



NEWS RELEASE

Savara Completes Enrollment of Pivotal Phase 3 IMPALA-2 Trial of Molgramostim Nebulizer Solution (Molgramostim) in Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

2023-06-26

- Target Enrollment was 160 Patients, IMPALA-2 Enrolled 164 Patients
- Company Remains On-Track to Report Top Line Data by End of 2Q 2024

AUSTIN, Texas--(BUSINESS WIRE)--Jun. 26, 2023-- **Savara Inc.** (Nasdaq: SVRA), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced that enrollment has been completed for the pivotal Phase 3 IMPALA-2 trial. A total of 164 patients were randomized. Target enrollment for the trial was 160 patients. The Company expects to report top line results by the end of 2Q 2024. IMPALA-2 is a global, 48-week, placebo-controlled clinical trial evaluating molgramostim, a novel inhaled biologic, for the treatment of aPAP, a rare lung disease with no approved pharmacological treatments.

“Enrollment completion marks an important milestone in the molgramostim development program,” said Matt Pauls, Chair and CEO, Savara. “We believe over-enrollment in the trial, on-time, during the COVID-19 pandemic speaks directly to both the high unmet need within this patient population and the therapeutic potential of molgramostim. We anticipate reporting top line safety and efficacy data by the end of 2Q 2024.”

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 the Phase 2/3 IMPALA clinical trial. Initiation of IMPALA-2 was based on results from IMPALA which were published in the New England Journal of Medicine in September 2020. In 2022, the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) designation and Innovative Passport Designation to molgramostim for



the treatment of aPAP.

About the IMPALA-2 Trial

IMPALA-2 is a global, pivotal, 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 trial is being conducted at approximately 50 clinical trial sites in 18 countries across North America, Europe, Japan, South Korea, and Australia. 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 is at week 24, however, efficacy will be assessed through week 48 to show durability of effect. Safety will be assessed through week 48. Pending applicable regulatory and ethics committee approvals, following the 48-week double-blind treatment period patients may continue in a 96-week open-label period and receive molgramostim 300 mcg administered once daily.

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

About aPAP

Autoimmune PAP is a rare lung disease characterized by the abnormal build-up of surfactant sediment in the alveoli (or air sacs) of the lungs. The surfactant consists of proteins and lipids and is an important physiological substance that lines the inside of the alveoli to prevent the lungs from collapsing. In a healthy lung, the old and inactivated surfactant is cleared and digested by immune cells called alveolar macrophages. Alveolar macrophages need to be stimulated by granulocyte-macrophage colony-stimulating factor (GM-CSF) to function properly in clearing surfactant, but in autoimmune PAP, GM-CSF is neutralized by antibodies against GM-CSF, rendering the macrophages unable to perform their tasks. As a result, an excess of surfactant accumulates in the alveoli, causing obstruction of gas exchange, and patients start to experience shortness of breath, often with cough and frequent fatigue. Patients may also experience chronic cough, as well as episodes of fever, chest pain, or coughing blood, especially if secondary lung infection develops. In the long-term, the disease can lead to serious complications, including lung fibrosis and the need for a lung transplant.

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). Molgramostim is delivered via an

investigational eFlow[®] Nebulizer System (PARI Pharma GmbH). 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 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 related to the timing of reporting of top line data. 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 widespread health concerns impacting healthcare providers or patients, disruptions or inefficiencies in the supply chain and geopolitical conditions on our business and operations, the outcome of our ongoing and planned clinical trials for our product candidate, 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 candidate in a timely manner, the ability to successfully develop our product candidate, 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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Source: Savara Inc.