TFF Pharmaceuticals Announces Final Data from Phase 1b Study of Inhaled Voriconazole Powder in Asthma Patients

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Final Safety and Pharmacokinetic Data Continue to Support Progression to Phase 2 in the Near Term for Treatment of Invasive Pulmonary Aspergillosis (IPA), Including Patients with Mild to Moderate Asthma

Pharmacokinetic Data Revealed No Differences in Patients Using Bronchodilators Compared to Healthy Subjects; Allows for Inclusion of Broader Patient Populations in Upcoming Phase 2 Studies

Company Expects to Generate Phase 2 Data in IPA in 2022; Data Suggest Potential Utility in Treating Allergic Bronchopulmonary Aspergillosis (ABPA), a Possible Follow-on Indication

AUSTIN, Texas, Dec. 21, 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 the full readout of safety and pharmacokinetic (PK) data from its Phase 1b study (NCT #04576325) of Inhaled Voriconazole Powder (TFF VORI) in asthma patients.

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 Pharmaceuticals' proprietary Thin Film Freezing technology platform allows the reformulation of voriconazole into a dry powder with properties ideally suited for inhalation. The data reported from the Phase 1b study are consistent with the initial data reported in November suggesting that TFF VORI is well tolerated in asthma patients and could therefore provide a differentiating benefit to a broad population of patients with IPA.

"The final data from our Phase 1b reactive airway study in patients with asthma confirm earlier readouts that TFF VORI appears to be well tolerated in a patient population that is vulnerable to IPA infections, but can be challenging to treat because inhaled anti-infective therapies can trigger bronchospasm," said Glenn Mattes, President and CEO of TFF Pharmaceuticals. "The broad therapeutic applications of our Thin Film Freezing technology continue to grow, and with this latest data readout we are now poised to advance one of our key internal product candidates into late-stage clinical testing in 2022."

Voriconazole is recommended as the first line treatment for IPA according to the Infectious Disease Society Practice Guidelines for the Diagnosis and Management of Aspergillosis (2016) but is associated with significant drug-drug interactions and toxicities. Delivery of voriconazole directly to the lung via TFF's inhaled formulation may allow for greater efficacy than orally administered voriconazole and improved safety through reduced systemic toxicities and reduced drug-drug interactions.

Patients with asthma and a portion of patients with cystic fibrosis and chronic obstructive pulmonary disease (COPD) are susceptible to IPA infections due to impaired mucociliary clearance but have hyperreactive airways where bronchoconstriction can be triggered following administration of drugs by inhalation. Many of these patients are taking other inhaled antibiotics that require treatment with a short acting bronchodilator prior to administration.

TFF Pharma's Phase 1b study was a randomized, double-blind, placebo-controlled trial to evaluate the safety, tolerability, pharmacokinetics, and induction of bronchospasm of TFF VORI in 16 patients with mild to moderate asthma who were also using bronchodilators daily for asthma treatments. All of the patients' airways in this study were considered reactive and could be triggered to bronchospasm.

The data show that TFF VORI was well tolerated in asthma patients and indicate that no drug-drug interactions with bronchodilators will limit the use of these common asthma medications in patients with reactive airway disease. The Company anticipates enrolling patients who are prescribed a bronchodilator for its planned Phase 2 trial in IPA patients in 2022.

Additional details from the study are below:

- The study was comprised of two cohorts. In cohort 1, 8 eligible subjects were randomized in a 3:1 ratio (6 on active and 2 on placebo) to receive 7 doses over 3.5 days of 40mg TFF VORI or inhaled placebo. In cohort 2, 8 eligible subjects were also randomized in a 3:1 ratio to receive 7 doses over 3.5 days of 80 mg TFF VORI or placebo. In both cohorts, doses were administered twice daily every 12 (± 1) hours.
- Systemic PK data following repeated dosing with an 80 mg twice daily dose showed no statistical differences between absorption and clearance between subjects with healthy lungs from the Phase 1 trial and asthma patients with diseased lungs in this Phase 1b study, supporting selection of an 80 mg dose for future clinical studies in IPA patients.
- Observational data from the Phase 1b trial support the inclusion of patients that have hyperreactive airway disease comorbidities in the Phase 2 trial and suggest that TFF VORI also may have the potential to treat Allergic Bronchopulmonary Aspergillosis (ABPA), which impacts up to 2.5%[1] of asthma patients (an estimated 600,000 patients in the U.S.).[2]

TFF Pharmaceuticals recently hosted a Science Day featuring a presentation by Key Opinion Leader Carsten Schwarz, M.D., Director of the Cystic Fibrosis Center in Potsdam, Germany. The presentation, available here, sheds light on the broad potential of TFF VORI to supplant current use of the oral formulation.

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: Inhaled Voriconazole Powder and Inhaled Tacrolimus 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 U.S. 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 version 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 results of the Company's Phase 2 clinical trials may not confirm the data provided by the Phase 1b study, (ii) 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, (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 2020 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.

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[1] Denning DW, Pleuvry A, Cole DC. Global burden of allergic bronchopulmonary aspergillosis with asthma and its complication chronic pulmonary aspergillosis in adults. Med Mycol. 2013 May;51(4):361-70. doi: 10.3109/13693786.2012.738312. Epub 2012 Dec 4. PMID: 23210682. Accessed November 5, 2021.

[2]Centers for Disease Control and Prevention. Asthma in the US. https://www.cdc.gov/vitalsigns/asthma/index.html. Accessed December 20, 2021.

Source: TFF Pharmaceuticals, Inc.