



NEWS RELEASE

# Savara Announces Expanded Access Program (EAP) for Molgramostim Inhalation Solution (Molgramostim) for Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

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Program Enables Physicians to Request Molgramostim for Eligible Patients in Select Geographies Where the Product is Not Commercially Available and in Compliance with Local Regulatory Requirements

LANGHORNE, Pa.--(BUSINESS WIRE)--Sep. 27, 2024-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced the Savara Early Access Program, a molgramostim Expanded Access Program (EAP) for patients with aPAP. The program enables physicians to request molgramostim for eligible aPAP patients in select geographies where the product is not commercially available and in compliance with local regulatory requirements.

The Savara Early Access Program has been reviewed and allowed to proceed by the U.S. Food and Drug Administration (FDA), and it is currently accepting requests from eligible patients in select countries in North America and Europe with plans to expand through 2026.

"Expanded access is granted to investigational products that address a serious condition for which there are no comparable therapies available," said Matt Pauls, Chair and CEO of Savara. "Given the high unmet need in aPAP, and positive results demonstrated in the Phase 3 IMPALA-2 clinical trial, we felt it was critically important to establish the Savara Early Access Program to allow eligible aPAP patients pre-approval access to molgramostim. This program reflects our ongoing commitment to the global aPAP community and the goal of potentially delivering an effective therapy for patients with this rare lung disease as quickly as possible."

Savara plans to complete submission of a Biologics License Application to the FDA for molgramostim in aPAP in the first half of 2025. Molgramostim has been granted Orphan Drug, Fast Track, and Breakthrough Therapy designations from the FDA, Orphan Drug designation from the European Medicines Agency and Innovative Passport and Promising Innovative Medicine designation from the UK's Medicines and Healthcare Products Regulatory Agency for the treatment of aPAP.

## About Expanded Access to Molgramostim

EAPs are intended to serve as a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical treatment outside of clinical trials before it is commercially available, when no comparable or satisfactory alternative therapy options are available. Healthcare professionals and autoimmune Pulmonary Alveolar Proteinosis (aPAP) patients who are interested to learn more about Savara's EAP for molgramostim, including eligibility criteria, may visit [www.clinicaltrials.gov, NCT06546098](https://www.clinicaltrials.gov/NCT06546098), or contact [medicalinfo@savarapharma.com](mailto:medicalinfo@savarapharma.com).

## About aPAP

Autoimmune PAP is a rare lung disease characterized by the abnormal build-up of surfactant in the alveoli (or air sacs) 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 autoimmune PAP, 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, 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® 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](https://www.savarapharma.com). (X, formerly known as Twitter:

@SavaraPharma, LinkedIn: [www.linkedin.com/company/savara-pharmaceuticals/](https://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 future expansion of the Savara Early Access Program, Savara’s goal of potentially delivering an effective therapy as rapidly as possible, and the anticipated timing of Savara’s BLA submission. 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 associated with our ability to successfully develop, obtain regulatory approval for, and commercialize molgramostim for aPAP; the actions and decisions of regulatory authorities; the risks and uncertainties related to the impact of widespread health concerns or changing economic or geopolitical conditions; 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; 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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