NEWS RELEASE

Savara Provides Update on IMPALA and AVAIL Pivotal Clinical Studies

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AUSTIN, Texas, Feb. 06, 2019 (GLOBE NEWSWIRE) -- **Savara Inc.** (Nasdaq: SVRA), an orphan lung disease company, today provided an update on its two pivotal Phase 3 clinical studies, IMPALA and AVAIL.

IMPALA

IMPALA is a pivotal Phase 3 clinical study evaluating Molgradex, an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of autoimmune pulmonary alveolar proteinosis (aPAP). It is the largest clinical study ever conducted in aPAP, with a total of 139 people across 34 study sites. Savara remains on track to report top line results from the ongoing study at the end of the second quarter 2019. Robust results from IMPALA would facilitate the submission of a Biologics License Application (BLA) in the first half of 2020.

Molgradex is also being investigated in an open-label, multicenter, safety extension study called IMPALA-X, to determine the long-term safety and use of Molgradex in people with aPAP. IMPALA-X offers people the opportunity to continue treatment with Molgradex for up to three years after completion of the IMPALA study. Enrollment in IMPALA-X continues to be active.

AVAIL

AVAIL is a pivotal Phase 3 clinical study evaluating AeroVanc, vancomycin hydrochloride inhalation powder, for the treatment of Methicillin-resistant Staphylococcus aureus (MRSA) lung infection in people living with cystic fibrosis (CF). With 143 people currently enrolled, out of a target of 200, Savara is updating its guidance for enrollment completion. Savara now expects to complete enrollment for AVAIL in the third quarter of 2019. While screening rates are high, enrollment for the primary analysis population of 150 younger people (6-21 years of age) has been slower than expected. This is largely due to a higher than anticipated screen failure rate (46%). The most common

reason for screen failures has been pulmonary exacerbations occurring between screening and randomization and the inability to meet the required lung function range. Top line data from AVAIL is currently expected in the second quarter of 2020.

“AVAIL is a high priority for the community of CF care centers and, as demonstrated by the high screening numbers, we have been successful in reaching a large number of MRSA-affected people and their families,” said Patrick Flume, M.D., Director of the Adult CF Center, Medical University of South Carolina, Charleston, and the Coordinating Principal Investigator for AVAIL. “As shown by the number of pulmonary exacerbations just prior to randomization, people with MRSA lung infection have a strong need for improved treatment options. I am optimistic that AeroVanc could improve outcomes for people living with MRSA and become the first FDA approved therapy to treat this debilitating disease.”

About the IMPALA Study

IMPALA is a Phase 3 randomized, double-blind, placebo-controlled clinical study designed to compare the efficacy and safety of Molgradex with placebo in subjects with autoimmune pulmonary alveolar proteinosis (aPAP). The study is being conducted in 18 countries worldwide. Subjects are randomized to receive treatment for 24 weeks in one of three arms: (i) Molgradex 300 µg administered once daily, (ii) Molgradex 300 µg and matching placebo administered daily in 7-day intermittent cycles of each, or (iii) inhaled placebo administered once daily.

The primary endpoint in the study is the absolute change from baseline in arterial-alveolar oxygen gradient, a measure of the subject’s oxygenation status, following 24 weeks of treatment. In addition, the U.S. Food and Drug Administration (FDA) will focus its review on three key secondary endpoints to evaluate improvement in clinical symptoms and function, including six-minute walk distance, St. George’s respiratory questionnaire, and the time-to-need of whole lung lavage.

About the AVAIL Study

AVAIL is a Phase 3, randomized, double-blind, placebo-controlled study designed to compare the efficacy and safety of vancomycin hydrochloride inhalation powder with placebo in subjects with Methicillin-resistant Staphylococcus aureus (MRSA) lung infection in people living with cystic fibrosis (CF). AVAIL will enroll approximately 200 subjects (150 ≤ 21 years old, 50 > 21 years old), at more than 80 clinical study sites across the United States and Canada. During Period 1 of the study, subjects are 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 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 primary endpoint is the mean absolute change in FEV1 percent predicted from baseline, which will be analyzed

sequentially at week 4 (the end of cycle 1), at week 12 (the end of cycle 2) and at week 20 (the end of cycle 3). Analysis of the primary endpoint will be based on subjects between 6-21 years of age. Secondary efficacy endpoints include: (i) time-to-use of another antibiotic medication for pulmonary infection, (ii) the number of successful FEV1-response cycles a subject achieves over Period 1 (weeks 4, 12, and 20), (iii) relative change from baseline in FEV1 percent predicted at weeks 4 and 20, (iv) change from baseline CF Questionnaire-Revised scores at weeks 4 and 20 and (v) change from Baseline in CF Respiratory Symptom Diary-Chronic Respiratory Symptom Score scores at weeks 4 and 20.

About Savara

Savara is an orphan lung disease company. Savara's pipeline comprises Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP), in Phase 2a development for nontuberculous mycobacterial (NTM) lung infection, and in preparation for Phase 2a development in cystic fibrosis (CF) affected individuals with chronic NTM lung infection; and AeroVanc, a Phase 3-stage inhaled vancomycin for treatment of persistent Methicillin-resistant Staphylococcus aureus (MRSA) lung infection in CF. 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. The most recent acquisition is aerosolized amikacin/fosfomycin, a Phase 2-ready, proprietary combination antibiotic, which has demonstrated potent and broad-spectrum antibacterial activity against highly drug resistant pathogens. Savara's management team has significant experience in orphan drug development and pulmonary medicine, 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**, LinkedIn: **www.linkedin.com/company/savara-pharmaceuticals/**)

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 regarding the timing of top line results from our IMPALA and AVAIL studies, that robust results from IMPALA would facilitate the submission of a Biologics License Application in the first half of 2020, statements regarding the enrollment of our IMPALA-X study, statements regarding the enrollment of our AVAIL study, including the timing of completion of enrollment, that AVAIL is a high priority for the community of CF care centers, that people with MRSA lung infection have a strong need for improved treatment options, statements regarding optimism that AeroVanc could improve outcomes for people living with MRSA and become the first FDA approved therapy to treat this debilitating disease, statements regarding the focus of FDA review on the results of the IMPALA

study, statements regarding the analysis of the AVAIL study results, and Savara's 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. 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 and planned clinical trials for our product candidates, 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, the ability to obtain the necessary patient enrollment for our product candidates in a timely manner, the ability to successfully identify product acquisition candidates, 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 amikacin/fosfomycin 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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