lung function stabilized without additional decreases in Forced Expiratory Volume in one second (FEV1) and with recovery in Forced Vital Capacity (FVC). The patient was able to tolerate inhaled voriconazole due to the limited systemic absorption compared to the oral administration route. Also, the patient tolerated TFF VORI without having to lower the dose of his tacrolimus immunosuppressant, which can have a severe drug-drug interaction with oral voriconazole. These results support the potential safety and efficacy advantages of TFF VORI, which TFF expects to further demonstrate in its ongoing Phase 2 study.

"Before treatment with TFF's inhaled voriconazole, this patient was deteriorating with limited treatment options," said Dr. Bradley Gardiner. "Following treatment with TFF VORI, he has stabilized and has not required hospitalization. These results are especially meaningful for patients who cannot tolerate oral voriconazole therapy due to other comorbidities such as skin cancers or upon experiencing one of the many well-known tolerance issues with oral antifungal therapies."

"We are excited to share these data showcasing how inhaled voriconazole powder could present a safer alternative for patients compared to oral treatment, especially for those who have undergone lung transplant or have other conditions that require medications that are susceptible to the well-known drug-drug interactions of oral voriconazole," said Dale Christensen, Ph.D., Head of Clinical Development at TFF Pharmaceuticals. "We are particularly encouraged by the clinical stability achieved for this patient, which supports our treatment hypothesis that inhaled voriconazole can be efficacious at lower doses and is well tolerated without the severe drug-drug interactions associated with oral voriconazole."

More information on the data being presented at the meeting can be found on the conference website.

ABOUT TFF PHARMACEUTICALS' THIN FILM FREEZING TECHNOLOGY PLATFORM

TFF Pharmaceuticals' proprietary Thin Film Freezing (TFF) technology allows for the transformation of both existing compounds and new chemical entities into dry powder formulations exhibiting unique characteristics and benefits. The Thin Film Freezing process is a particle engineering process designed to generate dry powder particles with advantageous properties for inhalation, as well as parenteral, nasal, oral, topical and ocular routes of administration. The process can be used to engineer powders for direct delivery to the site of need, circumventing challenges of systemic administration and leading to improved bioavailability, faster onset of action, and improved safety and efficacy. The ability to deliver therapies directly to the target organ, such as the lung, allows TFF powders to be administered at lower doses compared to oral drugs, reducing unwanted toxicities and side effects. Laboratory data suggests the aerodynamic properties of the powders created by Thin Film Freezing can deliver as much as 75% of the dose to the deep lung. Thin Film Freezing does not introduce heat, shear stress, or other forces that can damage more complex therapeutic components, such as fragile biologics, and instead enables the reformulation of these materials into easily stored and temperature-stable dry powders, making therapeutics and vaccines more accessible for distribution worldwide. The advantages of Thin Film Freezing can be used to enhance

traditional delivery or combined to enable next-generation pharmaceutical products.

ABOUT TFF PHARMACEUTICALS

TFF Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company engaging patented rapid freezing technology to develop and transform medicines into potent dry powder formulations for better efficacy, safety and stability. The company's versatile Thin Film Freezing (TFF) technology platform has broad applicability to convert any drug, including vaccines, small and large molecules and biologics, into an elegant dry powder highly advantageous for inhalation, with improved absorption so drugs can also be delivered to the eyes, nose and topically to the skin. TFF has two lead drug candidates in the clinic: Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder, and continues to expand its pipeline by collaborating with a broad array of pharmaceutical companies, academic institutions and government partners to revolutionize healthcare around the globe. The TFF Platform is protected by 120+ patents issued or pending in the U.S. 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 expectations for its continued development of Inhaled Voriconazole Powder, the benefits of the Company's TFF platform 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's ongoing Phase 2 study of Inhaled Voriconazole Powder may not confirm the findings of TFF's ongoing Australian compassionate use program, (ii) the risk that the Company may not be able to successfully conclude clinical testing or obtain pre-market approval of its Inhaled Voriconazole Powder or any of its dry powder product candidates, (iii) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (iv) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, (v) the risk that the Company will not be able to conclude a long-term commercial agreement with any third-party, and (vi) those other risks disclosed in the section "Risk Factors" included in the Company's 2021 Annual Report on Form 10-K filed with the SEC on March 24, 2022. 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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