



NEWS RELEASE

Savara Provides Pipeline and Business Update

2020-12-10

Announces Phase 3 AVAIL Trial Missed Primary Endpoint, Stopping Further Development of AeroVanc

Appoints Matt Pauls, Chairman and Interim CEO Since September 2020, Chairman and Permanent CEO

Reduces Operating Expenses to Align with Streamlined Development Programs

Discontinues Development of Apulmiq Program, Focuses Resources on Molgradex in aPAP

Revises Study-Start Guidance for IMPALA 2 Clinical Trial to Q2 2021

AUSTIN, Texas--(BUSINESS WIRE)--Dec. 10, 2020-- **Savara Inc.** (Nasdaq: SVRA), an orphan lung disease company, today provided an update on changes to the Company's pipeline, leadership, and business operations that are being taken to improve alignment of resources and increase our focus on Molgradex in aPAP and the Phase 3 IMPALA 2 trial.

"I am grateful for the opportunity to be a part of the Savara team," said Matt Pauls, Chairman and CEO, Savara. "Over the last few months, we have moved decisively and with urgency on our priorities and now enter 2021 focused on our key value driver, Molgradex in aPAP and the flawless and safe execution of the IMPALA 2 trial. Finally, I am excited to continue leading Savara and look forward to working on behalf of the aPAP community while creating shareholder value."

AVAIL Top Line Results

The Company announced that the Phase 3 trial of AeroVanc (vancomycin hydrochloride inhalation powder) in people living with cystic fibrosis (CF) who have Methicillin-resistant Staphylococcus aureus (MRSA) lung infection did

not meet the primary endpoint of mean absolute change from baseline in FEV₁ percent predicted analyzed sequentially at week 4 (end of cycle 1), week 12 (end of cycle 2), and week 20 (end of cycle 3). A dosing cycle was defined as 28 days of treatment followed by 28 days of observation. According to statistical hierarchy, if the trial did not show a statistically significant improvement in the FEV₁, the sequence of analysis ends. Data from the trial showed a mean change from baseline in FEV₁ percent predicted compared to placebo of 1.4 at week 4 (p=0.33), 1.3 at week 12 (p=0.33), and 3.0 at week 20 (p=0.07) in the primary analysis population of patients 6-21 years of age. Additionally, treatment with AeroVanc did not result in a reduction in the frequency of pulmonary exacerbations versus placebo. The exacerbation rate per year was 2.3 for both groups (risk ratio 1.0, 95% CI 0.7, 1.4). AeroVanc was generally well tolerated.

“We extend our gratitude to the patients and clinical trial staff who participated in AVAIL,” said Badrul Chowdhury, Chief Medical Officer, Savara. “On behalf of people living with CF, we hope data from the trial will benefit future research of inhaled antibiotics in MRSA lung infections. Unfortunately, based on the AVAIL results, we are discontinuing further development of AeroVanc.”

Operating Expense Reduction

The Company has implemented a plan to reduce overall operating expenses, including a reduction in workforce. While the Company is still in the process of determining final results for the fourth quarter of 2020, it expects to end the year with cash, cash equivalents, and short-term investments of approximately \$82 million (unaudited) and debt of approximately \$25 million.

Apulmiq (Inhaled Ciprofloxacin) in Non-Cystic Fibrosis Bronchiectasis (NCFB)

As part of a pipeline simplification strategy that focuses resources on Molgradex in aPAP and the IMPALA 2 trial, the Company has discontinued the Apulmiq clinical development program.

Phase 3 IMPALA 2 Update

While the Company is working to initiate the Phase 3 IMPALA 2 trial in North America, Europe, and Asia as quickly and as safely as possible, the impact of the COVID-19 pandemic on the trial continues to evolve. To ensure COVID-19 mitigation strategies are in place, the Company today revised guidance on the initiation of IMPALA 2 and now expects the trial to start in Q2 2021, versus the end of Q1 2021.

About the AVAIL Trial

AVAIL is a Phase 3, randomized, double-blind, placebo-controlled clinical trial designed to compare the efficacy and

safety of AeroVanc (vancomycin hydrochloride inhalation powder) with placebo in people living with cystic fibrosis (CF) who have Methicillin-resistant Staphylococcus aureus (MRSA) lung infection. Total target enrollment was 200 patients. In March 2020, the Company stopped enrollment due to COVID-19 concerns. The trial enrolled 55 patients in the adult population out of a target of 50 and 133 patients in the primary analysis population (those between 6-21 years of age) out of a target of 150.

During Period 1 of the trial, patients were randomly assigned in a blinded 1:1 fashion to receive either AeroVanc (30 mg) twice daily, or placebo, by inhalation for 24 weeks (or 3 dosing cycles). A dosing cycle was defined as 28 days of treatment followed by 28 days of observation. During Period 2 of the trial, patients received open-label AeroVanc (30 mg) twice daily for an additional 24 weeks (or 3 dosing cycles), to evaluate the long-term safety of AeroVanc.

The primary endpoint is the mean absolute change in FEV₁ percent predicted from baseline, which was analyzed sequentially at week 4 (end of cycle 1), week 12 (end of cycle 2) and week 20 (end of cycle 3). Analysis of the primary endpoint was based on patients between 6-21 years of age. Secondary efficacy endpoints included: (i) time-to-use of another antibiotic medication for pulmonary infection, (ii) the number of successful FEV₁-response cycles a patient achieves over Period 1 (weeks 4, 12, and 20), (iii) relative change from baseline in FEV₁ percent predicted at weeks 4, 12, and 20, (iv) change from baseline CF Questionnaire-Revised scores at weeks 4, 12, and 20 and (v) change from Baseline in CF Respiratory Symptom Diary-Chronic Respiratory Symptom Score scores at weeks 4, 12, and 20.

About Savara

Savara is an orphan lung disease company. Our lead program, Molgradex, is an inhaled granulocyte-macrophage colony-stimulating factor (GM-CSF) in Phase 3 development for autoimmune pulmonary alveolar proteinosis (aPAP). Our management team has significant experience in orphan drug development and pulmonary medicine, identifying unmet needs, and effectively advancing product candidates to approval and commercialization. More information can be found at www.savarapharma.com. (Twitter: @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 changes being taken to improve alignment of resources and increase our focus on Molgradex in aPAP and the Phase 3 IMPALA 2 trial; that we enter 2021 focused on our key value driver, Molgradex in aPAP and

the flawless and safe execution of the IMPALA 2 trial; that Mr. Pauls looks forward to working on behalf of the aPAP community while creating shareholder value; that we hope data from the AVAIL trial will benefit future research of inhaled antibiotics in MRSA lung infections; that we are discontinuing further development of AeroVanc; that the Company expects to end the year with cash, cash equivalents, and short-term investments of approximately \$82 million (unaudited) and debt of approximately \$25 million; and the expected timing of the start of the IMPALA 2 trial. 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 on our business and operations, 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 Molgradex 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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