NEWS RELEASE

Savara Announces the U.S. Food and Drug Administration (FDA) Filed the MOLBREEVI* Biologics License Application (BLA) in Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP)

2026-02-20

-- Priority Review Granted, Prescription Drug User Fee Act (PDUFA) Target Action Date Set for August 22, 2026 --

-- Company Plans to Submit the MOLBREEVI Marketing Authorization Applications (MAAs) for Autoimmune PAP to the European Medicines Agency (EMA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) By the End of Q1 2026 --

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

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical-stage biopharmaceutical company focused on rare respiratory diseases, announced the FDA has filed for review the BLA for MOLBREEVI as a therapy to treat patients with autoimmune PAP. The FDA granted Priority Review with a PDUFA action date of August 22, 2026.

“The FDA’s filing of the BLA marks another significant milestone for Savara and the autoimmune PAP community and brings us one step closer to a potential approval in the U.S. in August of this year,” said Matt Pauls, Chair and Chief Executive Officer, Savara. “We believe the considerable body of data in the application demonstrates MOLBREEVI improves pulmonary gas transfer, quality of life, and the clinical symptoms associated with this rare and debilitating lung disease. We are grateful to the FDA for the constructive feedback they have provided throughout development and the review process to date and look forward to continued dialogue with the Agency.”

FDA Priority Review designation directs overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard review applications.[1]

In addition to Fast Track and Breakthrough Therapy Designations, MOLBREEVI has been granted Orphan Drug Designation for the treatment of autoimmune PAP by the FDA and the EMA, as well as Innovation Passport (IP) and Promising Innovative Medicine (PIM) designations by the UK's MHRA.

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. 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 autoantibodies 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 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 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 timing of the PDUFA action date and potential FDA approval for MOLBREEVI, the anticipated timing of the MAA submissions in Europe and the UK, that MOLBREEVI has the potential to be the first and only approved therapy for autoimmune PAP in the U.S. and Europe, our belief that the considerable body of data in the application demonstrates MOLBREEVI improves pulmonary gas transfer, quality of life, and the clinical symptoms associated with autoimmune PAP, and that we look forward to continued dialogue with the FDA. 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; changes to applicable laws and regulations; 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.

[1]U.S. FDA website: **https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review**

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