



NEWS RELEASE

Savara Announces New U.S. Health Claims Data Analysis Finds Over 50% Increase in the Estimated Number of Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP) Patients Compared to Previous Claims Analysis

2025-09-02

-- Approximately 5,500 Autoimmune PAP Patients in the U.S. Identified in the Updated Analysis that Leveraged a More Recent and Comprehensive Claims Data Source --

-- New England Journal of Medicine (NEJM) Recently Published Results from Savara's Pivotal Phase 3 IMPALA-2 Clinical Trial of MOLBREEVI* in Autoimmune PAP --

-- On Track to Resubmit Biologics License Application (BLA) in December 2025 for MOLBREEVI in Autoimmune PAP, Will Request Priority Review --

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (the "Company") (Nasdaq: **SVRA**), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced an increased estimate of autoimmune PAP diagnosed prevalence in the U.S. The updated analysis indicates an ~50% larger autoimmune PAP patient population in the U.S. than the Company's previously estimated claims analysis from 2023 (~5,500 autoimmune PAP patients versus ~3,600). The recent analysis of health claims data was commissioned by the Company and used a different, more recent and comprehensive dataset of health claims records.

Highlights from the updated health claims data analysis:

- The refreshed analysis, conducted by a third-party advanced analytics provider, accessed a more current and

comprehensive view of patient and healthcare claims data using open and closed source databases—enabling access to more than three times the number of records than the analysis conducted in 2023

- PAP patients were identified by having a PAP diagnosis with an ICD-10 code of J84.01 and had a medical or pharmacy claim within the last two and a half years
- Autoimmune PAP is the most common form of PAP, accounting for over 90% of all PAP cases. ¹ Autoimmune PAP prevalence rates were applied to the confirmed PAP population (i.e., those with a J84.01 code and a medical/pharmacy claim within the last two and a half years), resulting in ~5,500 autoimmune PAP patients in the U.S.
- Patients were further validated with additional inclusion criteria ranging from the number of PAP diagnoses, to visits to specialty physicians (e.g., pulmonologists) to procedures and documented symptoms related to autoimmune PAP

“The increase in U.S. autoimmune PAP prevalence, based on recent data from a large and robust data source, may indicate that awareness and diagnosis rates are accelerating,” said Braden Parker, M.B.A., Chief Commercial Officer, Savara. “As a data-driven organization with deep expertise and experience in rare disease commercialization, we are committed to capturing the most accurate insights to increase awareness of this rare and debilitating lung disease and fuel earlier detection.”

“With no approved medicines in the U.S. to treat autoimmune PAP, these claims data reinforce our belief that there is a large unmet medical need as we push toward resubmitting the MOLBREEVI BLA,” said Matt Pauls, M.B.A., J.D., Chair and Chief Executive Officer, Savara. “Strong operational execution over the last quarter has put the Company on a solid path forward. We are finalizing the analytical data package for the BLA and expect to resubmit to the FDA in December. Additionally, we recently announced that results from the pivotal Phase 3 IMPALA-2 clinical trial, which demonstrated MOLBREEVI addresses the underlying pathophysiology of autoimmune PAP, were published in NEJM. We continue our work to elevate awareness for this chronic lung disease as we advance toward our goal of providing patients with the first approved pharmacologic therapy in the U.S.”

Access to the NEJM article can be found [here](#).

MOLBREEVI for the treatment of autoimmune PAP has been granted Fast Track and Breakthrough Therapy Designations by the FDA, Orphan Drug Designation by the FDA and the European Medicines Agency (EMA), as well as Innovation Passport (IP) and Promising Innovative Medicine (PIM) designations by the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA).

About Claims Data

Claims data are de-identified records of healthcare services and prescriptions submitted for reimbursement by public and/or private insurance companies in the U.S. These datasets offer a longitudinal view of patient interactions with the healthcare system across various settings. In the pharmaceutical industry, claims data are a key resource for understanding real-world treatment patterns and market dynamics. These analyses provide a data-driven perspective on patient journeys, support strategic decision-making, and highlight areas of unmet medical need.

About Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP)

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, surfactant balance is maintained 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, MOLBREEVI*, is a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (autoimmune PAP). MOLBREEVI is delivered via a proprietary investigational eFlow® Nebulizer System (PARI Pharma GmbH) specifically developed for inhalation of MOLBREEVI. 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](#).

*MOLBREEVI is the FDA and EMA conditionally accepted trade name for molgramostim inhalation solution. It is not approved in any indication. MOLBREEVI is a trademark of Savara Inc.

¹McCarthy et al. (2022). American Journal of Respiratory and Critical Care Medicine, <https://doi.org/10.1164/rccm.202112-2742SO>

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 expected timing for resubmission of the BLA and requesting priority review, the potential implications of the new health claims data, including that it may indicate awareness and diagnosis rates of autoimmune PAP are accelerating and that it reinforces our belief there is a large unmet medical need for an approved medicine in the U.S. for autoimmune PAP, and that we continue our work to elevate awareness of autoimmune PAP as we advance toward our goal of providing patients with the first approved pharmacologic therapy in the U.S. 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 MOLBREEVI for autoimmune PAP; 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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Source: Savara Inc.