NEWS RELEASE

Savara Announces European Medicines Agency (EMA) Validation of Marketing Authorization Application (MAA) for MOLBREEVI* in Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP)

2026-03-30

-- EMA Review of MOLBREEVI MAA Has Now Initiated, Decision Expected in Q1 2027 --

-- MOLBREEVI Biologics License Application (BLA) is Currently Under Priority Review with the U.S. Food and Drug Administration (FDA), with an Action Date of August 22, 2026 --

-- MOLBREEVI MAA Was Submitted to the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) in March 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 EMA has validated the submission of the MOLBREEVI MAA in autoimmune PAP; the submission will now be reviewed by the Committee for Medicinal Products for Human Use (CHMP). In the U.S., the FDA is reviewing the MOLBREEVI BLA under Priority Review with an August 22, 2026 Action Date.

“EMA’s validation of the MOLBREEVI MAA confirms the submission is complete and that the review of the application has begun,” said Matt Pauls, Chair and CEO, Savara. “This milestone represents an important advancement in our regulatory strategy, and we appreciate the EMA’s guidance throughout the process to-date. Today’s announcement follows the FDA’s filing of the MOLBREEVI BLA and our recent submission of the marketing application to the MHRA. If approved, MOLBREEVI would be the first drug indicated for the treatment of autoimmune PAP in the U.S. and Europe and has the potential to fundamentally change the way this rare and

chronic lung disease is treated."

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 and Promising Innovative Medicine designations by the 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 potential timing of decisions by regulatory authorities in the U.S. and Europe, the next steps in the regulatory review process, and that, if approved, MOLBREEVI would be the first drug indicated for the treatment of autoimmune PAP in the U.S. and Europe and has the potential to fundamentally change the way this rare and chronic lung disease is treated. 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.

Media and Investor Relations Contact

Savara Inc.
Temre Johnson, Executive Director, Corporate Affairs
ir@savarapharma.com

Source: Savara Inc.