



NEWS RELEASE

# Savara Awarded Innovation Passport in United Kingdom (UK) for Molgramostim Nebulizer Solution (Molgramostim), a Novel Investigational Inhaled Biologic

2022-06-16

Innovation Passport Awarded to Molgramostim for the Treatment of Autoimmune Pulmonary Alveolar Proteinosis (aPAP), a Rare Lung Disease

The Innovation Passport, a UK Designation for Innovative Medicines, is the Entry Point to the Innovative Licensing and Access Pathway (ILAP), a Program Designed to Accelerate the Time to Market and Facilitate Access to Medicines in the UK

Molgramostim is Being Investigated in a Pivotal Phase 3 Trial, IMPALA-2, for the Treatment of aPAP

AUSTIN, Texas--(BUSINESS WIRE)--Jun. 16, 2022-- **Savara Inc.** (Nasdaq: SVRA), a clinical stage biopharmaceutical company focused on rare respiratory diseases, today announced molgramostim has been awarded an Innovation Passport for the treatment of aPAP by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA). Innovation Passport is the entry point to the ILAP, a novel program aimed at accelerating the time to market and facilitating patient access to medicines in the UK.

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.

"Receiving this designation is an important step in the molgramostim regulatory strategy and has the potential to



help aPAP patients in the UK gain faster access to this novel inhaled biologic,” said Matt Pauls, Chair and CEO, Savara. “This most recent designation, MHRA’s Innovation Passport, in addition to Fast Track, Breakthrough Therapy and Orphan Drug designations, recognize aPAP as a seriously debilitating condition in need of a pharmaceutical treatment option—potentially an option like molgramostim. We look forward to working closely with the MHRA, and other regulators, to advance the molgramostim development program.”

## About ILAP:

ILAP was launched in January 2021 as part of the UK’s plan to attract life sciences development in the post-Brexit era. The pathway provides a single integrated platform for sustained collaborative working between the developer of the investigational medicine, the MHRA and its health technology assessment partners, including the All Wales Therapeutics and Toxicology Centre, National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC).

More background on the ILAP can be found at <https://www.gov.uk/guidance/innovative-licensing-and-access-pathway>

## 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](http://www.savarapharma.com). (Twitter: @SavaraPharma, LinkedIn: [www.linkedin.com/company/savara-pharmaceuticals/](http://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 that receiving this designation has the potential to help aPAP patients in the UK gain faster access to molgramostim; that MHRA’s Innovation Passport, in addition to Fast Track, Breakthrough Therapy and Orphan Drug designations, recognize aPAP as a seriously debilitating condition in need of a pharmaceutical treatment option—potentially an option like molgramostim; and that we look forward to working closely with the MHRA, and other

regulators, to advance the molgramostim development 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 and current 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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Source: Savara Inc.