



NEWS RELEASE

# Savara Presented New Data From Pivotal Phase 3 IMPALA-2 Trial of Molgramostim Inhalation Solution (Molgramostim) in Patients With Autoimmune Pulmonary Alveolar Proteinosis (aPAP) at American Thoracic Society Conference (ATS) 2025

2025-05-18

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical-stage biopharmaceutical company focused on rare respiratory diseases, today announced new data in two poster presentations at the ATS International Conference 2025. Data presented were from the Phase 3 IMPALA-2 clinical trial of molgramostim in aPAP and demonstrated that molgramostim reduces surfactant burden and improves health-related quality of life outcomes in patients with aPAP.

## ATS 2025 Posters

**Poster Title:** Molgramostim Reduces Surfactant Burden and Number of Whole Lung Lavage Procedures in Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP): Results From the IMPALA-2 Phase 3 Clinical Trial

**Presenter:** Tisha S. Wang, M.D., Professor of Clinical Medicine, Senior Executive Clinical Vice Chair, University of California Los Angeles Department of Medicine

**Poster Number:** 918

**Poster Location:** PD05, Room 3009/3011 West Building, Level 3

## Summary:

- Molgramostim reduced surfactant burden as measured by ground-glass opacification (GGO) scores, a radiological measure of surfactant burden. The mean reduction in GGO score from baseline to Week 24 was

greater in the molgramostim group (n=78) than in the placebo group (n=79) (-2.1 vs. -1.1; P=0.0004)

- Fewer patients in the molgramostim group required rescue whole lung lavages (WLL) compared with placebo. During the 48-week double-blind treatment period, 6 patients (7.4%) in the molgramostim group underwent a total of 15 WLLs and 11 patients (13.3%) in the placebo group underwent a total of 24 WLLs
- Molgramostim reduces pulmonary surfactant burden, which drives the clinical manifestations of aPAP, and provides support for the potential beneficial treatment effect of molgramostim

**Poster Title:** The Effects of Molgramostim on Respiratory Health-related Quality of Life and Patient-reported Outcomes in Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

**Presenter:** Ali Ataya, M.D., Associate Professor of Medicine, University of Florida, Division of Pulmonary and Critical Care Medicine

**Poster number:** P31

**Poster Location:** TP22, Area A, Hall F (North Building, Exhibition Level)

### Summary:

- Molgramostim showed benefit on measures of health-related quality of life (HRQoL) and patients' assessment of breathing problems and physical activity, including changes from baseline in St. George's Respiratory Questionnaire (SGRQ) Impact and Symptom scores, the EuroQol 5 Dimensions, 5 Levels (EQ-5D-5L), Patient Global Impression of Severity (PGIS), and Patient Global Impression of Change (PGIC) at Weeks 24 and 48, which were included as exploratory endpoints in the trial
- Molgramostim improved respiratory HRQoL as measured by changes from baseline to Week 24 in SGRQ Impact (P=0.0084) and Symptom scores compared with placebo, and the EQ-5D-5L, a generic HRQoL instrument comprised of a short descriptive system questionnaire that allows patients to rate their health across 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Odds ratios of responses on the EQ-5D-5L numerically favored the molgramostim group on 3 of the 5 dimensions (mobility, self-care, and usual activities) at Weeks 24 and 48
- Molgramostim reduced the severity of breathing problems, as assessed by PGIS, at both Weeks 24 (P=0.0305) and 48 (P=0.0049). Additionally, more molgramostim patients reported improvements in overall change in daily physical activity level, as measured by more patients assessing themselves as "Much better" or "A little better" compared with placebo at Week 24 (P=0.0368) and Week 48 (P=0.0193)

The abstracts were published in a supplement of the **American Journal of Respiratory and Critical Care Medicine**. For more details about the ATS International Conference 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 exchange 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 they are receiving molgramostim 300 mcg 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 exchange, 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 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 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 an investigational eFlow<sup>®</sup> Nebulizer System (PARI Pharma GmbH) specifically developed for inhalation of a large molecule. 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](http://www.savarapharma.com) and [LinkedIn](#).

### Media and Investor Relations Contact

Savara Inc.

Temre Johnson, Executive Director, Corporate Affairs

[ir@savarapharma.com](mailto:ir@savarapharma.com)

Source: Savara Inc.