



NEWS RELEASE

Savara Receives \$5 Million Award From Cystic Fibrosis Foundation Therapeutics, Inc. for the Development of AeroVanc

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Award Available to Support Pivotal Phase III AVAIL Study of AeroVanc, the First Inhaled Antibiotic Being Developed for MRSA Lung Infection in Cystic Fibrosis

AUSTIN, TX -- (Marketwired) -- 11/29/17 -- **Savara, Inc.** (NASDAQ: SVRA), an orphan lung disease company, today announced that it has received a development award of up to \$5 million from **Cystic Fibrosis Foundation Therapeutics, Inc.** (CFFT), the nonprofit drug discovery and development affiliate of the CF Foundation. The award is available to support the continued development of AeroVanc (vancomycin hydrochloride inhalation powder), the first inhaled antibiotic being developed for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in individuals living with cystic fibrosis (CF), and can be used to support the Company's ongoing Phase III pivotal **AVAIL** study of AeroVanc. The \$5 million award from the CFFT can be drawn down by Savara as needed upon the achievement of continued progress and certain milestones of the AeroVanc program and the AVAIL study.

In September 2017, Savara announced that its pivotal AVAIL study is now open for enrollment. The AVAIL study is a Phase III, randomized, double-blind, placebo-controlled study of AeroVanc for the treatment of MRSA lung infection in individuals living with cystic fibrosis. The AVAIL study will enroll approximately 200 subjects at more than 80 clinical study sites across the United States and Canada.

"We are delighted to have the CF Foundation's continued support and we believe this award serves as strong validation of our AeroVanc program," stated Rob Neville, CEO of Savara. "Our AVAIL study was planned in consultation with the CF Foundation's Therapeutic Development Network as well as key opinion leaders (KOLs) across the country, and we are excited to have the study started and enrolling."



"Cystic fibrosis has been a primary focus of my research interests for many years. Inhaled antibiotics have become the standard of care to treat *Pseudomonas aeruginosa* lung infection and we are now on the verge of demonstrating that a similar approach should be used for MRSA. AeroVanc has shown potential as a novel treatment for MRSA lung infection, a growing problem not currently addressed by any other available inhaled antibiotics," stated Patrick Flume, M.D., Director, Adult Cystic Fibrosis Center and Professor of Medicine and Pediatrics at the Medical University of South Carolina and coordinating principal investigator of the AVAIL study. "If the results from the AVAIL study are positive, I believe AeroVanc could become the new standard for inhaled antibiotic treatment of MRSA in CF."

About the AVAIL Study

The AVAIL study will enroll approximately 200 subjects at more than 80 clinical study sites across the United States and Canada. During Period 1 of the study, subjects will be randomly assigned in a blinded 1:1 fashion to receive either AeroVanc (30 mg) twice daily, or placebo, by inhalation for 24 weeks or 3 dosing cycles. A dosing cycle is defined as 28 days of treatment followed by 28 days of observation. During Period 2 of the study, subjects will receive open-label AeroVanc (30 mg) twice daily for an additional 24 weeks or 3 dosing cycles, to evaluate the long-term safety of AeroVanc. The Coordinating Investigator of the study is Dr. Patrick Flume, Professor of Medicine and Director of the Cystic Fibrosis Program, Medical University of South Carolina, Charleston, SC.

The primary efficacy endpoint in the AVAIL study is the mean absolute change from baseline in FEV1 percent predicted (Forced Expiratory Volume measured during the first second of exhalation). The primary efficacy analysis will be based on patients between 6 - 21 years of age. Secondary efficacy endpoints include: (i) time to use of another antibiotic medication (oral, IV, and/or inhaled) for pulmonary infection, (ii) the number of successful FEV1-response cycles a subject achieves over Period 1, (iii) relative change from baseline in FEV1 percent predicted, (iv) change from baseline Cystic Fibrosis Questionnaire-Revised score, and (v) change from baseline in Cystic Fibrosis Respiratory Symptom Diary-Chronic Respiratory Symptom Score.

About AeroVanc

AeroVanc (vancomycin hydrochloride inhalation powder) is the first inhaled antibiotic being developed for the treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in individuals living with cystic fibrosis (CF). In a randomized, double-blind, placebo-controlled Phase II study in CF patients with persistent MRSA infection, AeroVanc reduced MRSA density in sputum, and showed encouraging trends of improvement in lung function, and respiratory symptoms, as well as prolongation of the time to use of other antibiotics, with best responses in subjects under 21 years of age.

AeroVanc has been granted Orphan Drug Designation and Qualified Infectious Disease Product, or QIDP, status for the treatment of persistent MRSA lung infection in CF patients in the United States. The Orphan Drug Designation

makes AeroVanc eligible for seven years of exclusivity from approval in the United States, and the QIDP designation makes AeroVanc eligible for an additional five years of exclusivity in the United States. In 2017, a composition of matter patent covering AeroVanc was issued by the United States Patent and Trademark Office which affords Savara important protection for the program in the U.S., the largest market for the product, augments the Company's market protection strategy, and will expire no earlier than 2032.

About the Cystic Fibrosis Foundation

The CF Foundation is the world's leader in the search for a cure for cystic fibrosis, and nearly every CF-specific drug available today was made possible with the financial support of the Foundation. The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care. The CF Foundation is a donor-supported nonprofit organization. For more information, go to www.cff.org. Cystic Fibrosis Foundation Therapeutics Inc. (CFFT) is the CF Foundation's nonprofit drug discovery and development affiliate, created to help speed development of new CF treatments by funding promising scientific research in academia and the biotechnology and pharmaceutical industries. CFFT also supports the Therapeutics Development Network -- the largest CF clinical trials network in the world -- and operates its own research laboratory.

About Savara

Savara Inc. is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel therapies for the treatment of serious or life-threatening rare respiratory diseases. Savara's pipeline comprises: Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for pulmonary alveolar proteinosis, or PAP, and in preparation for Phase 2a development for nontuberculous mycobacteria, or NTM, lung infection; AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of MRSA infection in Cystic Fibrosis; and, Aironite, an inhaled sodium nitrite for heart failure with preserved ejection fraction, or HFpEF, in Phase 2 development. Savara's strategy involves expanding its pipeline of potentially best-in-class products through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in its field. Savara's management team has significant experience in orphan drug development and pulmonary medicine, in identifying unmet needs, developing and acquiring new product candidates, and effectively advancing them to approvals and commercialization. More information can be found at www.savarapharma.com. (Twitter: [@SavaraPharma](https://twitter.com/SavaraPharma))

Forward Looking Statements

Savara cautions you that statements in this press release that are not a description of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as "expect,"

"intend," "plan," "anticipate," "believe," and "will," among others. Such statements include, but are not limited to, statements relating to funds being available to support the continued development of AeroVanc, funds can be used to support the Company's ongoing Phase III pivotal AVAIL study of AeroVanc, planned enrollment and structure of the AVAIL study, CF Foundation's continued support, our belief that this award serves as strong validation of our AeroVanc program, being excited to have the study started and enrolling, being on the verge of demonstrating that a similar approach should be used for MRSA, that AeroVanc has shown potential as a novel treatment for MRSA infection, a growing problem not currently addressed by any other available inhaled antibiotics, the belief that AeroVanc could become the new standard for inhaled antibiotic treatment of MRSA in CF, that AeroVanc showed encouraging trends of improvement in lung function, and respiratory symptoms, as well as prolongation of the time to use of other antibiotics, that the patent affords Savara important protection for the program in the U.S. and augments the Company's market protection strategy and our strategy. Savara may not actually achieve any of the matters referred to in such forward looking statements, and you should not place undue reliance on these forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Savara's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with the outcome of our ongoing clinical trials for our product candidates (including AeroVanc), the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources for Savara's operations and to conduct or continue planned clinical development programs (including our AVAIL study of AeroVanc), the ability to obtain the necessary patient enrollment for our product candidates in a timely manner (including our AVAIL study), the ability to successfully develop our product candidates, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex, AeroVanc and Aironite that are safe and effective for use as human therapeutics and the timing and ability of Savara to raise additional equity capital as needed to fund continued operations. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of our risks and uncertainties, you are encouraged to review our documents filed with the SEC including our recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Savara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

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