Augmenta Bioworks and TFF Pharmaceuticals Announce Positive In Vitro Data Demonstrating Binding and Neutralization of the SARS-CoV-2 Delta Variant by Lead Anti-COVID-19 Antibody, AUG-3387

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Data Shows AUG-3387 Neutralizes SARS-CoV-2 Delta Variant in Infective Assays

Supports Earlier Data Showing AUG-3387 Binds Strongly to Delta Variant in Addition to Wild-Type Spike Protein and Other Variants of Concern

Catalent Selected as Contract Drug Manufacturing Organization (CDMO) for AUG-3387

Scale-up Manufacturing for AUG-3387 Proceeding Rapidly; Early Batches Show Promising Results

MENLO PARK, Calif. and AUSTIN, Texas, July 29, 2021 (GLOBE NEWSWIRE) -- Augmenta Bioworks, a biotechnology company enabling breakthroughs in medicine through immune profiling, and 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 positive *in vitro* data indicating that their lead anti-COVID-19 monoclonal antibody ("mAb") therapy, AUG-3387, binds to and neutralizes the SARS-CoV-2 Delta variant (B.1.617.2). The Delta variant is the current dominant strain of SARS-CoV-2 in the U.S., Europe and other geographic regions around the world.

Recent data indicates that the Delta variant, which was recently declared a "Variant of Concern" by the World Health Organization, is more transmissible than the wild-type SARS-CoV-2 strain and other variants. The Delta variant now accounts for 83% of new cases in the U.S., according to recent CDC data. Demonstration that AUG-3387 effectively neutralizes the Delta variant *in vitro* is an encouraging step towards developing the therapy to slow and prevent ongoing spread of COVID-19.

"We are very excited about these new data, which reinforce our view that AUG-3387 could represent an important new class of biologic-based treatment modalities that can effectively target the emerging and potentially more pathogenic variants of the SARS-CoV-2 virus," stated Dr. Christopher Emig, Chief Executive Officer of Augmenta Bioworks. "As global health officials look for innovative solutions to help curb human-to human spread of coronaviruses, we expect the treatment landscape for COVID-19 to evolve so that scalable, biologic-based therapies can play a more prominent role in efficiently combating viral transmission, particularly with respect to new, more infectious COVID-19 variants."

Glenn Mattes, Chief Executive Officer of TFF Pharmaceuticals, added, "The rapid progress we are making with respect to generating positive *in vitro* data speaks to the enthusiasm both TFF and Augmenta have for evaluating the potential of AUG-3387 to combat all prevalent forms of the SARS-CoV-2 virus. Our collaboration also demonstrates how combining two highly innovative and complementary technology platforms can accelerate rapid advancements in drug development to address severe threats to global public health. We look forward to reporting further updates on the AUG-3387 program later this year."

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.

The companies have selected a final formulation of AUG-3387 that will be used to complete *in vivo* preclinical efficacy studies in the coming weeks and will proceed with toxicology studies by the end of 2021. 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.

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 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 neutralization data against the delta variant reflects TFF and Augmenta's ongoing commitment to monitor activity of AUG-3387 against emerging SARS-CoV-2 variants, and to develop a therapy that is as effective as possible against currently dominant strains.

TFF Pharmaceuticals and Augmenta also announced that Catalent Biologics has been selected to conduct cell line development utilizing their proprietary GPEx® platform and to lead drug substance manufacturing and scale-up efforts for AUG-3387 as the program advances through clinical development. Commenting on the agreement, Dr. Emig continued, "With AUG-3387 quickly emerging as a promising treatment against COVID-19, including for currently dominant variants, the selection of the CDMO is a critical decision along our development pathway. As one of the leading global providers of advanced biologics, Catalent brings exceptionally strong expertise in manufacturing of monoclonal antibodies. Augmenta and TFF look forward to working with them as the AUG-3387 program continues to advance."

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^{TM} and SingleCyte^{R} 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

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 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, its Joint Development and Collaboration Agreement with Augmenta Bioworks, TFF's and Augmenta's potential joint development of AUG-3387 to combat the SARS-CoV-2 virus and its variants and the parties' potential joint development of two additional Augmenta mAbs for indications other than COVID-19. 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 results obtained in dry powder formulation and in vitro testing of AUG-3387 and any other Augmenta mAbs may not be indicative of results obtained in future preclinical or clinical trials; (ii) the risk that TFF Pharmaceuticals' dry powder formulation of AUG-3387 and any other Augmenta mAbs may not advance through the preclinical development and clinical trial process on a timely basis, or at all; (iii) the risk that the results of such trials will not warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; (iv) the risk that TFF Pharmaceuticals and Augmenta may not be able to successfully conclude clinical testing or obtain pre-market approval of their dry powder versions of AUG-3387 or any other Augmenta mAbs, (v) the fact that no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (vi) TFF Pharmaceuticals has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF Platform, and (vi) those other risks disclosed in the section "Risk Factors" included in the TFF Pharmaceuticals' 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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