



NEWS RELEASE

Savara Provides Regulatory Update on the MOLBREEVI* Development Program in Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP)

2026-03-06

-- Day 74 Letter Received from the U.S. Food and Drug Administration (FDA) Indicated the Agency Has No Plans to Convene an Advisory Committee --

-- Company has Submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA)

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-- Submission of the MAA to the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) Remains on Track by the End of Q1 2026 --

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (the "Company") (Nasdaq: **SVRA**), a clinical-stage biopharmaceutical company focused on rare respiratory diseases, today announced that it has received the Day 74 Letter from the FDA which indicated that an Advisory Committee meeting is not planned for the MOLBREEVI Biologics License Application (BLA) and the review is ongoing with a Prescription Drug User Fee Act (PDUFA) target action date of August 22, 2026.

Additionally, the Company recently submitted the MAA to the EMA for MOLBREEVI for the treatment of autoimmune PAP and is on track to submit the MAA to the U.K.'s MHRA by the end of Q1 2026.

"MOLBREEVI has the potential to be a first-in-class treatment for autoimmune PAP, a rare and debilitating lung disease with no approved therapeutics in the U.S. and Europe," said Matt Pauls, Chair and Chief Executive Officer, Savara. "We are confident in the potential of MOLBREEVI to address the unmet needs of this patient community and look forward to working with the FDA and EMA during the review processes."



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

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 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.

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 FDA's plans to convene an Advisory Committee for the MOLBREEVI BLA, the timing of the PDUFA target action date and potential FDA approval for MOLBREEVI, the anticipated timing of the MAA submission in the UK, that MOLBREEVI has the potential to be a first-in-class treatment for autoimmune PAP, and that we are confident in the potential of MOLBREEVI to address the unmet needs of this patient community and look forward to working with the FDA and EMA during the review process. 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.

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