TFF Pharmaceuticals and Augmenta Bioworks Publish Positive In Vivo Data Showing Dry Powder Formulation of COVID-19 Antibody, AUG-3387, Neutralizes SARS-CoV-2 Infection and Reduces Viral Load

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Results published in bioRxiv *Show That Delivery of Dry Powder AUG-3387 Following Viral Inoculation Led to Dose-Dependent Reduction in Lung Viral Load in Hamsters*

Dry Powder Formulations Show Equivalent Binding as Original Antibody with No Loss of Biologic Activity

Study Indicates AUG-3387 Binds to Both Lambda and Mu Variants of SARS-CoV-2

AUSTIN, Texas and MENLO PARK, Calif., Oct. 14, 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, and Augmenta Bioworks, a biotechnology company leveraging immune profiling technologies to enable breakthroughs in medicine, today announced the publication of a research paper highlighting positive preclinical study results of AUG-3387, a monoclonal antibody (mAb) therapy being developed in collaboration between the two companies for the treatment of SARS-CoV-2 infection. The findings have been published online through the *bioRxiv* preprint server, under the title "AUG-3387, a Human-Derived Monoclonal Antibody Neutralizes SARS-CoV-2 Variants and Reduces Viral Load from Therapeutic Treatment of Hamsters In Vivo."

The AUG-3387 mAb was formulated as a dry powder using TFF Pharmaceuticals' proprietary Thin Film Freezing process to enable direct delivery to the lungs and remove the need for intravenous infusion that is required for delivery of current COVID-19 antibody therapies. AUG-3387 was isolated using the SingleCyte® platform developed at Augmenta Bioworks. SingleCyte® rapidly profiles human immunity to discover antigen-specific antibodies using AI driven single cell imaging and retrieval technology.

Delivery of the dry powder formulation of AUG-3387 to infected hamsters resulted in a dose-dependent reduction of viral load when administration of the mAb was initiated 24 hours after infection with SARS-CoV-2. Previous mAbs that have received Emergency Use Authorization from the FDA for treatment of COVID-19 have only reported efficacy in the hamster model when the mAbs were delivered prophylactically 24 hours before infection with SARS-CoV-2. This study also represents the first report of successful reduction of viral load using inhaled delivery of a dry powder monoclonal antibody therapeutic for COVID-19 disease. The results suggest that AUG-3387 represents a viable opportunity to improve on current approved COVID-19 antibody treatments through convenient at-home administration, direct delivery to the lungs and distribution worldwide without requiring cold-chain storage.

In addition to the *in vivo* efficacy, AUG-3387 also showed binding activity against the Alpha, Beta, Delta, Gamma, Kappa, Lambda and Mu variants of SARS-CoV-2. Robust binding to all tested strains of SARS-CoV-2 suggests AUG-3387 targets a highly conserved region of the virus, making AUG-3387 likely to remain effective despite the frequent emergence of new variant strains.

"We are very excited to publish these additional results from our monoclonal antibody program in development with Augmenta, which demonstrate how we can apply our Thin Film Freezing technology to formulate monoclonal antibodies into an inhaled dry powder without changing the underlying biologic properties of the molecule itself," said Glenn Mattes, Chief Executive Officer of TFF Pharmaceuticals. "We completed this study as quickly and efficiently as possible knowing the urgent need for new COVID-19 treatments, but adhered to a rigorous model to ensure accurate assessment of our dry powder formulation of AUG-3387. Unlike prior *in vivo* studies of currently approved COVID-19 antibody therapies that failed to show viral load reduction in animals when delivered after inoculation with the SARS-CoV-2 virus, AUG-3387 demonstrated the ability to reduce viral load in a dose-dependent manner after the animals had been fully inoculated. In our view, AUG-3387 is fast emerging as one of the most promising new therapeutics for the treatment of COVID-19."

Augmenta and TFF Pharmaceuticals plan to develop AUG-3387 as an inhaled therapy for the treatment of COVID-19 disease in two types of individuals: (1) those already infected with SARS-CoV-2 who are at a high risk for severe disease but who have not yet been hospitalized, and (2) for the prevention of SARS-CoV-2 infection for individuals who are at a high risk for severe disease. With the completion of *in vivo* preclinical efficacy studies, Augmenta and TFF now plan to enter toxicology studies in early 2022 and human clinical trials shortly thereafter. Ongoing formulation development studies are expected to demonstrate that a sufficient dose of AUG-3387 to achieve a neutralizing concentration in the lungs can be delivered via already approved commercial dry powder inhaler devices. TFF and Augmenta are working with Catalent Biologics to conduct cell line development, drug substance manufacturing and scale-up efforts for AUG-3387 as the program advances through clinical development.

"This study confirms the power of Augmenta's SingleCyte ® platform to isolate therapeutic antibody candidates with unique functional properties, such as AUG-3387, which broadly neutralizes SARS-CoV-2," added Dr. Christopher Emig, Chief Executive Officer of Augmenta Bioworks. "We continue to be impressed with TFF's Thin Film Freezing platform and the stability of AUG-3387 formulated as a dry powder without any loss of potency. The successful validation of both of our technology platforms in this rigorously designed *in vivo* study suggests that AUG-3387 could play a key role in the ongoing global need for distribution of shelf-stable, highly effective COVID-19 antibody treatments."

In prior *in vitro* preclinical testing, AUG-3387 effectively neutralized SARS-CoV-2 and demonstrated activity against other major COVID variants of concern, including the previously identified Delta variant (B.1.617.2) Alpha variant (B.1.1.7), Beta variant (B.1.351), Gamma variant (P.1) and Kappa variant (B.1.617.1). The additional positive data demonstrating activity against Lambda and Mu variants validates Augmenta's discovery approach and

reflects TFF and Augmenta's ongoing commitment to develop a therapy that is effective against emerging variant strains of SARS-CoV-2.

About the Development Agreement Between Augmenta Bioworks and TFF Pharmaceuticals
In November 2020, Augmenta Bioworks and TFF Pharmaceuticals announced establishment of a worldwide Joint Development and Collaboration Agreement to develop novel commercial products incorporating Augmenta's human-derived monoclonal antibodies (mAbs) for potential COVID-19 therapeutics. TFF Pharmaceuticals also obtained the option to develop two additional Augmenta mAbs for indications other than COVID-19. These antibodies are expected to be developed utilizing TFF Pharmaceuticals' Thin Film Freezing technology to manufacture dry powder formulations for inhalation delivery directly to the lungs of patients. The Agreement also includes the development of formulations suitable for parenteral administration, where the Thin Film Freezing dry powder formulations can be reconstituted, potentially mitigating the impacts of cold-chain storage and handling.

About Augmenta Bioworks
Augmenta Bioworks is a venture-backed biotechnology company leveraging immune profiling technologies to enable breakthroughs in medicine. Through its DeepGrid™ and SingleCyte® Technologies, Augmenta profiles human immunity at unprecedented scale and speed, shrinking new drug discovery timelines from years to days. The company's platform utilizes the latest software, automation, microfluidics, high throughput DNA sequencing, and scalable computational analysis to identify immune receptors and their antigen specificity. The results are therapeutics derived from natural human immunity. The company works through partnerships in antibody discovery (infectious disease), cell therapy development (oncology), and other advanced research (auto-immunity).

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 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 version of AUG-3387, 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 and Augmenta Bioworks may not be able to successfully conclude clinical testing or obtain pre-market approval of a dry powder version of AUG-3387, (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 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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