UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
October 2, 2019

SAVARA INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-32157**	**84-1318182**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

6836 Bee Cave Road
Building III, Suite 200
Austin, TX 78746
(Address of principal executive offices, including zip code)

(512) 961-1891
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**SVRA**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On October 2, 2019, 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, presented additional data from Savara Inc.'s IMPALA pivotal Phase 3 clinical study evaluating Molgradex, an inhaled formulation of recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of autoimmune pulmonary alveolar proteinosis (aPAP) at the 2019 European Respiratory Society (ERS) International Congress in Madrid, Spain.

The presentation slides used by Dr. Trapnell are attached hereto as Exhibit 99.1.

Item 8.01. Other Events.

On October 2, 2019, Savara issued a press release announcing the response from a Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the Molgradex development program for aPAP. A copy of the press release is filed herewith as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation slides of Bruce Trapnell, M.D. from the 2019 European Respiratory Society (ERS) International Congress in Madrid, Spain.
99.2	Press Release of Savara Inc. dated October 2, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 2, 2019

SAVARA INC.
a Delaware corporation

By: /s/ Dave Lowrance
Dave Lowrance
Chief Financial Officer

Safety and Efficacy of Inhaled GM-CSF (Molgramostim) in Autoimmune Pulmonary Alveolar Proteinosis - The IMPALA Trial - Baseline Data and Blinded Treatment Period Results

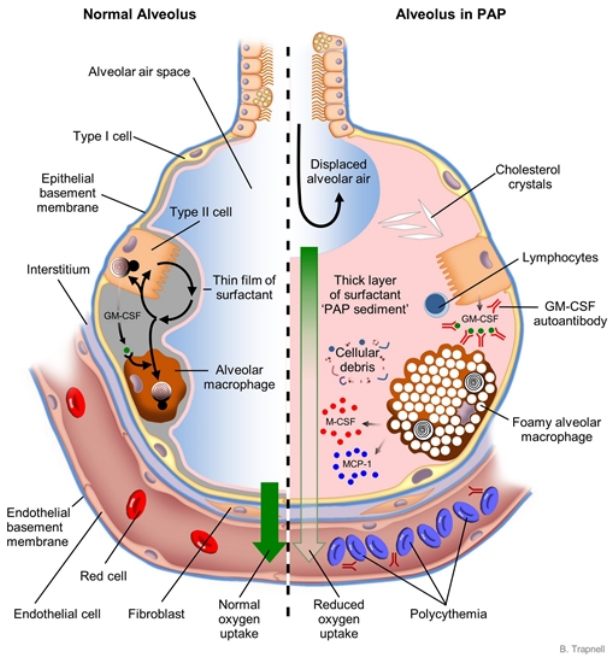
Bruce C. Trapnell, M.D.
Translational Pulmonary Science Center
Cincinnati Children's Hospital Medical Center
Professor of Medicine and Pediatrics
Division of Pulmonary, Critical Care, and Sleep Medicine
University of Cincinnati Medical Center

Disclosures

- The Impala trial was sponsored by Savara Pharmaceuticals
- I receive grant funding from the US National Institutes of Health
- I have consulted for: Boehringer Ingelheim, CSL Behring, Genzyme, Gilead, Grifols, GSK, Kiniksa, Medimmune, Merck, Savara, Sanofi, Takeda

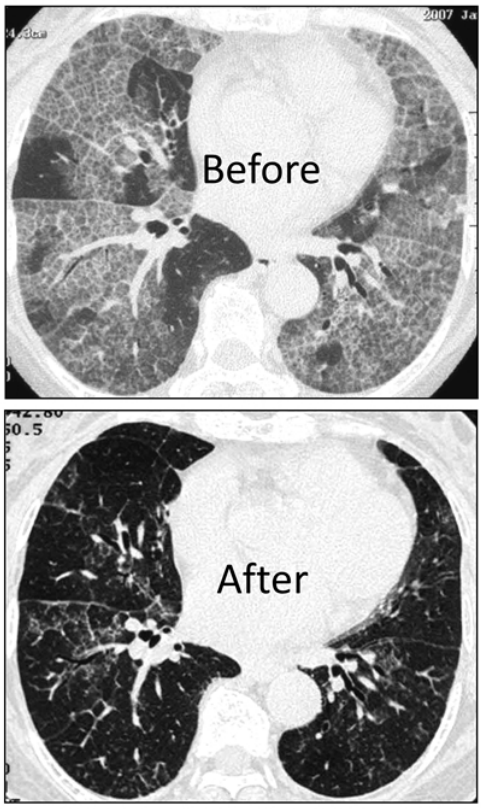
Background: Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

- aPAP is characterized by:
  - Pulmonary surfactant accumulation
  - Progressive hypoxemic respiratory failure
  - Increased PAP biomarkers
  - Polycythemia (systemic response to lung disease)
  - Increased infection risk (uncommon)
  - Pulmonary fibrosis (uncommon)
- GM-CSF is required to regulate alveolar macrophage
  - Differentiation
  - Functions
  - Population size
- GM-CSF autoantibodies cause aPAP by blocking stimulation of alveolar macrophages, which reduces their ability to clear surfactant



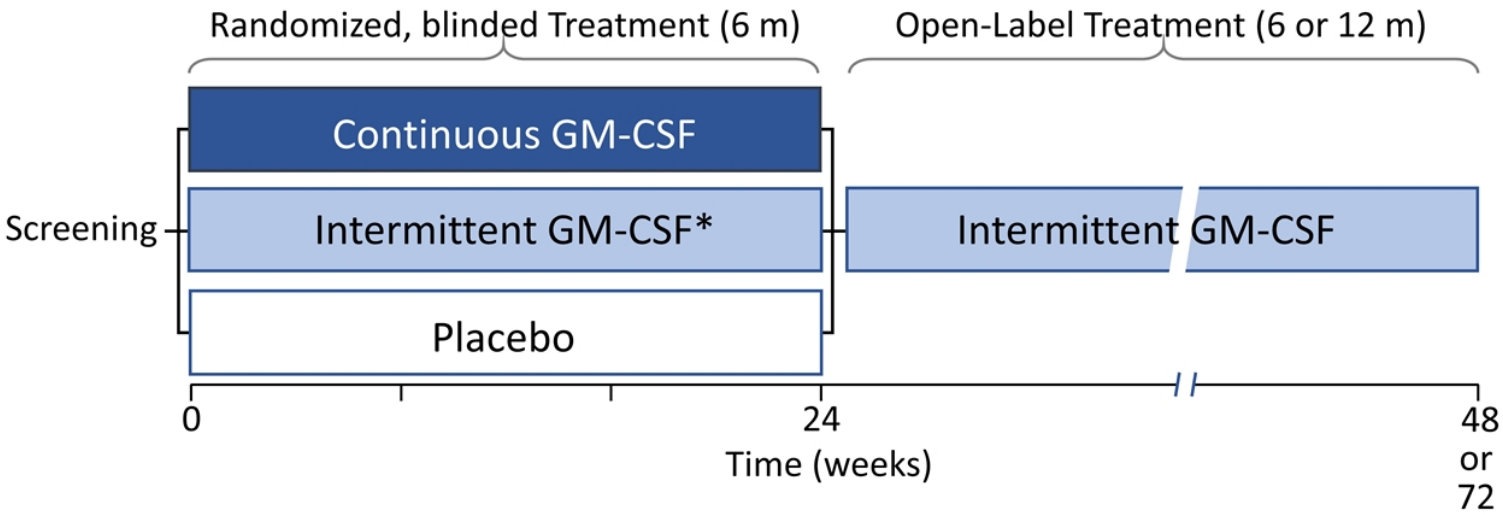
Background: Inhaled GM-CSF Therapy of aPAP

- 1996, Seymour: First patient treated with GM-CSF (SQ)
- 2000, Kavuru: 4 patients treated (SQ)
- 2001, Seymour: 14 patients treated (SQ)
- 2004, Aria: 1 patient treated (Inhaled)
- 2005, Tazawa: 3 patients treated (Inhaled)
- 2006, Wylam: 12 patients treated (Inhaled)
- 2005, Venkateshiah: 25 patients treated (SQ)
- 2010, Tazawa: 39 Patients treated (inhaled)
- 2014, Papiris: 6 Patients treated (inhaled)
- 2019, Tazawa: 64 Patients treated (inhaled)
- IMPALA Trial, 138 patients treated (inhaled)



Tazawa... 2010

Study Design of the IMPALA Trial



Study Groups

Continuous – Daily administration of inhaled GM-CSF (300 µg) (n=46)

Intermittent – Daily administration of GM-CSF (300 µg) every other week* (n=45)

Placebo – Daily administration (n=47)

*Placebo administered on 'off' weeks

Study Design: Endpoints

- **Safety**: Number of adverse events (AE) and serious adverse events (SAE)
- **Efficacy**: Change from baseline at 24 weeks in the following endpoints:

Disease element	Variable
• Pathology	• Chest CT ground glass opacification (GGO) score • Serum PAP biomarkers
• Physiology	• Alveolar-arterial difference in oxygen conc. (A-aDO_2)* • DLCO
• Health status & Function	• Saint Georges Respiratory Questionnaire (SGRQ) ** • Six-minute walk test - Distance**
• Rescue therapy requirement (Whole lung lavage - WLL)	• Time to first WLL** • Number of patients with WLL, Number of WLL
• Systemic response to chronic lung disease (polycythemia)	• Hemoglobin concentration

* = Primary end point, ** = Key Secondary end point

Baseline Characteristics: Demographics

Characteristic	Continuous	Intermittent	Placebo
Age, years	54.0 ± 13.3	49.2 ± 14.0	46.1 ± 14.8
Gender (Male), %	60.9	57.8	53.2
Smoking history, %			
Never smoker	28.3	35.6	34.0
Ex smoker	58.7	44.4	42.6
Current smoker	13.0	20.0	23.4
Geographic region, %			
Europe	34.8	46.7	70.2
Japan	43.5	22.2	21.3
USA	4.3	4.4	0
Other	17.4	26.7	8.5

Baseline Characteristics: Disease Severity

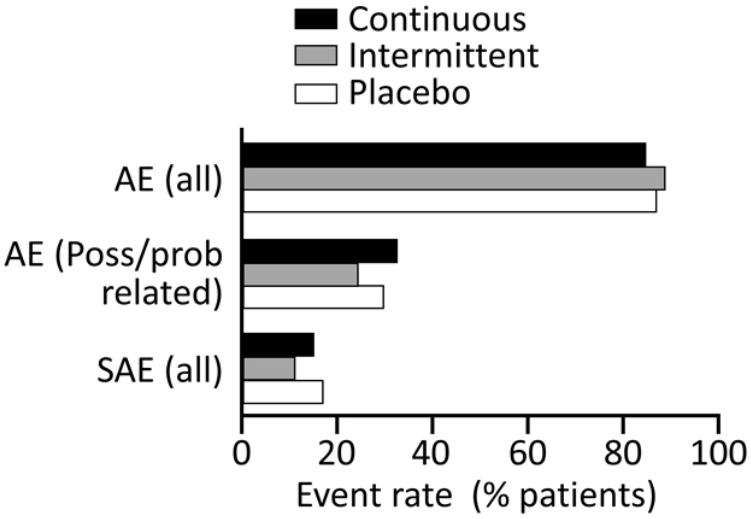
Characteristic	Continuous	Intermittent	Placebo
A-aDO_2*, mm Hg (FAS)	40.5 ± 19.6	40.9 ± 20.2	40.2 ± 14.3
DLCO, % predicted	52.1 ± 18.6	46.1 ± 14.5	49.6 ± 14.3
Disease severity score (DSS), %			
DSS 1 (Mild)	8.7	11.1	6.4
DSS 2	26.1	31.1	34.0
DSS 3	37.0	28.9	29.8
DSS 4	10.9	20.0	21.3
DSS 5 (Severe)	17.4	6.7	8.5
SGRQ Total score**	47.2 ± 20.4	44.4 ± 21.4	44.1 ± 21.7
6MWT-Distance**, m	412 ± 144	447 ± 117	447 ± 125
Vital capacity, % predicted	78.6 ± 32.2	74.8 ± 19.5	74.1 ± 18.6

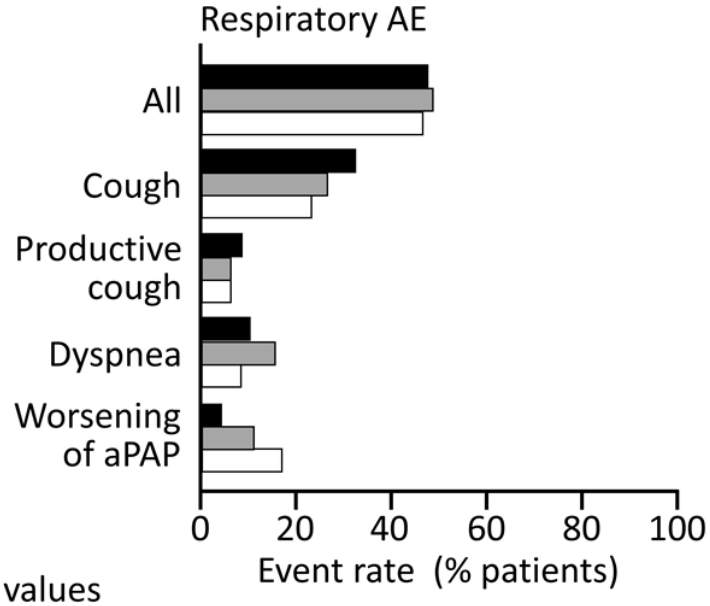
* = Primary end point, ** = Key Secondary end point

Baseline Characteristics: Previous Therapies

Characteristic	Continuous	Intermittent	Placebo
Supplemental oxygen use, %	32.6	26.7	23.4
Whole lung lavage			
Prior use of WLL (any), %	47.8	68.9	63.8
Total Number of WLLs	3.3 ± 2.2	3.3 ± 3.0	2.8 ± 3.0
Time since last WLL, m	25.0 ± 53.7	19.7 ± 27.4	17.7 ±20. 7
GM-CSF therapy (any), %	13.0	15.6	12.8

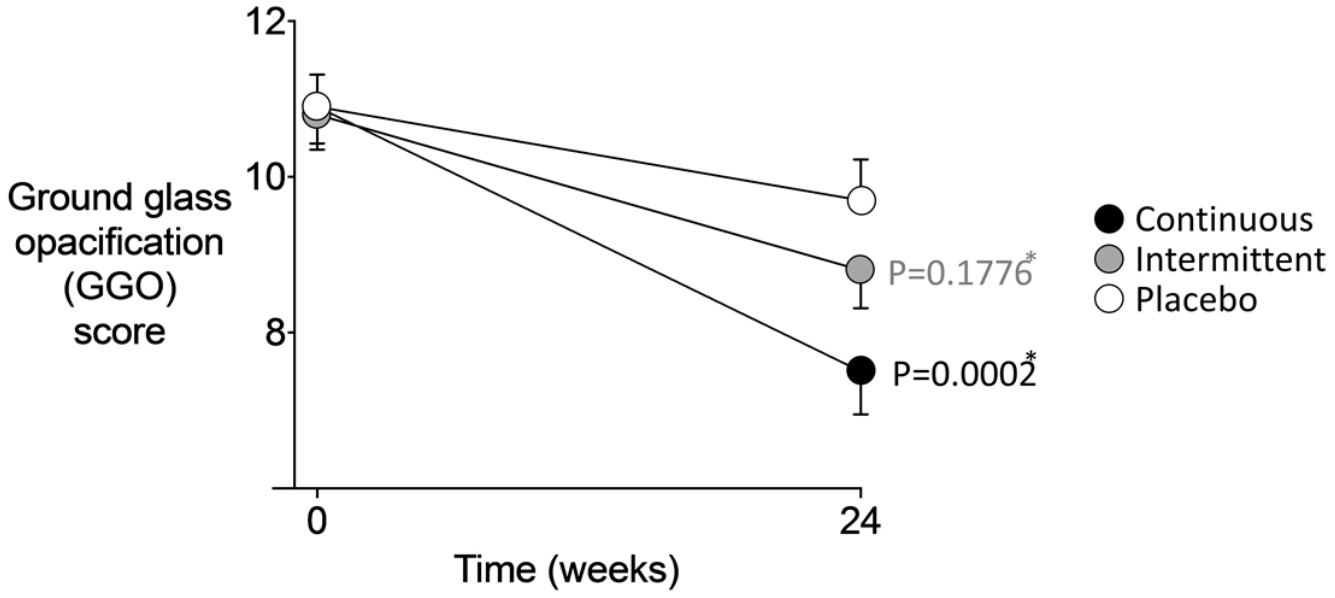
Safety: AE, SAE, and Respiratory AE Occurring in at least 5% of Patients





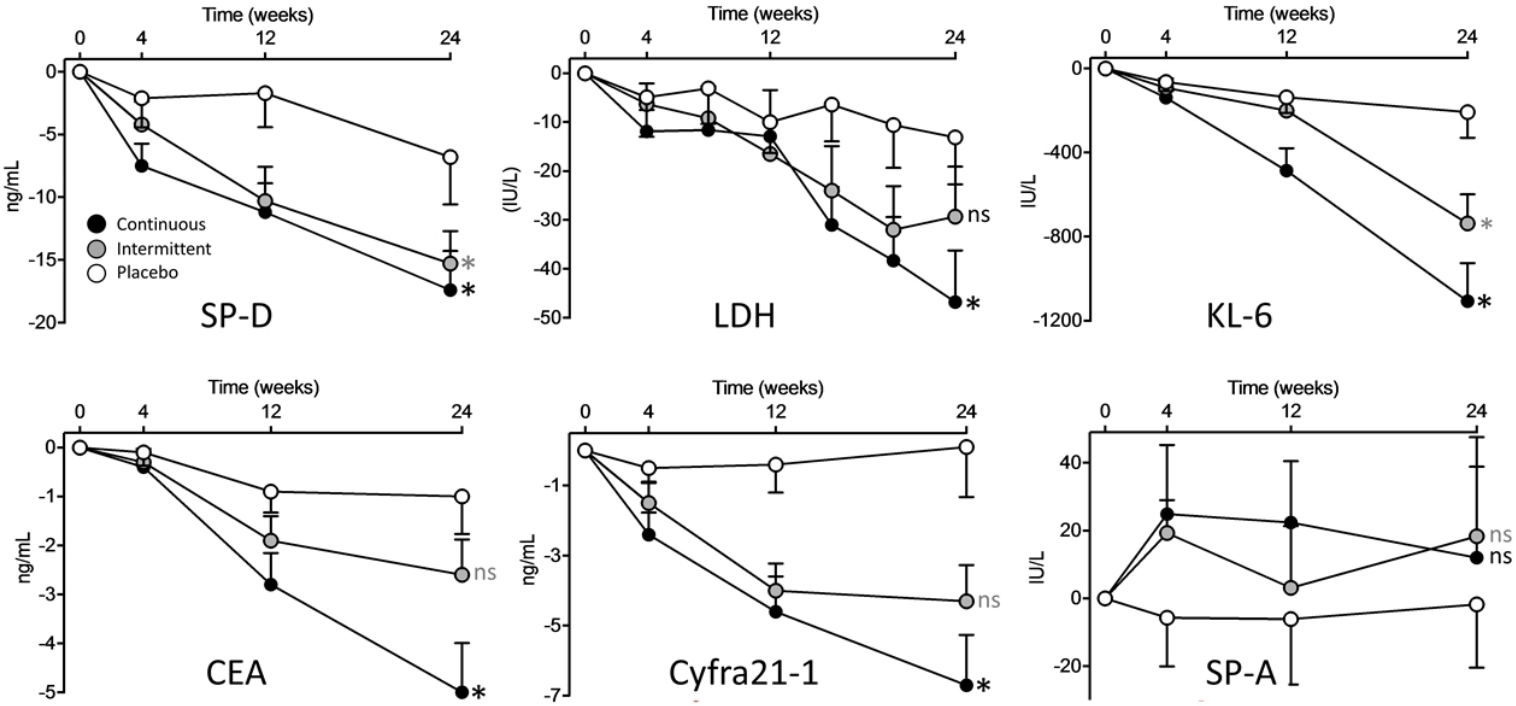
- No clinically significant changes in laboratory values
- No evidence of anti-drug antibody development
- Study completion: Continuous: 97.8%, Intermittent: 97.8%, Placebo: 91.5%

Pathology: GM-CSF Improved Chest CT GGO Score



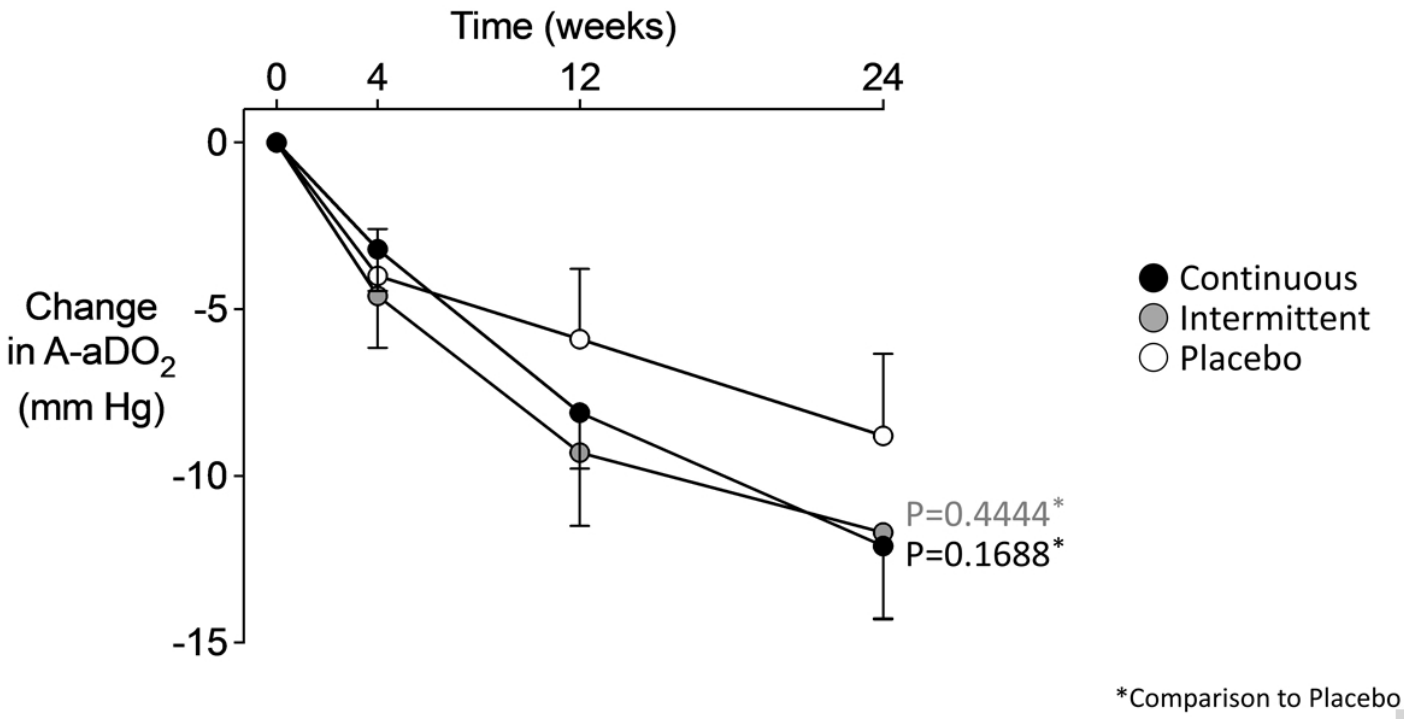
*Comparison to Placebo

Pathology: GM-CSF Improved Serum Biomarkers



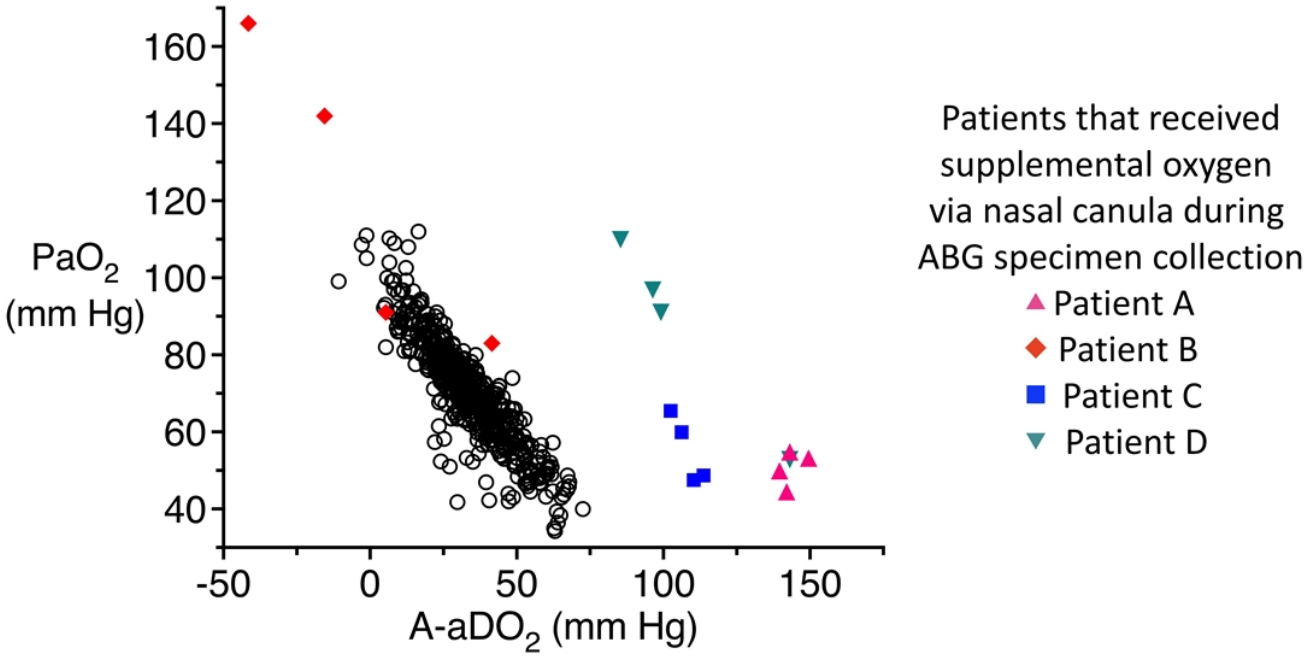
* = P<0.05, ns = P>0.05, comparison to Placebo

Physiology: GM-CSF Trended Towards Improvement in the Primary End Point ($A\text{-}aDO_2$) – Full Analysis Set (FAS)

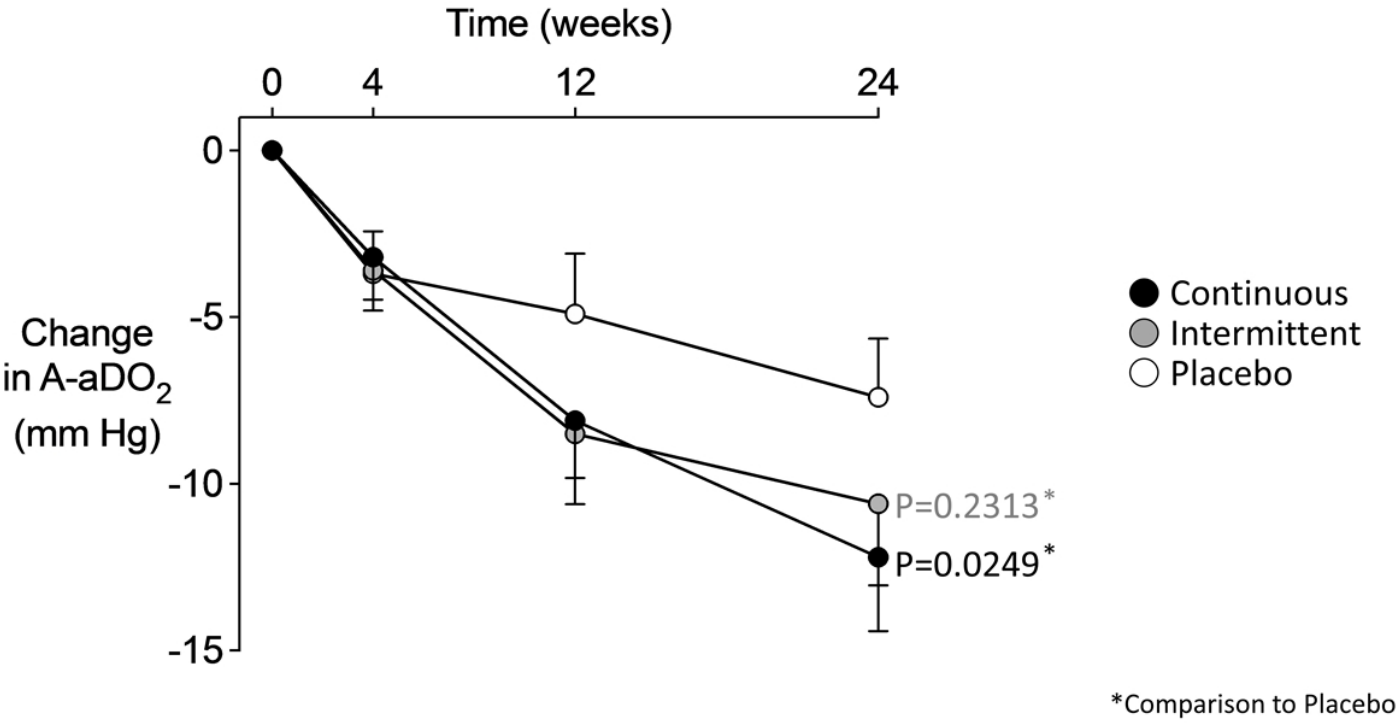


*Comparison to Placebo

Correlation of PaO_2 and A-aDO_2 Identifies Patients Who Received Oxygen Therapy During Blood Collection as Outliers

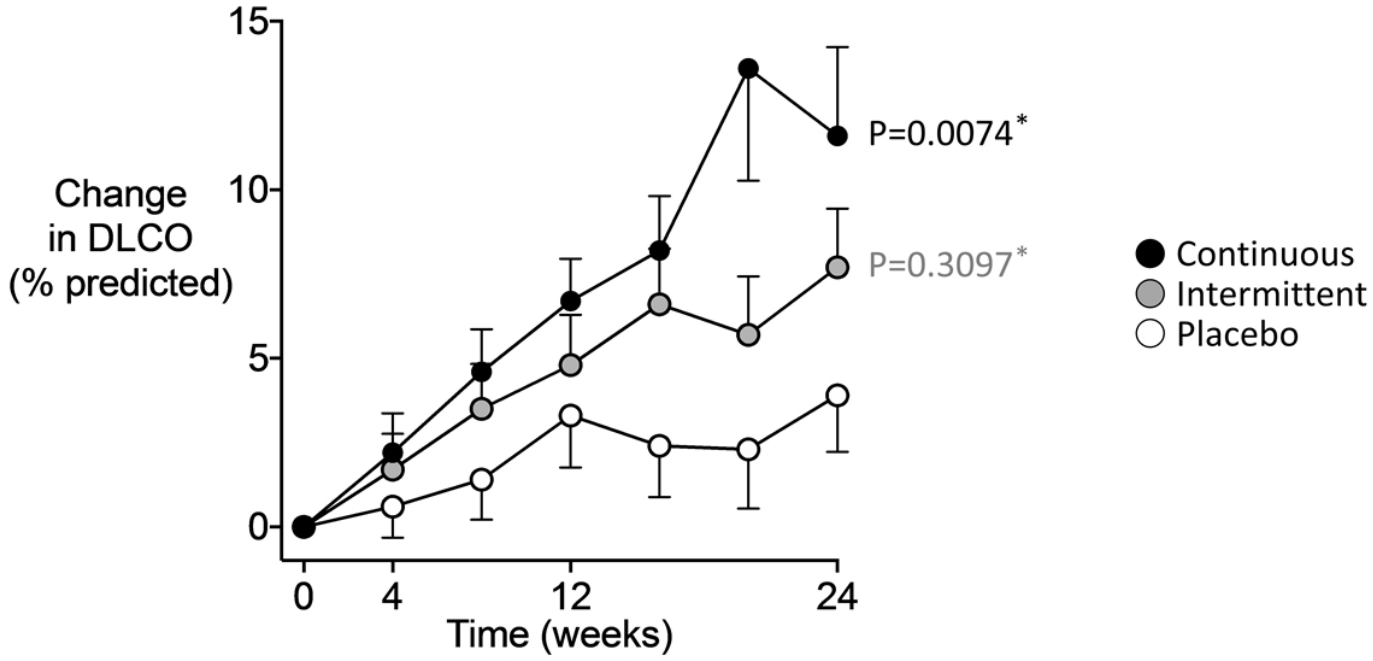


Exclusion of Data for Patients On Oxygen Therapy During Arterial Blood Collection Significantly Influenced the Primary Endpoint (A-aDO_2 – Revised)



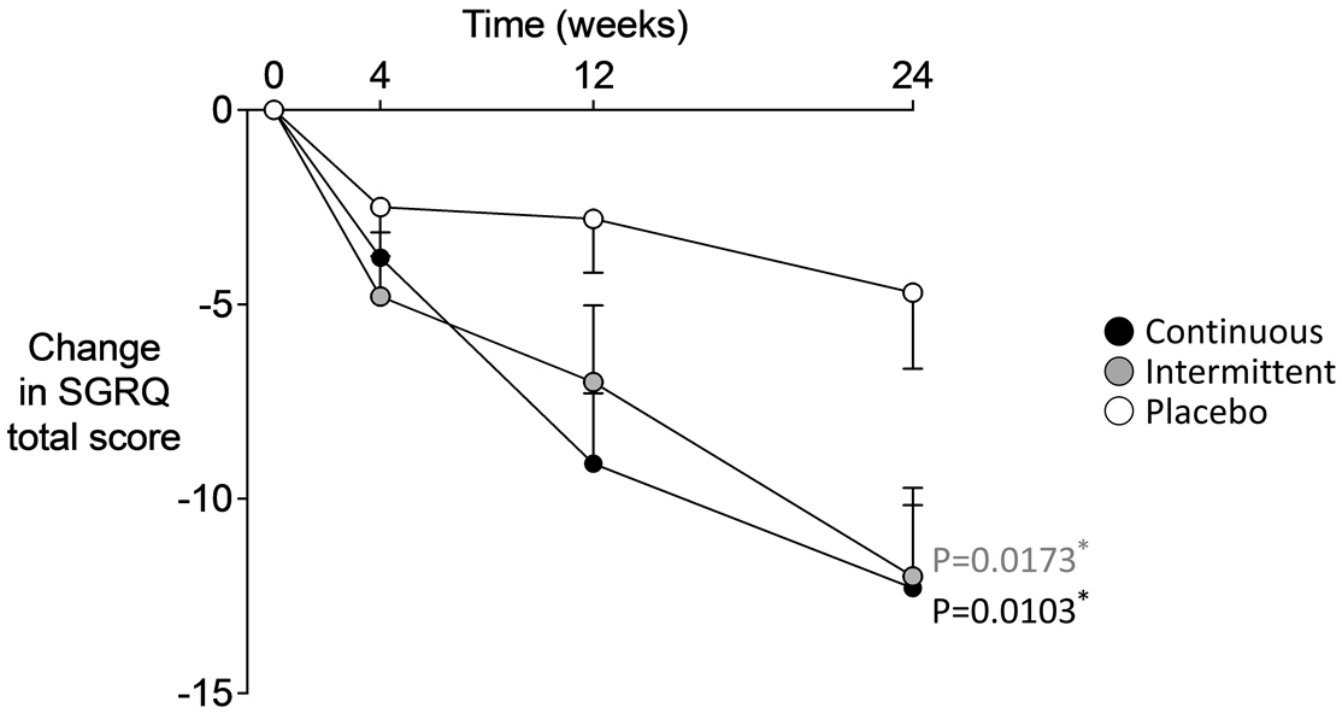
*Comparison to Placebo

Physiology: GM-CSF Improved DLCO



*Comparison to Placebo

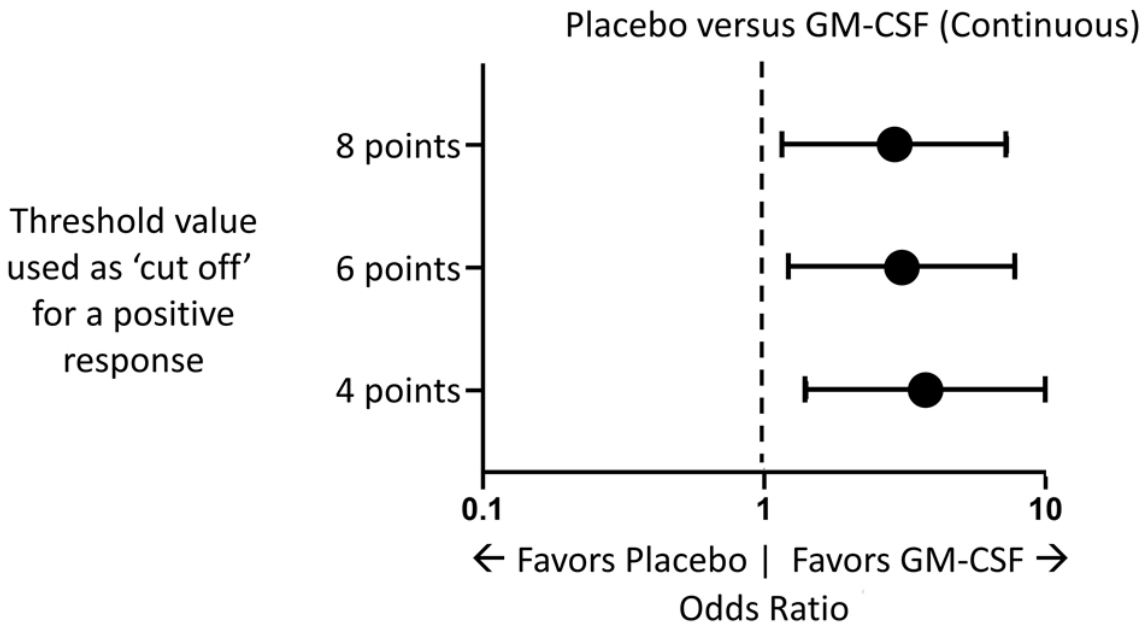
Health Status: GM-CSF Improved SGRQ Total Score



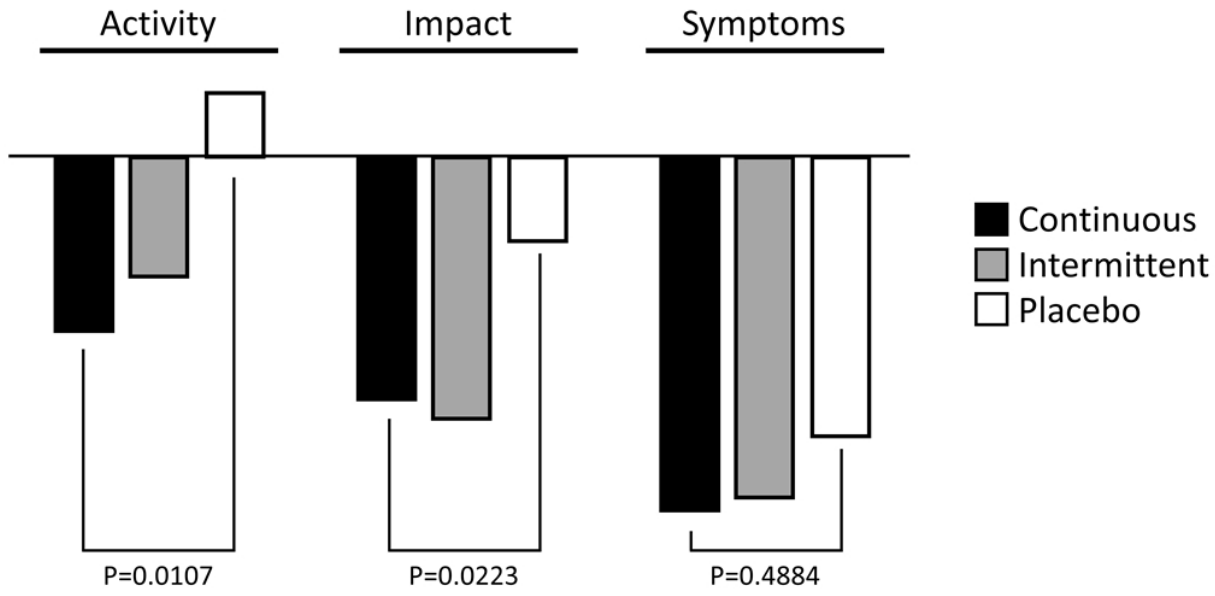
+ MCID is 4 Points in COPD patients

*Comparison to Placebo

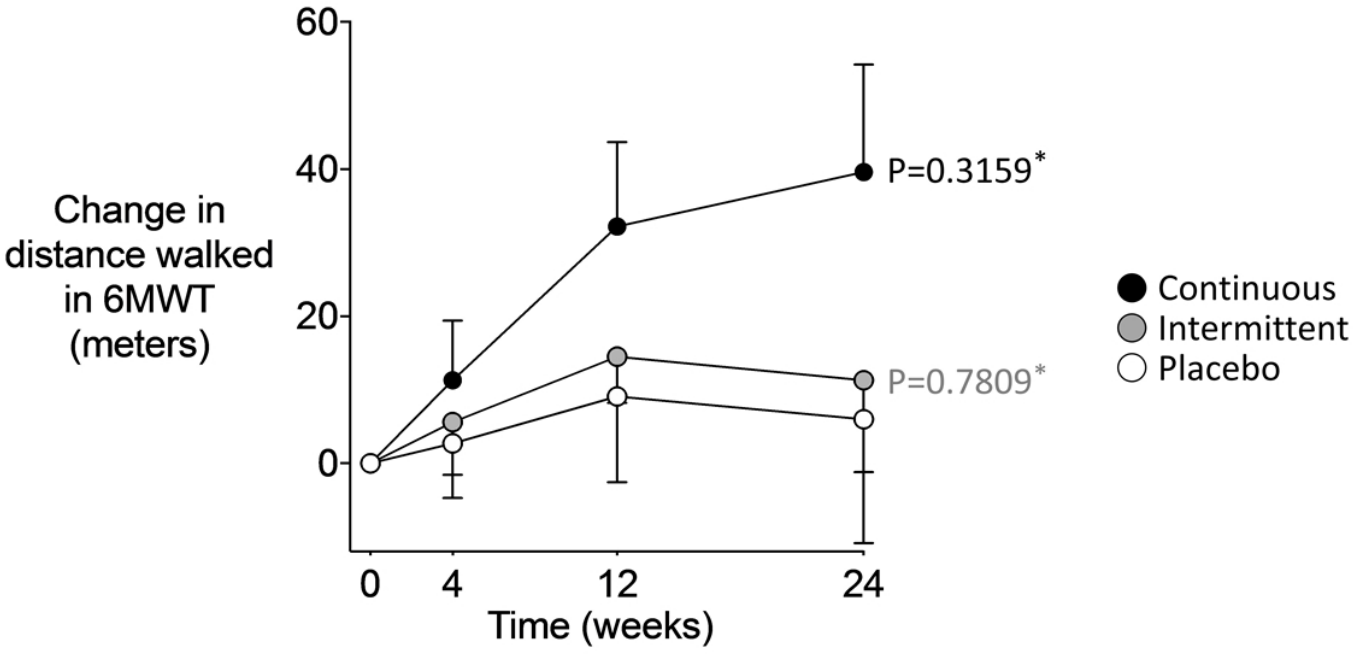
The Improvement in SGRQ was Robust as Shown by Responder Analysis



A Pattern of Improvement was Seen Across all SGRQ Domains

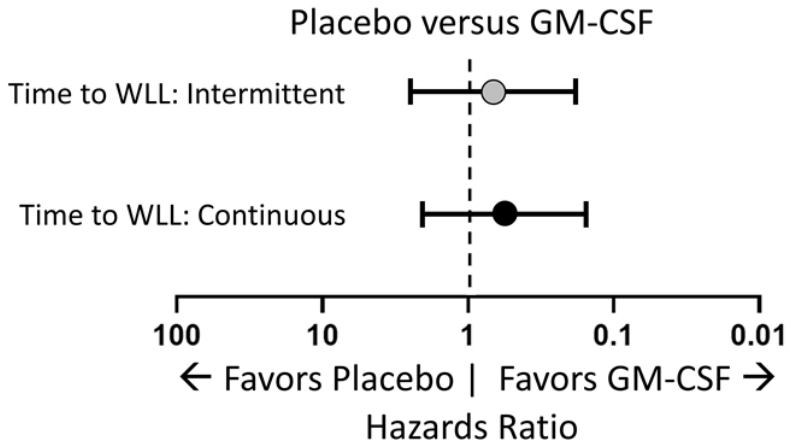


Function: GM-CSF Trended Towards Improved 6MWT-Distance



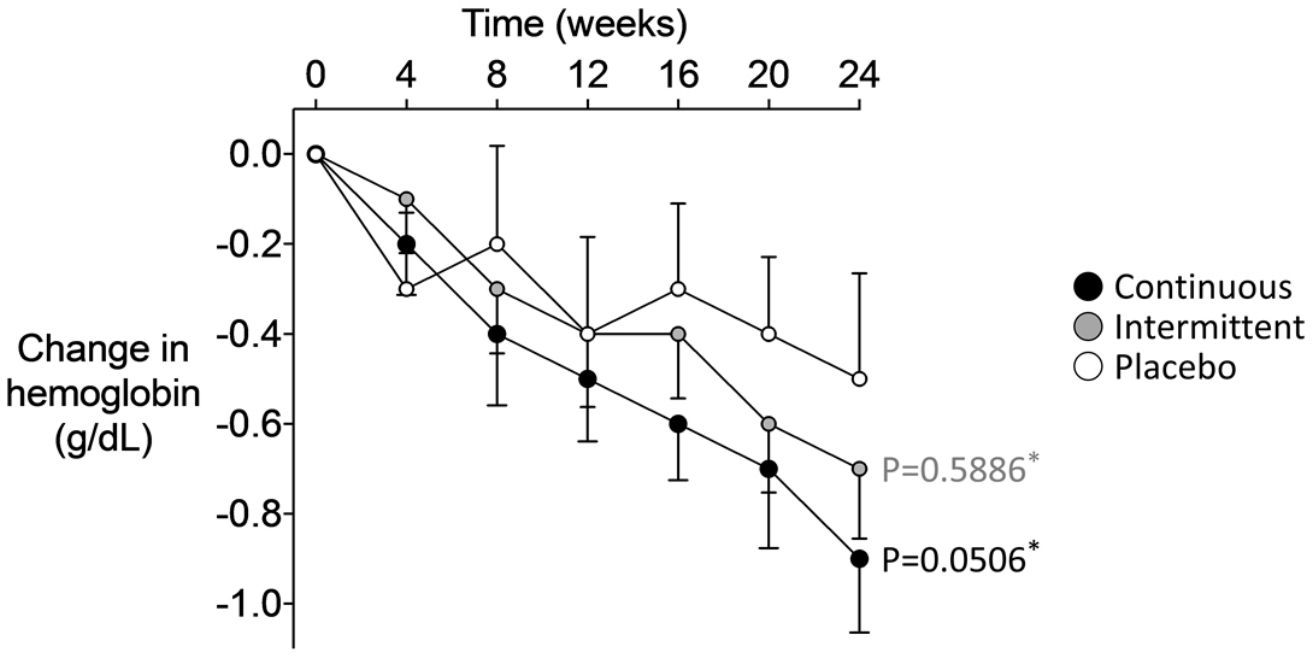
*Comparison to Placebo

Rescue Therapy: GM-CSF Trended Towards a Reduction in WLL



	WLL Therapy Requirement		
Group	# patients	# treatments	Rate Ratio vs Placebo
Continuous (n=46)	4	9	0.284
Intermediate (n=45)	4	7	0.367
Placebo (n=47)	6	17	-

Systemic Response: GM-CSF Trended Towards Reduced Hemoglobin Levels



*Comparison to Placebo

Totality of Outcome Data Favors Continuous GM-CSF over Placebo

Disease element	Endpoint	Units	Treatment effect	P-value
• Pathology	Chest CT – GGO	Score	-2.4	0.0002
	Serum LDH, KL-6, SP-D, CEA, Cyfra 21-1	IU/L pg/ml	All favor GM-CSF	<0.05
• Physiology	A-aDO_2* – FAS	mm Hg	-4.6	0.1688
	A-aDO_2* – Revised	mm Hg	-6.5	0.0249
	DLCO	% predicted	7.9	0.0074
• Health status & Function	SGRQ**	total score	-7.6	0.0103
	6MWT-Distance**	m	20.6	0.3159
• Rescue therapy	Time to WLL**	Hazard ratio	0.59	0.4204
	WLL frequency	Rate ratio	0.28	0.1918
• Systemic response	Hemoglobin	(g/dL)	-0.5	0.0506

* = Primary end point, ** = Key Secondary end point

Conclusions

- Baseline clinical features of aPAP
  - A large, global cohort of adult aPAP patients was identified and carefully characterized
  - Study groups were well-balanced for demographics and disease severity
- Clinical trial observations
  - The Placebo group experienced an unexpected degree of improvement in A-aDO_2
  - Inhaled recombinant human GM-CSF therapy (molgramostim) of aPAP is:
    - ➢ Safe and well-tolerated
    - ➢ Effective as shown by changes in lung pathology, physiology, health status, function, and the systemic response to chronic lung disease
    - ➢ More effective when administered continuously than on alternating weeks

Acknowledgments

We are grateful to and thank:

- Our PAP patients whose collaboration made the IMPALA trial possible
- IMPALA Investigators - PAP care providers and staff – at 30 centers in 18 countries including: **Australia** Troy S (Sydney); **Denmark** Bendstrup E (Arhus); **France** Jouneau S (Rennes); **Israel** Kremer M (Tikva); **Italy** Campo I (Pavia); **Germany** Bonella F (Essen), Kreuter M (Heidelberg), Behr J (Gauting), Bohnet S (Lübeck); **Greece** Papiris S (Athens); **Japan** Inoue Y (Osaka), Yamaguchi E, (Aichi), Nakata K (Niigata), Baba T (Yokohama), Kobayashi M (Sendai); **Portugal** A Morais (Porto) Ferreira L (Lisboa); **Russia** Ilkovich M (St. Petersburg); **Slovakia** Slivka R, Hagy V; **South Korea** Pyo Chung P, Woo Song J, Mi Choi S (Seoul); **Spain** Molina M (Barcelona); **Switzerland** Lazor R (Lausanne); **The Netherlands** Veltkamp M (Nieuwegein); **Turkey** Cetinkaya E (Istanbul); **United Kingdom** Morgan C (London); **United States** Wang T (Los Angeles), Ataya A (Gainesville), Trapnell B (Cincinnati)
- IMPALA Protocol Committee: **Denmark** Bendstrup E; **Germany** Costabel U, Bonella F; **Italy** Campo I; **Japan** Inoue Y; **France** Jouneau S; **UK** Morgan C; **Greece** Papiris S; **USA** Trapnell B
- Waterer G (Perth, Australia) who provided clinical and analytical expertise
- Savara Pharmaceuticals who sponsored the IMPALA trial

Exhibit 99.2

SAVARA ANNOUNCES FDA RESPONSE FROM TYPE C MEETING ON MOLGRADEX FOR APAP DEVELOPMENT PROGRAM

AUSTIN, TX – 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, 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.

Contacts:
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Anne Erickson (anne.erickson@savarapharma.com)
(512) 851-1366

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