



NEWS RELEASE

Savara Announces FDA Response From Type C Meeting on Molgradex for aPAP Development Program

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AUSTIN, Texas--(BUSINESS WIRE)--Oct. 2, 2019-- **Savara Inc.** (Nasdaq: SVRA), an orphan lung disease company, today announced the response from a Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the Molgradex development program for autoimmune pulmonary alveolar proteinosis (aPAP). Molgradex is an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF).

In the written response received by Savara on October 1, the FDA indicated that the data provided in the briefing package do not provide sufficient evidence of efficacy and safety and did not recommend that the Company submit a Biologics License Application (BLA). The Company is working to determine the next steps for the Molgradex development program.

"While we are disappointed in the FDA's response, considering the IMPALA study results presented today at the ERS annual conference, we remain committed to the Molgradex development program and believe that it will provide aPAP patients with a meaningful treatment option," said Rob Neville, Chief Executive Officer, Savara. "Our priority is to further assess the content of the FDA's feedback and determine the best development path forward."

As noted above, additional data from the IMPALA study were presented today at the 2019 European Respiratory Society (ERS) International Congress in Madrid, Spain. The data were presented in an oral session by Bruce Trapnell, M.D., lead Principal Investigator in the U.S. and Director, Translational Pulmonary Science Center, Scientific Director, PAP Foundation, Co-Director, Rare Lung Diseases Clinical Research Consortium, and Professor of Medicine and Pediatrics, University of Cincinnati College of Medicine. Slides from the presentation were attached to Savara's Form 8-K dated October 2, 2019 and will be posted to the Investor Relations section of the Company's website.



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. 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, statements regarding working to determine the next steps for the Molgradex development program, that we remain committed to the Molgradex development program and believe that it will provide aPAP patients with a meaningful treatment option, that our priority is to further assess the content of the FDA's feedback and determine the best regulatory path forward, 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, the outcome of our assessment of the feedback from our Type C meeting with the FDA regarding our IMPALA data and path forward, 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 and AeroVanc 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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