



NEWS RELEASE

Savara Announces the U.S. Food & Drug Administration (FDA) Has Extended the Review Period for the Molgramostim Inhalation Solution (Molgramostim) Biologics License Application (BLA) in Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP)

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-- Prescription Drug User Fee Act (PDUFA) Target Action Date Extended by Three Months to November 22, 2026 --

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced that the FDA has extended the review period for the molgramostim BLA in autoimmune PAP by three months. The Agency is reviewing the molgramostim BLA under Priority Review and the new PDUFA target action date is November 22, 2026.

The FDA determined that the Company's responses to recent information requests by the Agency constituted a major amendment to the BLA, resulting in a three-month extension of the PDUFA date. The Agency did not cite any safety, efficacy, or manufacturing concerns in their correspondence. This extension allows the FDA additional time to complete their review of the BLA, including recently submitted materials related to information requests.

In addition to Fast Track and Breakthrough Therapy Designations in the U.S., molgramostim has been granted Orphan Drug Designation for the treatment of autoimmune PAP by the FDA and the European Medicines Agency (EMA), as well as Innovation Passport and Promising Innovative Medicine designations by the U.K.'s Medicines and Healthcare Products Regulatory Agency (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, molgramostim, is a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (autoimmune PAP). 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 and [LinkedIn](#).

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 target PDUFA action date. 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 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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