



NEWS RELEASE

Savara Announces Molgradex Received Fast Track Designation by FDA for Treatment of Autoimmune Pulmonary Alveolar Proteinosis

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AUSTIN, Texas--(BUSINESS WIRE)--May 6, 2019-- **Savara Inc.** (NASDAQ: SVRA), an orphan lung disease company, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for Molgradex, an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF). Molgradex, the Company's lead product candidate, is being investigated in a pivotal Phase 3 study, called IMPALA, for the treatment of autoimmune pulmonary alveolar proteinosis (aPAP). Topline results from the study are expected in June 2019. Positive results would facilitate the submission of a Biologics License Application (BLA) in the first half of 2020, with an anticipated commercial launch later in 2020 or early 2021.

The Fast Track program facilitates the expedited development and review of new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. A drug granted Fast Track designation may be eligible for Priority Review or Rolling Review of the BLA, if relevant criteria are met.

"We are excited by this designation as it reinforces that a better treatment option is needed for people living with aPAP," said Rob Neville, Chief Executive Officer, Savara. "With the potential for Priority or Rolling Review, we are optimistic about the opportunity to accelerate the submission of Molgradex on behalf of patients with this devastating disease."

About Savara

Savara is an orphan lung disease company. Savara's pipeline comprises Molgradex, an inhaled granulocyte-



macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP), in Phase 2a development for nontuberculous mycobacterial (NTM) lung infection in both non-cystic fibrosis (CF) and CF-affected individuals with chronic NTM lung infection; and AeroVanc, a Phase 3-stage inhaled vancomycin for treatment of persistent methicillin-resistant *Staphylococcus aureus* (MRSA) lung infection in CF. Savara's strategy involves expanding its pipeline of potentially best-in-class products through indication expansion, strategic development partnerships and product acquisitions, with the goal of becoming a leading company in its field. The most recent acquisition is aerosolized amikacin/fosfomycin, a Phase 2-ready, proprietary combination antibiotic, which has demonstrated potent and broad-spectrum antibacterial activity against highly drug resistant pathogens. Savara's management team has significant experience in orphan drug development and pulmonary medicine, identifying unmet needs, developing and acquiring new product candidates, and effectively advancing them to approvals and commercialization. More information can be found at www.savarapharma.com. (Twitter: [@SavaraPharma](https://twitter.com/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, that positive results from IMPALA would facilitate the submission of a Biologics License Application in the first half of 2020, with an anticipated commercial launch later in 2020 or early 2021, our optimism about the opportunity to accelerate the submission of Molgradex on behalf of patients with aPAP, and Savara's strategy. 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, risks and uncertainties associated with the outcome of our ongoing and planned clinical trials for our product candidates, 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 candidates in a timely manner, the ability to successfully identify product acquisition candidates, the ability to successfully develop our product candidates, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Molgradex that are safe and effective for use as human therapeutics and the timing and ability of Savara to raise additional equity 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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