



NEWS RELEASE

Savara Announces New England Journal of Medicine (NEJM) Publication of IMPALA Study Results

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Inhaled Molgramostim Improved Outcomes that Reflect Physiological, Radiological, Biochemical, and Clinical Manifestations of aPAP

AUSTIN, Texas--(BUSINESS WIRE)--Sep. 8, 2020-- Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today announced that results from the Phase 3 IMPALA study were published online in NEJM. The manuscript, titled "Inhaled Molgramostim Therapy in Autoimmune Pulmonary Alveolar Proteinosis," appears in the September 7, 2020 online version of the publication and can be found at www.nejm.org.

The IMPALA study evaluated molgramostim nebulizer solution (an inhaled granulocyte-macrophage colony-stimulating factor) for the treatment of aPAP and was a 24-week, double-blind, placebo-controlled study. Patients were randomized to one of three arms, molgramostim 300 µg continuous daily dosing, molgramostim 300 µg daily dosing intermittently every other week, or placebo. The double-blind period was followed by a 24/48-week open-label period where all arms received molgramostim 300 µg daily dosing intermittently every other week. The A-aDO₂ gradient was the primary endpoint in the study. Key secondary endpoints included the St. George's Respiratory Questionnaire (SGRQ) total score, six-minute walk distance, and time-to-requirement for whole lung lavage.

"IMPALA was the largest treatment trial ever conducted in aPAP patients and demonstrated that daily administration of inhaled molgramostim led to greater improvement than placebo in outcomes that reflect physiological, radiological, biochemical, and clinical manifestations of aPAP," said Bruce Trapnell, M.D., Lead Investigator of the IMPALA study in the U.S. "Importantly, molgramostim was well tolerated with no notable safety concerns. I believe that the drug will be a significant improvement to the care of aPAP patients."



While IMPALA did not meet the primary endpoint of A-aDO₂ in the primary analysis, replacement (by imputation) of invalid A-a DO₂ data for four severely affected patients who required continuous nasal oxygen therapy resulted in a change in A-aDO₂ from baseline to week 24 that was greater in patients receiving continuous administration of molgramostim compared to placebo. Oxygen therapy during arterial blood gas measurement was permitted by protocol for ethical reasons (n=1 in each molgramostim arm, n=2 in the placebo arm). The estimated treatment difference was -6.2 mmHg, p=0.03. Additionally, improvement in A-aDO₂ was supported by another secondary measure of pulmonary gas transfer called diffusing capacity for carbon monoxide (DLCO). The mean change from baseline at week 24 in DLCO was greater in patients receiving continuous administration of molgramostim compared to placebo, with an estimated treatment difference of 7.8 percent predicted (95% CI 2.3 to 13.3). Regarding the key secondary endpoints, in the full analysis set, SGRQ total score showed improvement with continuous administration of molgramostim compared to placebo, with an estimated treatment difference of -7.4, p=0.012. Results in the six-minute walk distance and time-to-requirement for whole lung lavage were numerically in favor of patients receiving molgramostim but did not demonstrate statistically significant differences compared to placebo. In patients with aPAP, daily administration of inhaled molgramostim resulted in greater improvements in pulmonary gas transfer and functional health status than placebo, with similar rates of adverse events.

“With no other drugs on the market to treat this rare lung disease, and data from the IMPALA study that indicates the drug has effect, we believe molgramostim has the potential to transform the standard-of-care for aPAP patients,” said Badrul Chowdhury, Chief Medical Officer, Savara. “At the end of last year, the FDA granted molgramostim Breakthrough Therapy Designation for the treatment of aPAP and advancing this program is our highest priority. We now have a finalized study design for IMPALA 2, the Phase 3 confirmatory study required for regulatory approval, that incorporates the key learnings from the first IMPALA study as well as feedback from regulatory agencies. We look forward to initiating it in the first quarter of next year.”

About Savara

Savara is an orphan lung disease company with a pipeline comprised of three investigational compounds, all of which use an inhaled delivery route. Our lead program, Molgradex (molgramostim nebulizer solution), is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). Apulmiq is an inhaled ciprofloxacin in Phase 3 development for non-cystic fibrosis bronchiectasis (NCFB). AeroVanc is an inhaled vancomycin in Phase 3 development for persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in people living with cystic fibrosis. Savara’s strategy involves broadening its pipeline through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in its field. Our 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 approval and commercialization. More information can be found at www.savarapharma.com. (Twitter: [@SavaraPharma](https://twitter.com/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, Dr. Trapnell’s belief that molgramostim will be a significant improvement to the care of aPAP patients, that data from the IMPALA study indicates molgramostim has effect, the belief that molgramostim has the potential to transform the standard-of-care for aPAP patients, that advancing the molgramostim program is Savara’s highest priority, and that we look forward to initiating the IMPALA 2 study in the first quarter of next year. 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 impact of the COVID-19 pandemic on our business and operations, 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 planned clinical development programs, 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 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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