TFF Pharmaceuticals Announces Completion of Enrollment and Preliminary Data from its Phase 1 Clinical Trial of Tacrolimus Inhalation Powder

July 13, 2021

Inhaled Tacrolimus Powder Achieves Systemic Therapeutic Drug Levels
Anticipate Additional Safety Data in 3Q 2021
Initiation of Lung Transplant Study Expected in 2H 2021

AUSTIN, Texas, July 13, 2021 (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 the enrollment has been completed for the Phase 1 clinical trial for Tacrolimus Inhalation Powder ("inhaled tacrolimus").

As discussed during our recent Science Day event, lung transplant patients receiving tacrolimus for maintenance immunosuppression are carefully monitored so that drug concentration levels can be adjusted to achieve efficacious immunosuppression while minimizing toxicities. Following lung transplant, therapeutic drug monitoring (TDM) is used to achieve maintenance tacrolimus blood levels from 5-15 ng/mL to prevent acute allograft rejection.

In the Single Ascending Dose (SAD) phase of the trial, single doses of inhaled tacrolimus of 0.5 mg, 1.0 mg, 2.5 mg to 5.0 mg were administered to healthy subjects. Peak blood levels were measured 15 min after dosing, and trough blood levels were measured 12 hours after dosing for each subject. Peak levels were monitored to determine if they correlated with any acute adverse effects, while trough blood levels were measured to determine if subjects were reaching levels of tacrolimus that are sufficient for immunosuppression.

In the subjects that received inhaled tacrolimus in the low dose group, the mean trough blood levels reached 1.1 ng/mL, while blood levels in the highest dose group reached 10.0 ng/mL. In addition, when subjects received inhaled tacrolimus dosing at 2.5 mg while fasting or 30 minutes after a high fat meal, there were no significant differences in systemic exposure demonstrating that delivery by inhalation was not associated with food effects in this cohort of subjects. By contrast, the rate and extent of absorption of tacrolimus is significantly decreased when tacrolimus is administered orally when taken with food, and this effect is most pronounced after a high-fat meal.

Furthermore, during the Multiple Ascending Dose (MAD) phase, repeated dosing of inhaled tacrolimus every 12 hours over 7 days demonstrated that subjects receiving doses of 0.5 mg twice daily and 1.0 mg twice daily achieved 12-hour trough steady state blood levels that averaged 6.8 and 14.9 ng/mL, respectively. These data demonstrate that low dosing of Tacrolimus Inhalation Powder (0.5-1.0 mg) can achieve blood levels that are sufficient for efficacious immunosuppression.

"Completion of enrollment in the Phase 1 study of Tacrolimus Inhalation Powder represents a critical milestone for TFF Pharmaceuticals, and the emerging data provide strong clinical evidence to support our thesis that inhaled tacrolimus can be effectively delivered to solid organ transplant patients with lower total doses than the oral forms of the drug due to our formulation's enhanced bioavailability and the lack of food effects," stated Glenn Mattes, the Chief Executive Officer of TFF Pharmaceuticals.

TFF Pharmaceuticals expects to report topline safety data in the third quarter of 2021 and believes the strong bioavailability data will enable initiation of a clinical trial in lung transplant patients in the second half of 2021. TFF Pharmaceuticals expects that the dosing regimen for the study in lung transplantation will be tailored to potentially provide effective immunosuppression in the lung while reducing renal toxicities.

In addition to leveraging its proprietary Thin Film Freezing technology platform to develop Inhaled Tacrolimus Power, TFF Pharmaceuticals is also developing two additional in-house programs: inhaled voriconazole for the treatment of pulmonary-based fungal infections, and inhaled niclosamide for the treatment of COVID-19 (SARS-CoV2) infections.

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.

SAFE HARBOR

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 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 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 10, 2021. 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.

Company Contacts:
Glenn Mattes
President and CEO
TFF Pharmaceuticals, Inc.
gmattes@tffpharma.com
737-802-1973

Kirk Coleman
Chief Financial Officer
TFF Pharmaceuticals, Inc.
kcoleman@tffpharma.com
817-989-6358

Investor Relations Contact:
Corey Davis, Ph.D.
LifeSci Advisors
212-915-2577
cdavis@lifesciadvisors.com

Media Contact:
Gwendolyn Schanker
LifeSci Communications
(269) 921-3607
gschanker@lifescicomms.com

Source: TFF Pharmaceuticals, Inc.