TFF Pharmaceuticals' Inventor Dr. Robert O. Williams III Presents Session on Repurposing Niclosamide for COVID-19 Treatment at AAPS Meeting

April 30, 2020

Data presented on repurposing the existing, broad-spectrum antiviral agent using Thin Film Freezing and other techniques to enhance its effect for COVID-19 therapy

AUSTIN, Texas--(BUSINESS WIRE)--Apr. 30, 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 Dr. Robert O. Williams, inventor of the firm's Thin Film Freezing technology, presented at the American Association of Pharmaceutical Scientists symposium on "*COVID-19 - Current Pharmaceutical Developments for Cures and Prevention*" on Tuesday, April 28. Dr. Williams and co-author Dr. Zachary N. Warnken presented data focusing on repurposing the existing antiviral drug, niclosamide, in a session titled, "*Leveraging Repurposed Drugs – An Activity that Must be Exhausted*."

Niclosamide is an oral anthelminthic drug, first approved by the US FDA for use in humans to treat tapeworm infection in 1982 and is included in the World Health Organization's list of essential medicines [1]. It has been used to safely treat millions of patients. And over the past years, niclosamide has been identified as a multifunctional drug via drug repurposing screens with strong potential in being repurposed to treat a variety of viral infections, such as severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), Zika virus (ZIKV), and others, given its inexpensive cost and low *in vivo* toxicity profile as an FDA-approved drug in clinical use.[2] Niclosamide has been shown to inhibit SARS-CoV-2 replication and totally abolished viral antigen synthesis at a concentration of 1.56 μM.[3]

However, niclosamide has very limited aqueous solubility as well as low absorption and oral bioavailability [4] creating challenges for its development as a potential anti-viral therapy. Successful repurposing would need a mechanism for overcoming the inherent delivery issues posed by this low absorption and bioavailability.

A team of researchers in University of Texas at Austin College of Pharmacy, Division of Molecular Pharmaceutics and Drug Delivery, led by Robert O. Williams III and Hugh D. Smyth, has investigated Thin Film Freezing and other methods of drug delivery to repurpose existing drugs, particularly inhaled forms of niclosamide, for protecting and treating respiratory mode of infection, including a brittle matrix powder made by thin-film freezing, which TFF Pharmaceuticals is progressing to filing an IND with the FDA. Since COVID-19 has shown to be particularly damaging to the lungs, delivering an antiviral directly to the site may prove an effective prevention strategy and provide additional treatment options. Niclosamide has been shown to be considerably more potent when compared with other drugs such as chloroquine, lopinavir and remdesivir, against COVID-19, and because of its activity as an antiviral drug, it could prove to be an option for treating the virus. [5]

"One significant advantage of using an existing drug to treat COVID-19 is it can lessen the time it would take to get it into the hands of doctors and patients," said Robert Williams, Head of the University of Texas at Austin's Division of Pharmaceutics. "Outcomes can improve if an existing drug can prove a viable therapeutic option with a new delivery method, lessening the mortality rate and severe medical complications stemming from the virus."

"Drug repurposing represents one of the fastest and most efficient means of addressing the current global pandemic, as new drug development can take years," said Zachary Warnken. "FDA-approved drugs can provide safe alternatives where antiviral activity can be demonstrated. And since the first SARS-CoV and the novel coronavirus are very similar, we expect that drugs which show strong antiviral activity against SARS-CoV to potentially be effective as COVID-19 therapies."

TFF Pharmaceuticals Inc. is currently performing an exhaustive exercise reviewing drugs previously approved by the Food and Drug Administration that may be repurposed in an effort to combat the novel coronavirus behind the COVID-19 pandemic outbreak.

References:

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About the University of Texas at Austin

The University of Texas at Austin College of Pharmacy is one of the premier institutions of pharmaceutical education and research in the country. The Williams Lab at the College's Division of Pharmaceutics, headed Robert O. Williams III, Ph.D., focuses on the formulation development, optimization, and delivery of small organic compounds, peptides, and proteins by a variety of technologies, including depot drug delivery, oral drug delivery and pulmonary/nasal/ophthalmic drug delivery. Significant effort is devoted to research to enhance drug solubility and dissolution through novel particle engineering technologies, including thin film freezing and precipitation processes, and thermal processes such as hot melt extrusion.

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 existing antiviral drugs 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) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (ii) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform and (iii) 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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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 and Media Contact:
Paul Sagan
LaVoieHealthScience
psagan@lavoiehealthscience.com
617-953-4779

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