



NEWS RELEASE

# Aironite Fails to Meet Primary Endpoint in the Indie Phase 2 Clinical Study Conducted by the Heart Failure Clinical Research Network

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## Savara to Discontinue Support of Aironite Development

AUSTIN, TX -- (Marketwired) -- 03/11/18 -- **Savara Inc.** (NASDAQ: SVRA), an orphan lung disease company, today announced results from the INDIE study of Aironite (sodium nitrite inhalation solution) evaluating the use of inhaled inorganic nitrite for symptom relief in patients with heart failure with preserved ejection fraction (HFpEF). The study did not meet its primary endpoint of improvement in peak exercise capacity assessed by cardiopulmonary exercise testing (CPET), or its secondary endpoints. The topline results were presented at the American College of Cardiology 67<sup>th</sup> Annual Scientific Sessions & Expo by Barry A. Borlaug, M.D., FACC, Chair for Research, Division of Circulatory Failure, Department of Cardiovascular Medicine, Mayo Clinic and principal investigator for the study. The study was sponsored by Duke Clinical Research Institute as the Coordinating Center for the Heart Failure Clinical Research Network and was conducted primarily with grant funding from the National Heart, Lung, and Blood Institute.

"We would like to thank Dr. Borlaug, the Duke Clinical Research Institute, as well as the Heart Failure Clinical Research Network for their tireless efforts in conducting the study," said Rob Neville, chief executive officer of Savara. "These results were obviously disappointing, but we hope the study will nevertheless serve to increase the understanding of the disease mechanisms in HFpEF, and perhaps help develop other treatment concepts for this difficult clinical condition. Savara's core business focusing on the treatment of orphan lung diseases is unaffected by the results in the INDIE study, and will remain the main value driver of the company."

Aironite is an investigational product that was added to Savara's pipeline as part of Savara's acquisition of Mast Therapeutics in April 2017, and the INDIE study was one of two investigator sponsored Aironite studies in patients with HFpEF initiated prior to the merger. Following the negative outcome of the INDIE study, Savara does not plan

to support any new development of Aironite.

### **About the INDIE Study**

The Inorganic Nitrite Delivery to Improve Exercise Capacity in HFpEF (INDIE-HFpEF) study was a multicenter, randomized, double-blind, placebo-controlled, crossover study to evaluate the effect of Aironite on peak exercise capacity as assessed by CPET. One hundred five patients with a diagnosis of HFpEF were enrolled across 17 clinical centers in the United States. The primary endpoint was peak oxygen consumption (VO<sub>2</sub>) after four weeks of treatment with Aironite or placebo as assessed by CPET performed at peak drug levels. Secondary objectives included (i) submaximal activity tolerance chronically, (ii) quality of life, (iii) chronic filling pressures as assessed by echocardiography and natriuretic peptide levels, (iv) ventilatory efficiency at maximal exercise, and (v) submaximal exercise capacity at peak drug levels; as well as evaluation of the safety and tolerability of Aironite.

### **About Savara**

Savara Inc. is an orphan lung disease company. Savara's current pipeline comprises: Molgradex, an inhaled granulocyte-macrophage colony-stimulating factor, or GM-CSF, in Phase 3 development for PAP, and in preparation for Phase 2a development for NTM lung infection; and AeroVanc, a Phase 3 stage inhaled vancomycin for treatment of MRSA infection in cystic fibrosis. 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, in 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)

### **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 about Savara's core business focusing on the treatment of orphan lung diseases being unaffected by the INDIE study results and remaining Savara's main value driver, Savara's plan not to support any new development of Aironite 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such 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 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 timing and ability of Savara to raise additional equity capital to fund continued operations; the ability to successfully develop our product candidates, and 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. 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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