



NEWS RELEASE

# Savara Obtains Global Rights to Develop and Commercialize Apulmiq

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Management to Host Conference Call / Webcast with Bronchiectasis Expert Dr. James Chalmers

AUSTIN, Texas--(BUSINESS WIRE)--Apr. 2, 2020-- Savara Inc. (Nasdaq: SVRA), an orphan lung disease company, today announced the Company has entered into an exclusive license and collaboration agreement with Grifols for Apulmiq (inhaled liposomal ciprofloxacin). Also known as Linhaliq in Europe, Apulmiq is a late-stage investigational inhaled antibiotic in Phase 3 development for the treatment of non-cystic fibrosis bronchiectasis (NCFB).

"We are very excited about Apulmiq and believe it represents a transformational addition to our pipeline," said Rob Neville, Savara's Chief Executive Officer. "Acquiring the rights provides us with another high potential Phase 3 program that leverages our core capabilities in inhaled orphan drug development and complements our existing pipeline. With an estimated prevalence of more than 150,000 NCFB patients in the U.S. and potentially more in Europe, Apulmiq could represent a game-changing opportunity in a therapeutic area with little competition and significant unmet need. Our goal is to offer a novel pharmaceutical treatment option to patients living with this chronic and debilitating disease."

Under the terms of the agreement, Savara has obtained the worldwide rights to develop and commercialize Apulmiq. Savara provided an upfront payment and, if regulatory approval is obtained, Grifols will be eligible for regulatory milestone payments as well as royalties and potential tiered sales milestones upon commercialization.

"I am excited that Savara will be advancing this important investigational therapy," said James Chalmers, MBChB, PhD, Chair of EMBARC, the European Bronchiectasis Registry and British Lung Foundation Professor of Respiratory Research at the University of Dundee. "I look forward to working with Savara on the confirmatory Phase 3 study that will benefit from the learnings of previous clinical studies of Apulmiq and other inhaled antibiotics in NCFB."

Bronchiectasis patients have no approved drug options available and I believe many patients could substantially benefit from an effective inhaled antibiotic.”

The Company expects to work with regulatory agencies to plan a confirmatory Phase 3 study. Key learnings from previous studies of inhaled antibiotics for NCFB will be leveraged in order to optimize patient population and endpoints in the study.

## About Apulmiq

Apulmiq is an investigational inhaled liposomal ciprofloxacin being evaluated for the treatment of NCFB and was granted Orphan Drug Designation as well as designated a Qualified Infectious Disease Product (QIDP). Apulmiq was previously evaluated in two Phase 3 clinical studies (ORBIT-3 and ORBIT-4) in a total of 582 patients. On the time-to-exacerbation primary endpoint in those studies, treatment with Apulmiq resulted in a statistically significant benefit in one study, however the difference in the other study showed a positive trend but did not reach statistical significance. Apulmiq also reduced the frequency of exacerbations (in the pooled analysis) as well as the density of *Pseudomonas aeruginosa* bacteria and demonstrated an encouraging safety profile. In 2018, a New Drug Application (NDA) for Apulmiq received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA), with the agency indicating that an additional Phase 3 study would be required prior to approval.

## About NCFB

NCFB is an orphan, chronic, and progressive respiratory disorder that is characterized by dilated airways with thickened and scarred walls due to infection and inflammation. Symptoms include persistent cough, dyspnea, fatigue, and recurrent infective pulmonary exacerbations that often lead to hospitalization and are associated with higher mortality. With an estimated prevalence of more than 150,000 patients in the U.S. and a potentially higher prevalence in Europe, and no approved pharmaceutical treatment options available, there is a high unmet medical need.

## Conference Call/Webcast

Savara management will host a conference call/webcast, with guest speaker Dr. James Chalmers, on Friday, April 3 at 8:30 a.m. Eastern Time (ET) / 5:30 a.m. Pacific Time (PT). Shareholders and other interested parties may access the call by dialing (855) 239-3120 from the U.S., (855) 669-9657 from Canada, and (412) 542-4127 from elsewhere outside the U.S. and requesting the “Savara Inc.” call. A live webcast of the call can be accessed on the Investors page of Savara’s website at <https://www.savarapharma.com/investors/events-presentations/>.

Approximately one hour after the call, a telephone replay will be available and will remain available through April 10, 2020 by dialing (877) 344-7529 from the U.S., (855) 669-9658 from Canada and (412) 317-0088 from elsewhere outside the U.S. and entering the replay access code 10141275. A webcast replay will be available on the Investors

page of Savara's website and will remain available for 30 days.

## 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](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 regarding our excitement about Apulmiq and belief that it represents a transformational addition to our pipeline, that acquiring the rights provides us with another high potential Phase 3 program that leverages our core capabilities in inhaled orphan drug development and complements our existing pipeline, that there is an estimated prevalence of more than 150,000 NCFB patients in the U.S. and potentially more in Europe, that Apulmiq could represent a game-changing opportunity in a therapeutic area with little competition and significant unmet need, that our goal is to offer a novel pharmaceutical treatment option to patients living with this chronic and debilitating disease, that Grifols will be eligible for regulatory milestone payments, as well as royalties and potential tiered sales milestones upon commercialization, statements regarding Dr. Chalmers' excitement that Savara will be advancing this important investigational therapy, that Dr. Chalmers looks forward to working with Savara on the confirmatory Phase 3 study that will benefit from the learnings of previous clinical studies of Apulmiq and other inhaled antibiotics in NCFB, Dr. Chalmers' belief many patients could substantially benefit from an effective inhaled antibiotic, that the Company expects to work with regulatory agencies to plan a confirmatory Phase 3 study, that key learnings from previous studies of inhaled antibiotics for NCFB will be leveraged in order to optimize patient population and endpoints in the study, 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 develop our product candidates, the risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates such as Apulmiq 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, except as may be required by law.

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