NEWS RELEASE

Savara Awarded Promising Innovative Medicine (PIM) Designation in the United Kingdom (UK) for Molgramostim Nebulizer Solution (Molgramostim) in Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

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PIM Designation Recognizes Molgramostim as a Promising Candidate for the UK Early Access to Medicines Scheme (EAMS) – A Program that Aims to Give Patients with Life Threatening or Seriously Debilitating Conditions with Unmet Medical Need Access to Medicines That Do Not Yet Have Marketing Authorization

Molgramostim, a Novel Investigational Inhaled Biologic, is in Phase 3 Development for the Treatment of aPAP, a Rare Lung Disease

AUSTIN, Texas--(BUSINESS WIRE)--Aug. 25, 2022-- **Savara Inc.** (Nasdaq: SVRA), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced that the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) granted Promising Innovative Medicine (PIM) designation to molgramostim for the treatment of aPAP, a rare lung disease with no approved pharmaceutical treatments. PIM designation is an early indication that molgramostim is a promising candidate for the EAMS, a program that provides an opportunity for important therapies to be used in UK clinical practice in parallel with the later stages of the regulatory process. Medicines with a positive scientific opinion could be made available to UK patients 12-18 months before formal marketing authorization is granted.

On June 15, 2022, molgramostim was awarded Innovation Passport designation by MHRA. In 2019, molgramostim was granted Fast Track Designation and Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of aPAP, and in 2012 and 2013 was granted Orphan Drug Designation for the treatment of aPAP in the United States and European Union, respectively.

“This PIM designation was granted on the basis of molgramostim nonclinical and clinical data and further reinforces the potential of molgramostim to provide significant benefit in the treatment of aPAP,” said Matt Pauls, Chair and CEO, Savara. “We look forward to working with the MHRA, on both the Innovation Passport and PIM designations, to advance this program and leverage the potential benefits of the EAMS program.”

About PIM Designation:

For the MHRA to grant a PIM designation, medicinal products must meet the following criteria:

- The condition should be life-threatening or seriously debilitating with a high unmet need for which there is no method of treatment, diagnosis or prevention available or where existing methods have serious limitations.
- The medicinal product is likely to offer a major advantage over methods currently used in the UK.
- The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance.

More background on PIM designation can be found **here**.

About aPAP:

Autoimmune pulmonary alveolar proteinosis (aPAP) is a rare lung disease that belongs to a family of distinct rare lung diseases collectively known as pulmonary alveolar proteinosis (PAP). aPAP represents about 90% of all patients with PAP. While aPAP can affect people of any age, race or sex, onset occurs most frequently in people between the ages of 30 and 40. PAP is characterized by the build-up of surfactant in the alveoli, or air sacs, of the lungs. The surfactant consists of proteins and lipids and is an important physiological substance that lines the inside of the alveoli to prevent the lungs from collapsing. The root cause of aPAP is an autoimmune response against GM-CSF, a naturally occurring protein in the body. Pulmonary macrophages need to be stimulated by GM-CSF to function properly, but in aPAP, GM-CSF is neutralized by antibodies against GM-CSF, rendering the macrophages unable to perform their tasks, including the clearance of surfactant from the alveoli. In aPAP, the feeling of having trouble breathing is the most common symptom. People with aPAP can also experience chronic cough, fatigue, sputum production, reduced ability to exercise and episodes of fever due to underlying pulmonary infections. There are currently no approved pharmaceutical treatment options for aPAP.

About Savara:

Savara is a clinical stage biopharmaceutical company focused on rare respiratory diseases. Our lead program, molgramostim nebulizer solution, is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). Molgramostim is delivered via an

investigational eFlow® Nebulizer System (PARI Pharma GmbH). 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**. (Twitter: **@SavaraPharma**, LinkedIn: **www.linkedin.com/company/savara-pharmaceuticals/**).

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 regarding the potential availability of medicines under the EAMS program, that receiving this designation further reinforces the potential of molgramostim to provide significant benefit in the treatment of aPAP, and that we look forward to working with the MHRA, on both the Innovation Passport and PIM designations, to advance this program and leverage the potential benefits of the EAMS program. 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 and uncertainties relating to the impact of the COVID-19 pandemic or other widespread health concerns impacting healthcare providers or patients, disruptions or inefficiencies in the supply chain, and geopolitical conditions on our business and operations, the outcome of our ongoing and planned clinical trials for our product candidate, 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, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as molgramostim that are safe and effective for use as human therapeutics, 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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