Augmenta Bioworks and TFF Pharmaceuticals Announce Selection of Lead Monoclonal Antibody Candidate AUG-3387 for Clinical Development Against COVID-19

June 22, 2021

AUG-3387 Active Against All Variants Tested Including the UK (B.1.1.7), South African (B.1.351), Indian (B.1.617.1), and Brazil (P.1) Variants

MENLO PARK, Calif. and AUSTIN, Texas, June 22, 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 that AUG-3387 has been selected as the first lead monoclonal antibody for clinical development against COVID-19 under their Joint Development and Collaboration Agreement. Targeting the SARS-Cov2 spike protein, AUG-3387 was isolated from an asymptomatic patient and then identified through Augmenta's platform in less than two weeks.

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-CoV2 who are at high risk for severe disease but who have not yet been hospitalized, and (2) for the prevention of SARS-CoV2 infection for individuals who are at high-risk for severe disease.

Notably, in in vitro preclinical testing, AUG-3387 effectively neutralizes SARS-CoV2 and has demonstrated activity against all variant strains tested to date, including the major COVID variants of concern, including the previously identified UK (B.1.1.7 - Alpha), South African (B.1.351 - Beta), Brazil (P.1 - Gamma) and India (B.1.617.1 - Kappa) variants. TFF and Augmenta have an ongoing commitment to monitor activity of AUG-3387 against emerging SARS-CoV2 variants and will be completing *in vivo* preclinical efficacy studies in the coming weeks.

"The activity of AUG-3387 against all SARS-CoV2 variants tested to date provides strong justification for the continued development of this unique monoclonal antibody therapy, especially when combined with the potential to break the cold chain requirement of other therapies and the cost-effective delivery of lower doses via inhalation, made possible through the TFF process," stated Dr. Christopher Emig, Chief Executive Officer of Augmenta Bioworks.

"By combining the novel pan-variant activity of AUG-3387 with the enhanced stability and ease of delivery provided by the TFF technology, we believe this drug could potentially make significant impact on bringing COVID-19 disease under control where vaccines with extreme cold chain requirements are not feasible," added Glenn Mattes, Chief Executive Officer of TFF Pharmaceuticals. "We look forward to continued scale up manufacturing, completion of toxicology studies and enablement of human clinical trials in the coming months."

In November 2020, the Companies 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 will 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 patented DeepGrid™ and SingleCyte® Technologies, Augmenta endeavors to profile human immunity at increased scale and speed, shrinking new drug discovery timelines. 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 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 Voriconazole and Tacrolimus, the potential development of one or more dry powder mAbs through its collaboration with Augmenta Bioworks and the Company's plans to add to its existing pipeline of product candidates and license its technology to other third-parties.

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 the 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 the 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 the 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, 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.

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

Christopher Emig, Ph.D.
President and CEO
Augmenta Bioworks, Inc
chris@augbio.com
650-731-2842

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

Source: TFF Pharmaceuticals, Inc.