NEWS RELEASE

Savara Completes Submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for MOLBREEVI* as a Treatment for Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

2025-03-26

-- Priority Review Was Requested, Commercial Launch Preparations Underway --

-- MOLBREEVI Has the Potential to Be the First and Only Approved Therapy for aPAP in the U.S. and Europe --

-- Company Remains on Track to Submit the Marketing Authorization Application (MAA) in Europe by the End of 2025 --

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced that it has completed submission of the BLA to the FDA for MOLBREEVI as a treatment for aPAP.

“Submission of the BLA marks an important milestone for the Company and the aPAP community,” said Matt Pauls, Chair and Chief Executive Officer, Savara. “We believe this unprecedented body of data demonstrates MOLBREEVI improves pulmonary gas exchange and the clinical symptoms associated with this rare lung disease. As part of the submission, Priority Review was requested and, if granted, would shorten the FDA’s review to six months (from the standard ten months) following the Agency’s acceptance of the application. We look forward to continuing our dialogue with the FDA and extend our gratitude to the patients and physicians who participated in our clinical trials. Our commercial preparations are on-track to support a potential launch in early 2026.”

The IMPALA-2 trial met its primary endpoint, with MOLBREEVI achieving statistically significant improvement from baseline in percent predicted diffusing capacity of the lungs for carbon monoxide (DLCO), a well-established measure of pulmonary gas exchange, compared to placebo at Week 24. This significant improvement was sustained at Week 48 (a secondary endpoint), demonstrating durability of treatment effect. In addition to gas exchange improvement, trial results provided evidence of clinical benefit as measured by improvements in the St. George's Respiratory Questionnaire (SGRQ) Total and Activity Scores and Exercise Capacity as measured by an exercise treadmill test and expressed as peak METs (metabolic equivalents, an established measure of exercise capacity). MOLBREEVI showed evidence of clinical benefit for all three secondary endpoints, as demonstrated by statistically significant improvements in SGRQ Total Score at Week 24, and numerically greater improvements in the MOLBREEVI group compared to placebo for SGRQ Activity Score and Peak METs at Weeks 24 and 48.

MOLBREEVI was well-tolerated in the IMPALA-2 trial, with 97% of patients completing the double-blind period of the trial and no discontinuations from adverse events that were considered drug-related.

In addition to Fast Track and Breakthrough Therapy Designations, MOLBREEVI has been granted Orphan Drug Designation for the treatment of aPAP 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 Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

aPAP 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, MOLBREEVI*, is a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). MOLBREEVI 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** 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.

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 potential for MOLBREEVI to be the first and only approved therapy for aPAP in the U.S. and Europe, the anticipated timing of our MAA submission, our belief that the unprecedented body of data demonstrates MOLBREEVI improves pulmonary gas exchange and the clinical symptoms associated with this rare lung disease, statements related to the impact of Priority Review, and that our commercial preparations are on-track to support a potential launch in early 2026. 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 aPAP; 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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