NEWS RELEASE

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

2024-12-18

-- Company Expects to Complete BLA Submission by End of 1Q 2025 --

LANGHORNE, Pa.--(BUSINESS WIRE)--Dec. 18, 2024-- **Savara Inc.** (Nasdaq: **SVRA**) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, initiated a rolling submission of a BLA to the FDA for MOLBREEVI for the potential treatment of aPAP, a chronic and debilitating rare lung disease characterized by the abnormal build-up of surfactant in the alveoli of the lungs.

MOLBREEVI was granted Fast Track and Breakthrough Therapy Designations in 2019 for the treatment of patients with aPAP. As a result, the Company is allowed to submit individual modules of the BLA as they are completed rather than waiting to submit the application once all modules are available. The Company will request a priority review of the BLA when the submission is completed.

“Given the positive results of the pivotal, Phase 3 IMPALA-2 trial, we believe MOLBREEVI demonstrates a favorable benefit-risk profile and could fundamentally change the way aPAP is treated,” said Matt Pauls, Chair and Chief Executive Officer, Savara. “Initiation of the BLA is an important milestone in potentially addressing the unmet need in aPAP, for which there are no approved medicines in the U.S. and Europe. We look forward to working closely with the FDA throughout the review process and expect to complete the submission of the rolling BLA by the end of 1Q 2025.”

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 by the European Medicines Agency (EMA), Innovation Passport (IP) and Promising Innovative Medicine (PIM) designations by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA).

## About Autoimmune PAP

Autoimmune PAP is a rare lung disease characterized by the abnormal build-up of surfactant in the alveoli (or air sacs) 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**, X: **@SavaraPharma** and **LinkedIn**.

*MOLBREEVI is the FDA and EMA conditionally accepted trade name for molgramostim inhalation solution.

## 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 anticipated timing of the completion of our BLA submission, the plan to request for

priority review, and our belief that MOLBREEVI demonstrates a favorable benefit-risk profile and could fundamentally change the way aPAP 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 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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Source: Savara Inc.