NEWS RELEASE

Savara Presents New Data From the Phase 3 IMPALA-2 Clinical Trial of Molgramostim Inhalation Solution (Molgramostim) in Patients With Autoimmune Pulmonary Alveolar Proteinosis (aPAP) at the European Respiratory Society (ERS) Congress 2025

2025-09-29

– The Beneficial Clinical Effects of Molgramostim Were Similar in Patients with aPAP Regardless of Disease Severity Defined by DLco% –

– Changes in DLco%, the Primary Endpoint in IMPALA-2, Were Significantly Correlated with Changes in Measures of Quality of Life, Patient Functionality, and Surfactant Burden in Patients with aPAP –

– Savara's Partner, TrilliumBiO, Presented Data on the Development of a Dried Blood Spot Test to Aid in the Diagnosis of aPAP –

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (the "Company") (Nasdaq: **SVRA**), a clinical-stage biopharmaceutical company focused on rare respiratory diseases, today announced additional analyses from its pivotal Phase 3 IMPALA-2 clinical trial of molgramostim in aPAP were presented as poster presentations at the ERS Congress 2025 in Amsterdam, The Netherlands.

ERS 2025 Posters

Savara

Title: Efficacy of Inhaled Molgramostim According to Severity of Autoimmune Pulmonary Alveolar Proteinosis

(aPAP)

Presenter: Cormac McCarthy, M.D., Ph.D., FRCPI, Associate Professor of Medicine at the University College Dublin (UCD) and Consultant Respiratory Physician, St. Vincent's University Hospital, Dublin, Ireland

Poster Number: PA3026

Poster Summary:

- Prespecified analyses were conducted to determine if the beneficial clinical effects of molgramostim in IMPALA-2, a Phase 3 clinical trial, were similar in patients with aPAP based on their disease severity as measured by hemoglobin-adjusted percent predicted diffusing capacity of the lungs for carbon monoxide, or DLco% (≤50% or >50%) at randomization
- Molgramostim demonstrated improvement compared with placebo on the primary endpoint, change in DLco% from baseline to Week 24, in patients with aPAP regardless of disease severity
- Molgramostim significantly improved measures of pulmonary gas transfer (DLco%), respiratory health-related quality of life (St. George's Respiratory Questionnaire [SGRQ] Total and Activity scores), and patient functionality (exercise capacity expressed as peak metabolic equivalents [METs]) compared with placebo in both subgroups of patients with DLco% values of ≤50% or >50% at randomization

Title: Relationship Between Pulmonary Gas Transfer, Respiratory Health-related Quality of Life (HRQoL), Exercise Capacity, and Surfactant Burden in Autoimmune Pulmonary Alveolar Proteinosis (PAP)

Presenter: Francesco Bonella, M.D., Ph.D., Head of the Center for Interstitial and Rare Lung Diseases and Assistant Professor, Ruhrlandklinik University Hospital, Essen, Germany

Poster Number: PA3027

Poster Summary:

- DLco% (a measure of pulmonary gas transfer) was chosen as the primary endpoint in the IMPALA-2 Phase 3 clinical trial because it is a standardized measure of pulmonary gas transfer widely used in clinical practice
- Previous research has shown that changes in DLco% correlate with changes in aPAP disease severity (i.e., surfactant accumulation/burden) and may predict the need for whole-lung lavage
- Post-hoc correlation analyses of IMPALA-2 data were conducted to evaluate the relationship between DLco% and measures of HRQoL, patient functionality, and surfactant burden in patients with aPAP
- Significant negative correlations were observed between DLco% and measures of respiratory HRQoL (SGRQ Total and Activity scores; higher scores indicate worse quality of life), as well as DLco% and surfactant accumulation (ground-glass opacity scores; lower scores indicate less surfactant) at Week 24. Significant positive correlations were observed between DLco% and patient functionality (exercise capacity expressed as peak METs; higher scores indicate improved exercise capacity) at Weeks 24 and 48

- Results further support the clinical relevance of changes in DLco% in aPAP; changes in DLco% are associated with changes in clinical outcomes and the extent of pulmonary pathology, making it a clinically meaningful measure in this rare lung disease

TrilliumBiO

Title: Development of a Dried Blood Spot Assay for the Detection of GM-CSF Autoantibodies to Aid in the Diagnosis of Autoimmune Pulmonary Alveolar Proteinosis

Presenter: Eagappanath Thiruppathi, Ph.D., Director of Test and Method Development, TrilliumBiO and Joannah Kim, Vice President of Development and Operations, TrilliumBiO

Poster Number: PA3025

Poster Summary:

- The study was conducted to develop and validate a novel particle-based flow cytometry assay using dried blood spot (DBS) samples for detection of quantitative GM-CSF autoantibody levels to aid in the accurate and timely diagnosis of aPAP
- A strong linear correlation was observed between GM-CSF autoantibody levels measured in serum from venipuncture and those measured using serum-derived dried blood spot samples
- The novel assay demonstrated high precision and sensitivity for the detection of GM-CSF autoantibodies in dried blood spot samples. This approach offers a practical and convenient diagnostic tool to help confirm or rule-out aPAP, representing a significant advancement in the detection of this rare and serious lung disease

For more details about the ERS Congress please visit their **website**.

The posters are available on the **Congresses & Publications** page of the Company's corporate website.

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 self-administered once daily by inhalation with matching placebo in patients with aPAP. The trial is being conducted at 43 clinical trial sites across 16 countries, including the U.S., Canada, Japan, South Korea, Australia, and countries in Europe, including Turkey. The primary efficacy assessment was diffusing capacity of the lungs for carbon monoxide (DLco%), a gas transfer measure, and the primary endpoint was change from baseline to Week 24 in percent predicted DLco%, with a secondary endpoint of change from baseline to Week 48 in percent predicted DLco%. Three additional secondary efficacy variables evaluated clinical measures of direct patient benefit: St. George's Respiratory Questionnaire (SGRQ) Total score, SGRQ Activity score, and exercise capacity using a treadmill test, with each endpoint measured at Weeks 24 and 48.

The primary time point for efficacy assessments was at Week 24; however, efficacy was assessed through Week 48 to evaluate durability of effect. Safety was assessed through Week 48. All patients who completed the 48-week double-blind treatment period continued into a 96-week open-label period during which molgramostim 300 mcg is administered once daily.

About Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

Autoimmune PAP is a rare lung disease characterized by the abnormal build-up of surfactant in the alveoli of the lungs. Surfactant consists of proteins and lipids and is an important physiological substance that lines the alveoli to prevent them from collapsing. In a healthy lung, excess 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 aPAP, GM-CSF is neutralized by antibodies against GM-CSF, rendering macrophages unable to adequately clear surfactant. As a result, an excess of surfactant accumulates in the alveoli, causing impaired gas transfer, resulting in clinical symptoms of shortness of breath, often with cough and frequent fatigue. Patients may also experience episodes of fever, chest pain, or coughing up blood, especially if secondary 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 inhalation solution (molgramostim), is a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). Molgramostim is delivered via a proprietary investigational eFlow® Nebulizer System (PARI Pharma GmbH) specifically developed for inhalation of molgramostim. 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** and **LinkedIn**.

Media and Investor Relations Contact

Savara Inc.
Temre Johnson, Executive Director, Corporate Affairs
ir@savarapharma.com

Source: Savara Inc.