Feasibility Arrangement for Shelf-stable Powder Form of Messenger RNA COVID-19 Vaccine Candidate Announced by GreenLight Biosciences and TFF Pharmaceuticals

March 9, 2021

Feasibility arrangement to test GreenLight Bioscience Inc's COVID-19 messenger RNA vaccine candidate as a shelf-stable dry powder formulation using TFF Pharmaceuticals' Thin-Film Freezing technology.

An easily reconstituted and shelf-stable dry powder formulation of messenger RNA COVID-19 vaccine could overcome the extreme low temperature cold chain requirements for current RNA vaccines.

Eliminating extreme cold from the supply chain simplifies global distribution and opens vaccine availability to the large populations in regions and countries with limited refrigeration infrastructure

Should the study prove successful, the next phase may include non-needle administration of mRNA vaccines, including nasal spray and lung inhalation form.

MEDFORD, Mass. & AUSTIN, Texas--(BUSINESS WIRE)--Mar. 9, 2021-- GreenLight Biosciences, Inc., a privately-held RNA vaccine developer and manufacturer, 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 the two biotech companies have partnered for feasibility studies aimed at opening broader global vaccine distribution through production of a shelf-stable powder form of messenger RNA COVID-19 vaccine that would be easily reconstituted prior to injection and not require the extreme cold chain of current RNA vaccines.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210309005642/en/

While messenger RNA COVID-19 vaccines have proved among the fastest to develop, produce and adapt to new variants of concern, maintaining stability has required supply chain temperatures for some vaccines as low as -80°C (-112°F).

This requirement for extreme cold increases distribution complexity, cost and also constrains vaccine distribution to regions and countries with limited cold chain infrastructure.

To address this challenge, GreenLight Biosciences and TFF Pharmaceuticals have entered into a feasibility and material transfer agreement to evaluate a shelf-stable dry powder formulation of GreenLight's COVID-19 messenger RNA vaccine candidate.

"We are excited to partner with GreenLight Biosciences on their unique messenger RNA production platform," said Glenn Mattes, President & CEO of TFF Pharmaceuticals. "Their platform technology represents a breakthrough in efficient production of messenger RNA vaccines, and by combining both of our technologies, this collaboration could be a real game changer for people around the world suffering through this pandemic."

Should the feasibility study prove successful, a further stage of work will include non-needle administration methods for the GreenLight mRNA vaccine candidate in a dry powder form that could be administered via nasal spray or lung inhalation.

Under the Feasibility Agreement, GreenLight Biosciences is delivering its COVID-19 messenger RNA product candidate materials to TFF in order to perform feasibility formulation work and testing.

The goal of this feasibility work is to formulate and identify an optimal formulation of the GreenLight Biosciences messenger RNA product candidate in a dry powder form, which has superior stability, maintains particle size of the encapsulated messenger RNA as well as high encapsulation efficiency and has rapid reconstitution characteristics for injection.

If successful, this should make messenger RNA vaccines available to the whole world, simplifying cold-chain supply challenges. Thin film technology potentially allows vaccines to be transported at fridge, or even room temperatures as a powder. It can then be reconstituted by a health care worker at the point of use.

This agreement is part of GreenLight Biosciences goal of using its unique manufacturing platform to produce vaccines in volumes that can serve the world's need for billions of doses. This partnership offers the hope of speeding these doses into use.

"Overcoming the COVID-19 pandemic requires a large volume of second generation vaccines that adapt rapidly and can be delivered to all parts of the world, regardless of local cold chain infrastructure," said Andrey J. Zarur, Ph.D, CEO of GreenLight Biosciences. "Thin Film Freezing has the potential to deliver on this promise by reformulating the complex messenger RNA molecules of our vaccine candidate into a shelf-stable powder readily reconstituted by a healthcare worker just prior to injection."

TFF has two drug candidates in phase one clinical trials, Voriconazole Inhalation Powder and Tacrolimus Inhalation Powder. TFF requires approximately six weeks from receipt of materials to prepare an initial dry powder form of GreenLight's vaccine candidate to test for reconstitutability and viability.

About GreenLight Biosciences, Inc.

GreenLight Biosciences has several messenger RNA Covid vaccine candidates in development built off of GreenLight's manufacturing platform, which delivers high-quality RNA at a lower cost and higher speed than comparable processes.

GreenLight is a bio-performance company with a unique, cell-free production platform that delivers high-performing RNA solutions to human, plant and animal challenges. GreenLight develops RNA products for plant and life science applications, and collaborates with industry leaders to advance vaccine development, pandemic preparation, crop management, and plant protection. The GreenLight team is committed to social justice, diversity, inclusion, and equality, and promises to use collaboration to remain scientifically imaginative and passionately focused on making a difference in the world. For more information, visit https://www.greenlightbiosciences.com/.

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/.

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 GreenLight Bioscience Inc's COVID-19 messenger RNA vaccine candidate. 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 GreenLight Bioscience may not be able to successfully conclude clinical testing or obtain pre-market approval of its COVID-19 messenger RNA vaccine candidate, (ii) the risk that GreenLight Bioscience and the Company may not be able to produce a dry powder version GreenLight Bioscience Inc's COVID-19 messenger RNA vaccine candidate, (iii) the risk that GreenLight Bioscience and the Company may not be able to successfully conclude clinical testing or obtain pre-market approval of a dry powder version GreenLight Bioscience Inc's COVID-19 messenger RNA vaccine candidate, (iv) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, and (iv) those other risks disclosed in the section "Risk Factors" included in the Company's prospectus supplement filed with the SEC on December 8, 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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