NEWS RELEASE

Savara Resubmits the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for MOLBREEVI* for the Potential Treatment of Autoimmune Pulmonary Alveolar Proteinosis (Autoimmune PAP)

2025-12-22

-- The BLA was Resubmitted with FUJIFILM Biotechnologies (Fujifilm) as the Drug Substance Manufacturer and Priority Review was Requested --

LANGHORNE, Pa.--(BUSINESS WIRE)-- **Savara Inc.** (Nasdaq: **SVRA**) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, announced today that it has resubmitted the MOLBREEVI BLA to the FDA, with Fujifilm as the drug substance manufacturer. The MOLBREEVI BLA submission is seeking approval for the treatment of autoimmune PAP, a chronic and debilitating rare lung disease characterized by the abnormal build-up of surfactant in the alveoli. The Company has requested Priority Review of the application.

MOLBREEVI was granted Fast Track and Breakthrough Therapy Designations by the FDA, Orphan Drug Designation by the FDA and by the European Medicines Agency (EMA), and Innovation Passport (IP) and Promising Innovative Medicine (PIM) designations by the UK's Medicines and Healthcare Products Regulatory Agency (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.

Media and Investor Relations Contact

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

Source: Savara Inc.