



NEWS RELEASE

Savara Announces U.S. Launch of the aPAP ClearPath™ Dried Blood Spot Test to Detect Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

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-- The Simple, No-cost Test Can Detect Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) Autoantibodies in the Blood with Only a Finger Prick --

LANGHORNE, Pa.--(BUSINESS WIRE)--Mar. 6, 2025-- **Savara Inc.** (Nasdaq: SVRA) (the Company), a clinical stage biopharmaceutical company focused on rare respiratory diseases, announced the launch of the aPAP ClearPath Dried Blood Spot (DBS) Test in the U.S., an evolution of the first serum-based assay the Company launched. The DBS test helps obtain a diagnosis of aPAP, a rare autoimmune lung disease caused by antibodies targeting GM-CSF, with only a finger-prick blood sample.

The DBS test demonstrates a high correlation between GM-CSF autoantibody levels in dried serum and traditional serum samples, ensuring reliable results, and has achieved 100% analytical sensitivity and specificity in a cohort of individuals with confirmed GM-CSF autoantibody status. The Company partnered with TrilliumBiO, a health solutions provider with a Clinical Laboratory Improvement Amendments (CLIA)-certified lab, to develop and validate the simple, no-cost, and noninvasive test.

"I'm pleased to see that Savara has continued to evolve aPAP ClearPath and is now offering a dried blood spot version that provides a convenient alternative to traditional venous blood draws," said Ali Ataya, M.D., Associate Professor of Medicine, University of Florida, Division of Pulmonary and Critical Medicine. "Having a simplified and reliable diagnostic reduces logistical barriers for both patients and healthcare providers and may help physicians diagnose aPAP earlier, as well as avoid common and lengthy misdiagnoses associated with the disease."

“We are happy to introduce a version of aPAP ClearPath that can provide physicians with a tool to help confirm or rule out aPAP with just a few drops of blood,” said Matt Pauls, Chair and CEO, Savara. “As we near the completion of our rolling BLA submission for MOLBREEVI™ in aPAP, which is on track for the end of 1Q 2025, we are steadfastly committed to our goal of providing the aPAP community with the first and only approved treatment option in the U.S.”

Only a physician or healthcare provider can order the test and make a diagnosis of aPAP. To learn more about aPAP ClearPath, the importance of early testing for aPAP, and to order a test kit, please visit www.apapclearpath.com.

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 and [LinkedIn](#).

*MOLBREEVI is the FDA and EMA conditionally accepted trade name for molgramostim inhalation solution. It is not approved in any indication.

About TrilliumBiO

TrilliumBiO is a diagnostics company with expertise in novel diagnostic tests developed in conjunction with biopharma partners and other healthcare innovators. Trillium applies clinical insights to help solve the distinct challenges of its partners through scientifically validated, innovative, and customizable products and services, which are physician-approved every step of the way. TrilliumBiO embraces technological advancements and uses state-of-the-art methods to redefine the way they collect, perform, develop, and deliver personalized testing. More information about TrilliumBiO can be found at www.TrilliumBiO.com.

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 benefits and impact of aPAP ClearPath, including on the time to diagnosis, the occurrence of misdiagnoses, and the diagnosed prevalence of aPAP, statements related to the aPAP ClearPath DBS test helping physicians confirm or rule out aPAP with a small amount of blood, statements related to the anticipated timing of our BLA submission, our goal of providing the aPAP community with the first and only approved treatment option in the U.S., and statements related to the Company’s advancement of disease awareness campaigns and the potential impact of those campaigns. 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 degree to which aPAP ClearPath is accepted and used by healthcare providers, 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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