NEWS RELEASE

Savara Announces First Patient Dosed in Pivotal Phase 3 Autoimmune Pulmonary Alveolar Proteinosis (aPAP) Trial

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- The IMPALA-2 trial will evaluate the efficacy and safety of molgramostim nebulizer solution (molgramostim) in aPAP, a rare lung disease with no approved pharmacological treatment options
- Key learnings from the Phase 2/3 IMPALA trial informed the Phase 3 IMPALA-2 trial design

AUSTIN, Texas--(BUSINESS WIRE)--Jun. 30, 2021-- **Savara Inc.** (Nasdaq: SVRA), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced that the first patient has been dosed in the pivotal IMPALA-2 clinical trial. IMPALA-2 is a Phase 3 trial designed to evaluate the efficacy and safety of molgramostim compared to placebo. Molgramostim is an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF). The trial is expected to be conducted at ~50 sites across the U.S., Canada, Japan, South Korea, and various countries in Europe and is anticipated to enroll ~160 patients with aPAP.

“Autoimmune PAP is caused by abnormal accumulation of surfactant sediment in the alveoli, leading to impaired gas exchange between the lungs and blood,” said Bruce Trapnell, M.D., IMPALA-2 International Coordinating Investigator, Professor of Medicine and Pediatrics, University of Cincinnati College of Medicine. “The disease has a meaningful impact on a patient’s quality of life, causing them to become increasingly breathless, often with cough and frequent fatigue. With an unpredictable yet progressive clinical course, aPAP can include serious secondary infections, respiratory failure or pulmonary fibrosis requiring a lung transplantation. Research has demonstrated that treatment with inhaled GM-CSF can improve the clinical signs and symptoms of aPAP, which makes sense as it’s a logical replacement of a protein that has been neutralized by autoantibodies.”

“With the first patient dosed in IMPALA-2, we hit a critical milestone in-line with our guidance for the trial,” said Badrul Chowdhury, M.D., Ph.D., Chief Medical Officer, Savara. “Our highest priority is to continue activating sites

and working with the global aPAP community to enroll patients. Data from the IMPALA trial gave us confidence that molgramostim has the potential to address a significant unmet need in aPAP and we look forward to building on those supportive data to advance the development of molgramostim as the first potential pharmacological treatment for this debilitating disease."

Initiation of IMPALA-2 is based on results from the Phase 2/3 IMPALA clinical trial which were published in the New England Journal of Medicine in September 2020. While the IMPALA trial did not meet the primary endpoint of alveolar-arterial oxygen gradient (A-aDO_2), the totality of data showed that multiple key secondary and exploratory endpoints either achieved nominal statistical significance or trended in favor of the active drug arms, and results from the open-label period demonstrated a sustained treatment effect, or continued improvement, after longer term exposure to molgramostim. In December 2019, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for molgramostim in aPAP based on data from the double-blind treatment period of IMPALA.

IMPALA-2 is a Phase 3, 48-week, randomized, double-blind, placebo-controlled clinical trial designed to compare the efficacy and safety of molgramostim 300 mcg administered once daily by inhalation with matching placebo in patients with aPAP. The primary efficacy variable is change from baseline in percent predicted diffusing capacity for carbon monoxide (DLCO), a gas exchange measure. Three secondary efficacy variables evaluate clinical measures of direct patient benefit: St. George's Respiratory Questionnaire (SGRQ) Total Score, SGRQ Activity Component Score, and exercise capacity using a treadmill test. The primary time point for efficacy assessment will be at week 24, however, efficacy will be assessed through week 48 to show durability of effect. Safety will be assessed through week 48. Following the 48-week double-blind treatment period, patients will roll-over to a 48-week open-label period and will receive molgramostim 300 mcg administered once daily.

More information on the IMPALA-2 trial (NCT04544293) can be found at **clinicaltrials.gov**.

About Savara

Savara is a clinical stage biopharmaceutical company focused on rare respiratory diseases. Our lead program, molgramostim nebulizer solution, is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). Our management team has significant experience in rare respiratory diseases and pulmonary medicine, identifying unmet needs, and effectively advancing product candidates to approval and commercialization. More information can be found at **https://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 expected number and location of sites participating in the IMPALA-2 trial, the anticipated enrollment, that our highest priority is to continue activating sites and working with the global aPAP community to enroll patients, that molgramostim has the potential to address a significant unmet need in aPAP, and that we look forward to building on the supportive data from IMPALA to advance the development of molgramostim as the first potential pharmacological treatment for this debilitating disease. 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, the risks and uncertainties relating to the impact of the COVID-19 pandemic on our business and operations, the outcome of our ongoing and planned clinical trials, 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 in a timely manner, the ability to successfully develop molgramostim, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as molgramostim that are safe and effective for use as human therapeutics, and the timing and ability of Savara to raise additional 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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