# Corporate Overview

## Developing New Therapies *for* Rare Respiratory Diseases

December 2024

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# Safe Harbor Statement

Savara Inc. (“Savara” or the “Company”) cautions you that statements in this presentation that are not a description of historical fact are forward-looking statements which may be identified by the use of words such as “expect,” “intend,” “plan,” “anticipate,” “believe,” and “will,” among others. Such statements include, but are not limited to, statements regarding the strategy and focus of Savara; the Savara investment thesis; the safety, efficacy, potential health benefits and projected development timeline of MOLBREEVI; the timing of regulatory submissions; the potential for and impact of regulatory approval; and the potential addressable patient population, market size, commercial opportunity, and competitive landscape for MOLBREEVI; anticipated physician prescribing behavior; expectations regarding pricing and payer coverage; Savara’s disease awareness campaign and GM-CSF autoantibody testing, and the potential impact of those programs; and the sufficiency of our resources to fund the advancement of our development program and potential sources of additional capital. Savara may not actually achieve any of its plans or product development goals in a timely manner, if at all, or otherwise carry out its current intentions or meet the expectations or projections disclosed in its 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 that analysis of the full data set from the IMPALA-2 clinical trial could result in observations not seen in the topline results; the risks associated with our ability to successfully develop, obtain regulatory approval for and commercialize MOLBREEVI for aPAP; the risks and uncertainties related to the impact of widespread health concerns and geopolitical conditions on our business and operations; risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations; the ability to successfully conduct clinical trials for our product candidate; the availability of sufficient resources and the timing and ability of Savara to raise additional capital as needed to fund continued operations. The risks and uncertainties facing Savara are described more fully in Savara's filings with the Securities and Exchange Commission including our filings on Form 8-K, our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and our Quarterly Report on Form 10-Q for the quarter ended Sept. 30, 2024.

You are cautioned not to place undue reliance on our 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. Third-party information included herein has been obtained from sources believed to be reliable, but the accuracy or completeness of such information is not guaranteed by, and should not be construed as a representation by, the Company. Additionally, this presentation includes internal research and estimates performed by the Company, which have not been independently verified.

**MOLBREEVI (molgramostim inhalation solution) is an investigational product that has not been approved for sale or determined to be safe or effective by the U.S. Food & Drug Administration or any regulatory authority.**







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# Executive Leadership Team

**Matthew Pauls, J.D., M.B.A.**
*Chair & Chief Executive Officer*

**Anne Erickson**
*Chief Business Officer*

**Dave Lowrance**
*Chief Financial & Administrative Officer*

**Rob Lutz, M.B.A.**
*Chief Operating Officer*

**Braden Parker, M.B.A.**
*Chief Commercial Officer*

**Ray Pratt, M.D. FACP**
*Chief Medical Officer*

**Sid Advant, Ph.D.**
*EVP, Global Technical Operations*

**Yasmine Wasfi, M.D., Ph.D.**
*EVP, Head of Clinical Operations/Development*



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# Near- and Long-Term U.S. Market Opportunity in aPAP is Sizeable

| | |
|---|---|
| **~3,600** | Current U.S. TAM of confirmed diagnosed patients |
| **$300K-$500K** | Orphan rare disease potential pricing power |
| **~3,700** | Large pool of likely patients that are currently undiagnosed |
| **Multiple** | Patents currently being prosecuted |
| **12-years** | Biologic exclusivity in U.S. upon approval |
| **Long-term** | Durable revenue stream with biosimilar competition unlikely |

**>$1B**

Potential
U.S. Opportunity

TAM = Total addressable market



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# aPAP and MOLBREEVI* (molgramostim inhalation solution)

*FDA and EMA conditionally accepted trade name for molgramostim inhalation solution

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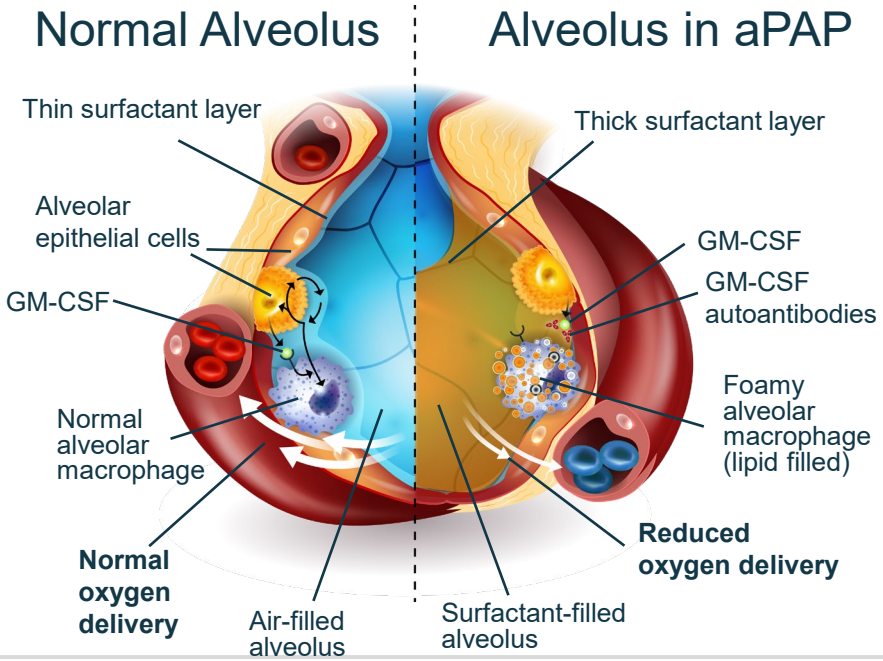
# aPAP: An Autoimmune Disease of Alveolar Macrophage Dysfunction

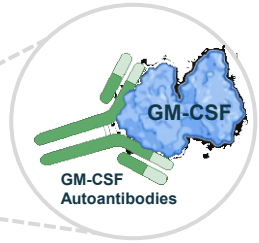
## NORMAL LUNG FUNCTION

**Alveoli** need surfactant to keep from collapsing

**GM-CSF** is critical for alveolar macrophage function and allows for alveolar surfactant homeostasis, structure, function, and host defense



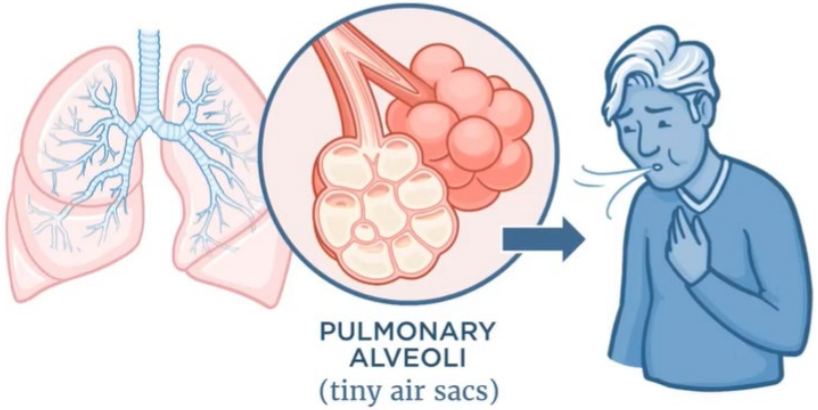

## aPAP




**Rare lung disease** caused by GM-CSF autoantibodies which block GM-CSF signaling and reduce surfactant clearance. This results in:

Surfactant accumulation that blocks movement of oxygen from the alveoli into the blood

Reduced blood oxygenation results in difficulty breathing and, ultimately, hypoxemic respiratory failure



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# aPAP is a Rare, Long-Term, Chronic Disease

## Progressive Shortness of Breath

- Gas exchange in the lungs is impaired and patients may experience shortness of breath
- At first it occurs upon exertion, but as disease progresses, it can occur even when a person is at rest

## Fatigue, Decreased Exercise Tolerance

- Fatigue and significantly reduced exercise capacity can dramatically impact the simplest of daily activities, e.g., getting winded walking up a flight of stairs

## Cough and Episodes of Fever

- Cough, sputum production, and episodes of fever, especially if secondary lung infection develops

## Fibrosis and Lung Transplant

- In the long-term, the disease can lead to serious complications, including fibrosis, and may lead to the need for lung transplantation

**There are no approved drugs for the treatment of aPAP.**
**Only option is a lung lavage, an invasive procedure.**



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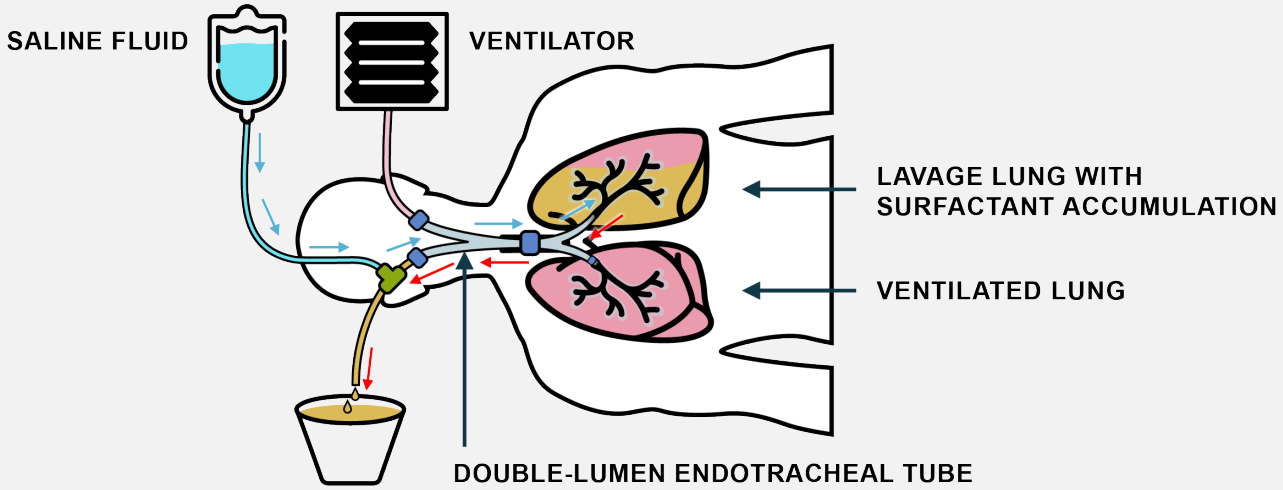
- A lung lavage physically removes excess surfactant from the lungs and requires hospitalization
- Performed under general anesthesia
- Unavailable at many medical institutions

# A Lung Lavage is an Invasive Procedure Performed in a Tertiary Center and is Not Standardized




Requires insertion of double-lumen endobronchial tube for lung separation

Treated lung is repeatedly filled with up to 15-50L of saline and then drained by gravity

Patient is percussed to emulsify the surfactant sediment

Saline is drained by gravity and continued until lavage fluid becomes clear

*Sources: 1: Campo, Assessment and Management of PAP in a Reference Center, Orphanet Jour. of Rare Dis., 2013; 2: Campo, Nat. History of PAP Data from Italian Nat. Reference Center, ERJ, 2019.; Seymour, J. J. Pulmonary alveolar proteinosis: Progress in the First 44 Years, Am. J. Respir Crit. Care Med, 2002. 3: Udwadia, Jain. NEJM (2007) 357:19, 4 McCarthy, Autoimmune Pulmonary Alveolar Proteinosis, Amer. Journal of Respiratory and Critical Care Med., 2022.*





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# Savara Investigational Drug-Device Treatment for aPAP

- Once daily 300 μg inhaled MOLBREEVI
- Proprietary eFlow® Nebulizer System (PARI)
  - Optimized for MOLBREEVI administration
  - Well-established manufacturer of devices used for inhalation therapy
  - 5 FDA approved nebulizers based on eFlow® Technology

# Phase 3 IMPALA-2 Top Line Results

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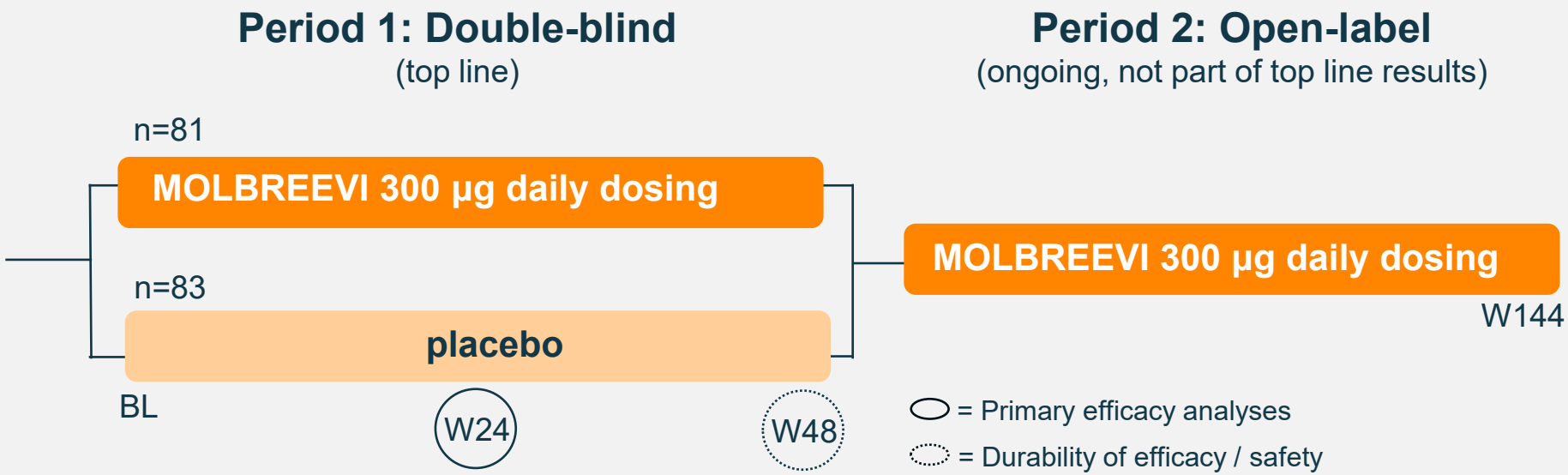
# Phase 3 IMPALA-2 Trial Design

### 6-Week Screening

- DLCO ≤70% predicted at first screening and baseline
- Change in % predicted DLCO <15% points to ensure stably impaired patients




## PRIMARY ENDPOINT

- Change from baseline in DLCO at W24

## SECONDARY ENDPOINTS

Change from baseline in:

- DLCO at W48
- SGRQ Total Score at W24 and W48
- SGRQ Activity Score at W24 and W48
- Exercise Capacity at W24 and 48



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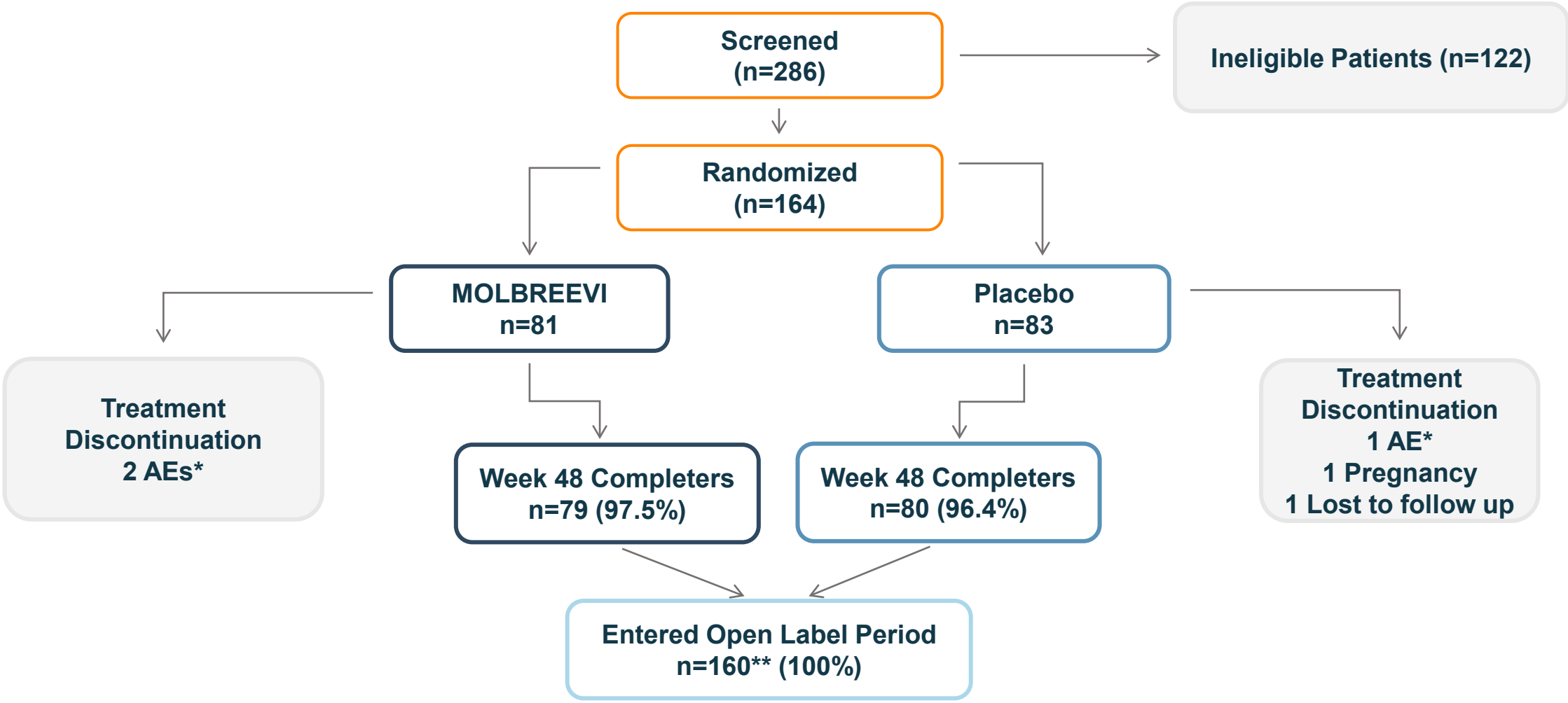
# Discontinuations in Double-Blind Period Were Low: 3%
## Participation in Open Label Period Was High: 100% of Double-Blind Period Completers

### IMPALA-2 PATIENT DISPOSITION




*Not considered trial drug related

**One placebo patient stopped blinded trial drug but continued trial participation through Week 48 and entered the open label period





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# Demographics Were Well-Balanced Across Treatment Groups

| | | MOLBREEVI N=81 | Placebo N=83 |
|---|---|---|---|
| **Age years** | Mean (SD) | 50.8 (13.03) | 48.4 (12.69) |
| **Sex n (%)** | Male<br>Female | 44 (54.3)<br>37 (45.7) | 54 (65.1)<br>29 (34.9) |
| **Race n (%)** | White<br>Asian<br>Black or African American<br>Other | 38 (46.9)<br>36 (44.4)<br>3 (3.7)<br>4 (4.9) | 40 (48.2)<br>37 (44.6)<br>2 (2.4)<br>4 (4.8) |
| **DLCO at baseline** | Mean (SD) | 52.6 (11.71) | 52.6 (10.39) |
| **DLCO stratification group** | ≤ 50%<br>> 50% | 31 (38.3)<br>50 (61.7) | 32 (38.6)<br>51 (61.4) |



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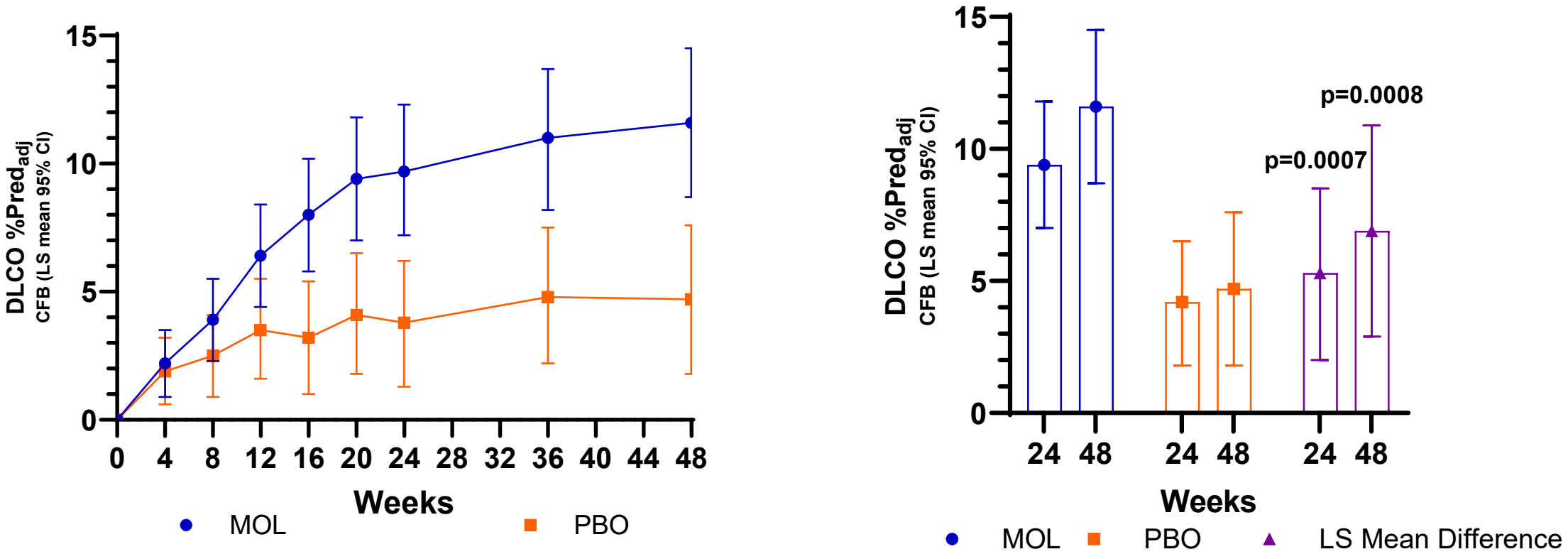
# Primary Endpoint Met (DLCO): Achieved Statistical Significance

## MOLBREEVI Superior to Placebo on Change From Baseline in DLCO at W24 (Primary Endpoint) and W48 (Secondary Endpoint)




P-values are for difference in LS Mean CFB between MOLBREEVI and placebo

**DLCO minimal clinically important difference (MCID) in change from baseline in severe COPD is a 10% increase. MOLBREEVI in aPAP showed a ~10% increase in change from baseline at W24 and ~12% increase in change from baseline at W48.**



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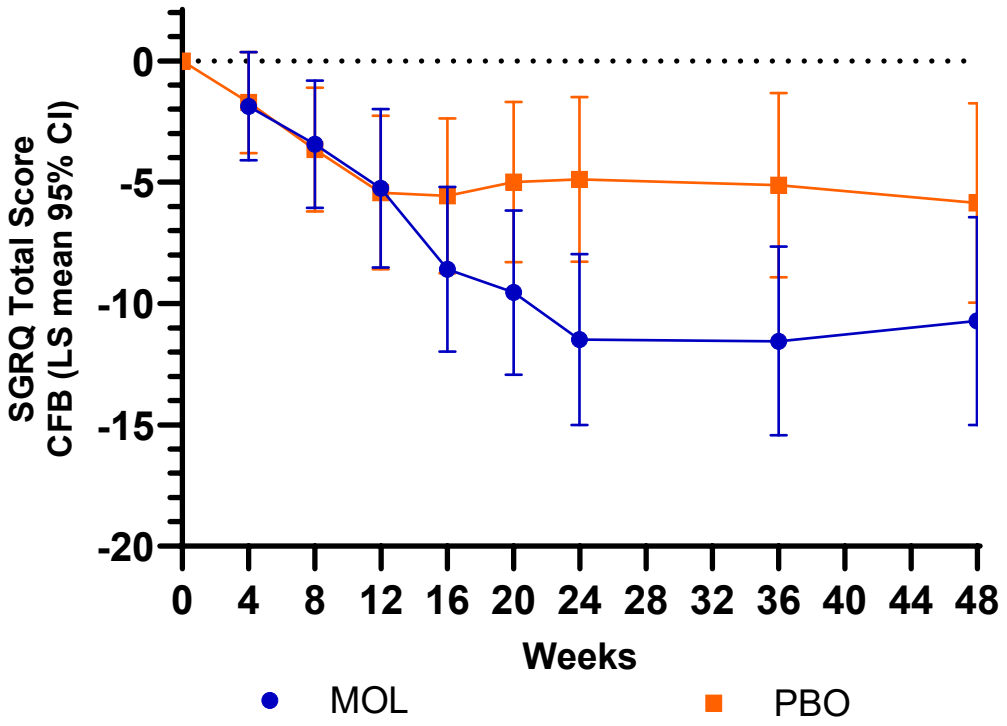
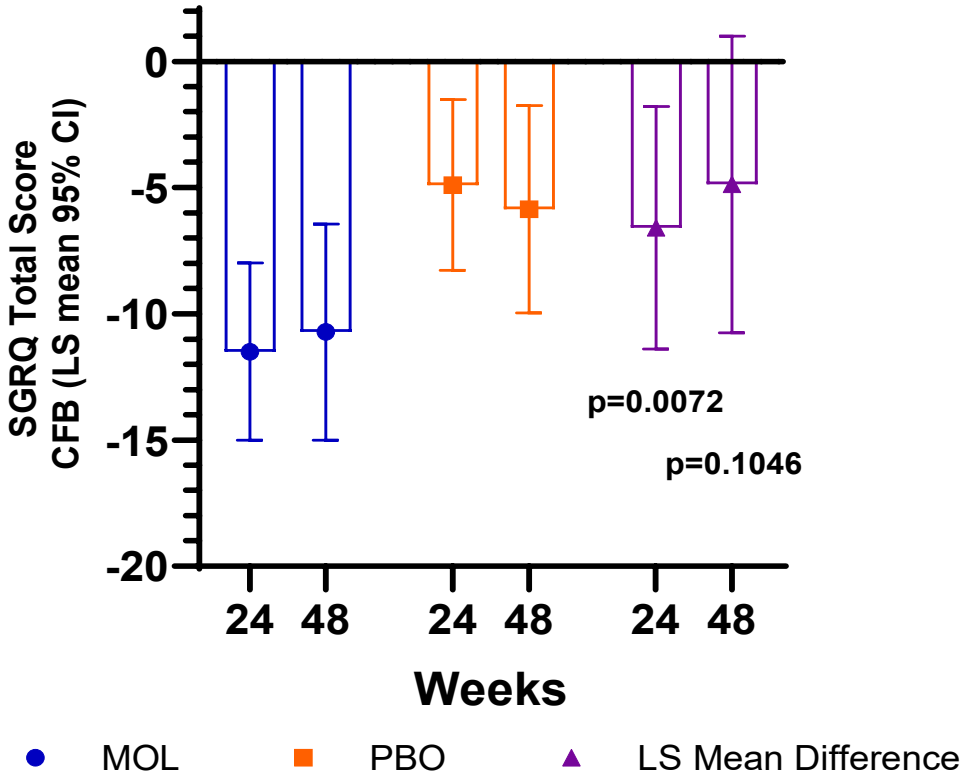
# MOLBREEVI Superior to Placebo on Change From Baseline in SGRQ Total Score at W24, Favorability Continues Through W48




P-values are for difference in LS Mean CFB between MOLBREEVI and placebo





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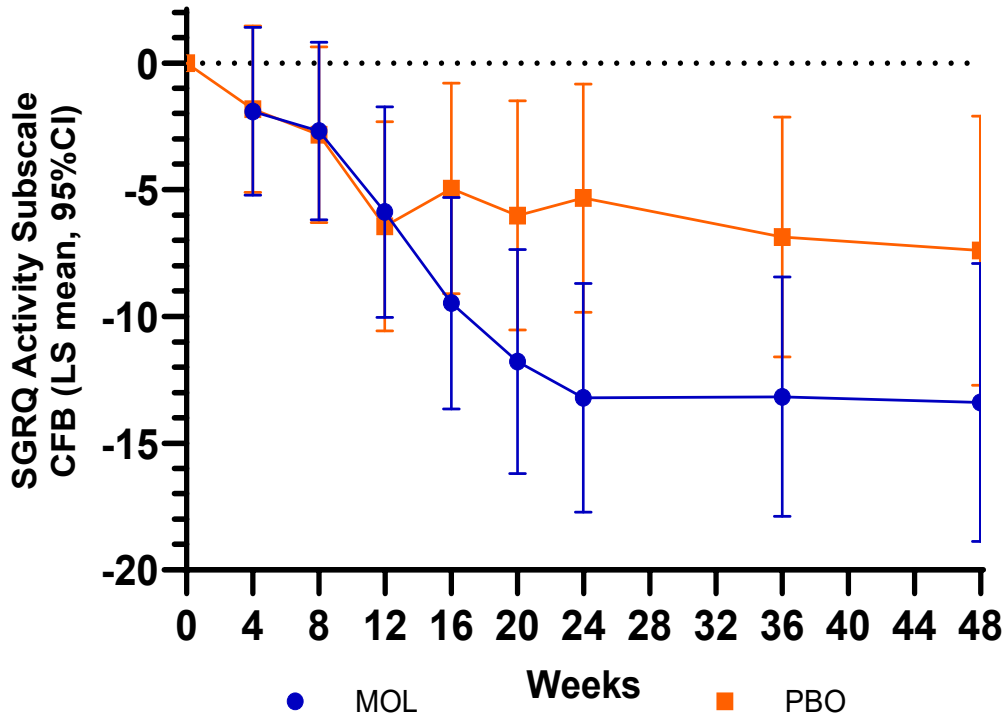
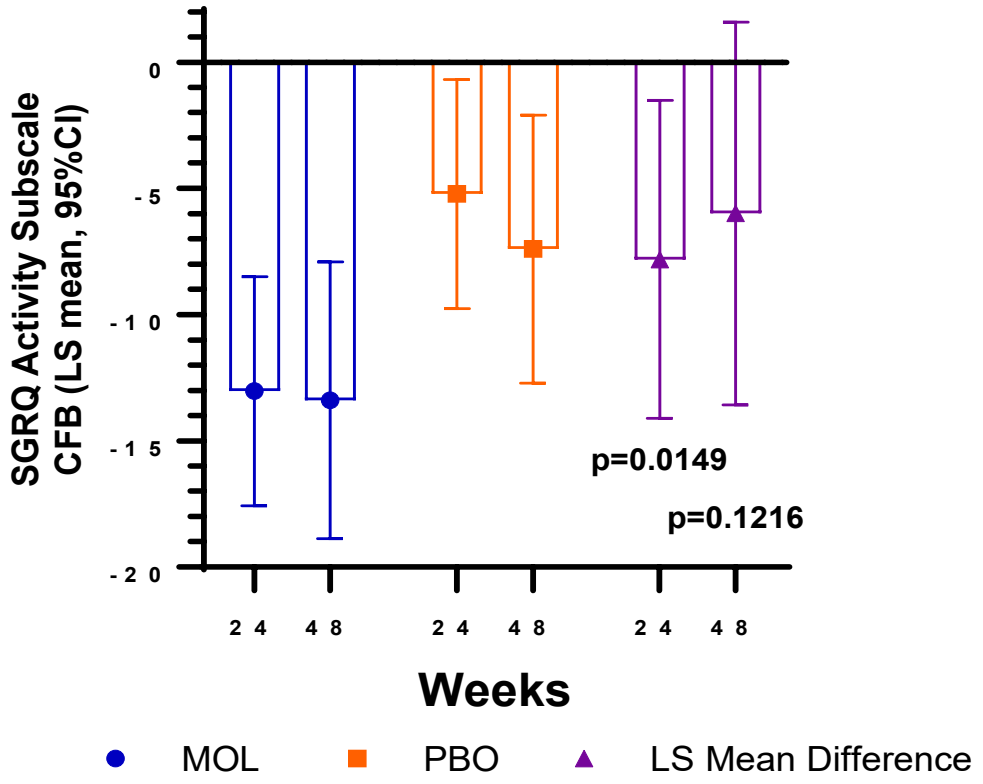
# MOLBREEVI Nominally Significant on Change From Baseline in SGRQ Activity Score at W24, Favorability Continues Through W48




P-values are for difference in LS Mean CFB between MOLBREEVI and placebo





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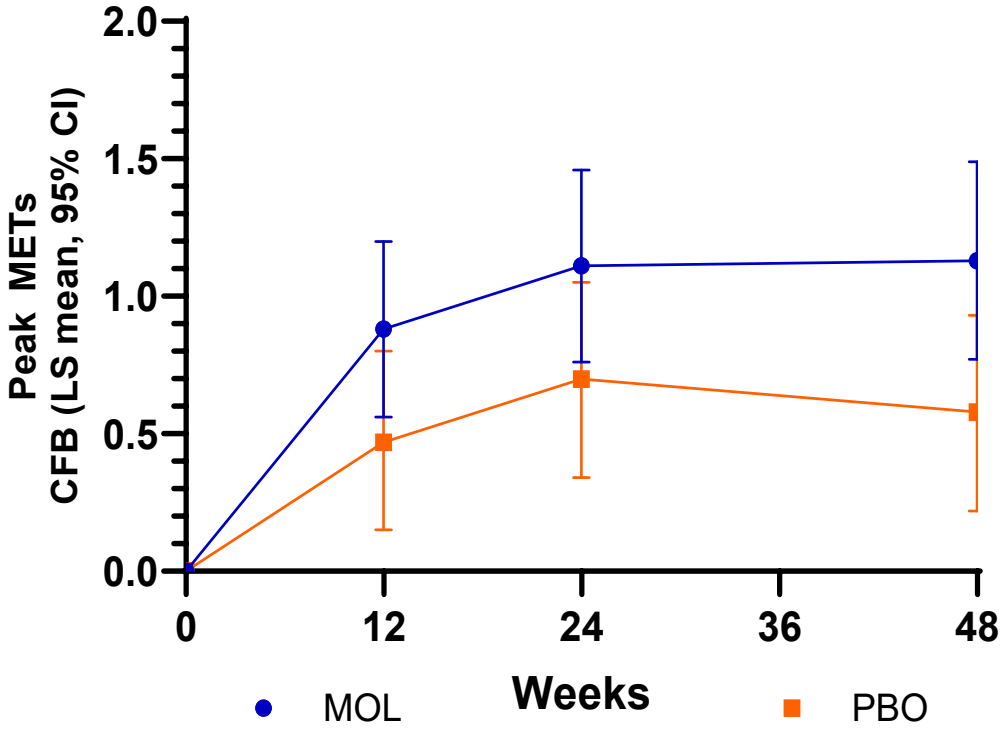
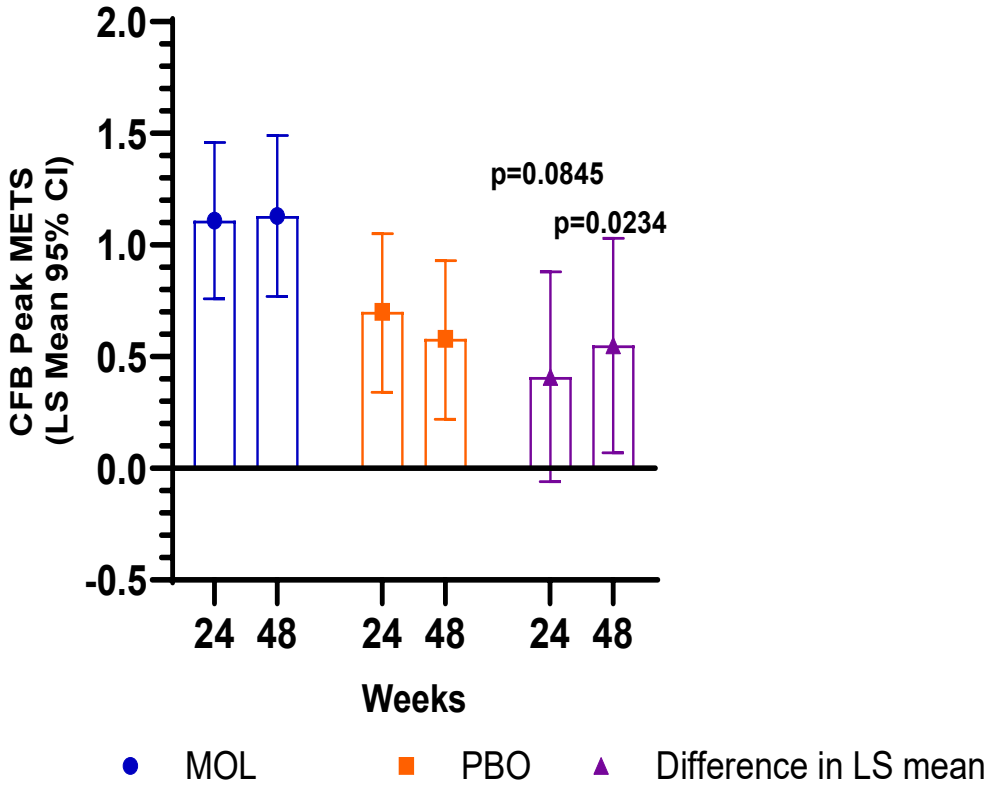
# MOLBREEVI Nominally Significant on Change From Baseline in Exercise Capacity (Peak METs) at W48




P-values are for difference in LS Mean CFB between MOLBREEVI and placebo





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# Lung Lavage Was Permitted as a Rescue Therapy During the Trial

**During 48-week double-blind period**

- 17 (~10%) patients underwent at least one lung lavage
  - MOLBREEVI: n=6 (7.4%)
  - Placebo: n=11 (13.3%)





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# IMPALA-2 Safety Summary: MOLBREEVI Was Well-Tolerated

| Treatment Emergent Adverse Events | MOLBREEVI N=81 n (%) | Placebo N=83 n (%) |
|---|---|---|
| **Any** | **69 (85)** | **71 (86)** |
| Severe | 13 (16) | 16 (19) |
| **Treatment related** | **20 (25)** | **16 (19)** |
| **Serious** | **14 (17)** | **20 (24)** |
| Not treatment related | 13 (16) | 20 (24) |
| Treatment related[1] | 1 (1) | 0 |
| **Leading to death** | **0** | **0** |
| **Leading to trial drug discontinuation** | **2 (2)** | **1 (1)** |
| **Special interest (chest pain, hypersensitivity)** | **9 (11)** | **6 (7)** |
| Serious and of special interest | 0 | 1 (1) |

[1]SAE of delusions resulting in psychiatric hospitalization in patient with a past medical history of seizure disorder treated with levetiracetam, which is labeled for psychiatric side effects, including delusions; the event was assessed as possibly related to study drug by the investigator.



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# IMPALA-2 Safety Summary: Most Common Adverse Events

**ADVERSE EVENTS IN >10% OF PATIENTS IN ANY TREATMENT ARM DURING DOUBLE-BLIND TREATMENT PERIOD**

| Treatment Emergent Adverse Events | MOLBREEVI (N=81) n (%) | Placebo (N=83) n (%) |
|---|---|---|
| **Any** | **69 (85)** | **71 (86)** |
| **Most common** | | |
| COVID-19 | 18 (22) | 8 (10) |
| Cough | 17 (21) | 18 (22) |
| Pyrexia | 11 (14) | 9 (11) |
| Nasopharyngitis | 11 (14) | 7 (8) |
| Arthralgia | 9 (11) | 7 (8) |
| Headache | 9 (11) | 7 (8) |
| Diarrhea | 9 (11) | 2 (2) |
| Alveolar proteinosis | 4 (5) | 12 (14) |
| **Treatment related** | **20 (25)** | **16 (19)** |



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# Overview of IMPALA-2 Results: Top Line, DSS, Responder Analyses, and GGO Data

| | Measure | Timeframe | P-Value / Results |
|---|---|---|---|
| **Pulmonary gas exchange** | DLco% | Week 24<br>Week 48 | **0.0007**<br>**0.0008** |
| | Disease Severity Score (DSS) | Week 24<br>Week 48 | **0.0239***<br>**0.0006*** |
| | Responder Analysis - DLco% | Weeks 24 and 48 | Significantly higher proportions of patients achieved each responder threshold (5%, 7%,10%) with MOLBREEVI compared to placebo |
| **Respiratory health-related quality of life** | SGRQ Total Score | Week 24<br>Week 48 | **0.0072**<br>0.1046 |
| | SGRQ Activity Score | Week 24<br>Week 48 | **0.0149†**<br>0.1216 |
| | Responder Analysis – SGRQ Total | Week 24<br>Week 48 | Numerically (W24) & significantly (W48) higher proportions of patients achieved each responder threshold (-4, -8, -12-points) with MOLBREEVI compared to placebo |
| **Patient functionality** | Exercise Capacity (Peak METs) | Week 24<br>Week 48 | 0.0845<br>**0.0234†** |
| **Surfactant burden** | Chest Computed Tomography – GGO | Week 24 | **0.0004*** |
| | Whole Lung Lavage | Over 48 Weeks | Numerically favorable to MOLBREEVI compared to placebo |

*Post-hoc analysis. †P-value nominally significant: P-value ≤ 0.0500 but did not meet the p-value threshold required in the pre-specified hierarchical testing procedure.

DLco%, hemoglobin-adjusted percent predicted diffusing capacity of the lungs for carbon monoxide; GGO, ground glass opacification; METs, metabolic equivalents; SGRQ, St. George's Respiratory Questionnaire.





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# Regulatory and Intellectual Property

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## United States:
## BLA Rolling Submission Initiated in Dec. 2024, on Track to be Completed by End of 1Q 2025

## Europe:
## MAA Submission on Track for End of 2025

### MOLBREEVI IN aPAP REGULATORY DESIGNATIONS

- Orphan Drug Designation, Europe (eligible for 10 years exclusivity)
- Orphan Drug Designation, U.S. (eligible for 7 years exclusivity)
- Fast Track Designation, U.S.
- Breakthrough Therapy Designation, U.S.
- Innovation Passport Designation, U.K.
- Promising Innovative Medicine Designation, U.K.

### IMPALA-2

- Trial design endorsed by regulatory authorities in the U.S., Canada, Japan, South Korea, Australia, U.K., and countries in Europe where the trial is being conducted

### BIOLOGIC EXCLUSIVITY

- Upon Biologics License Application (BLA) approval FDA would grant 12 years marketing exclusivity

### INTELLECTUAL PROPERTY

- Pending patent applications for MOLBREEVI drug formulation and methods of use including treating aPAP with MOLBREEVI
- Worldwide exclusive license to proprietary eFlow® Nebulizer System (PARI) for MOLBREEVI in aPAP and pending joint patent application with PARI for the drug/device combination
- Proprietary cell bank for MOLBREEVI



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# Commercial Outlook

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# Significant U.S. Opportunity with ~3,600 Diagnosed aPAP Patients

## CONFIRMED DIAGNOSED aPAP PATIENTS[1]

**~3,600**

(U.S. Claims Data Analysis)

**Analysis of comprehensive claims dataset**

- **Counted PAP ICD9/10 diagnosis codes from 300M+ lives***
- **Physicians managing the patients are located across ~1,100 centers**
- **~3,600 unique aPAP patients identified**

*Adjusted for autoimmune PAP (aPAP)

## UNCONFIRMED HIGHLY LIKELY AND LIKELY aPAP[1]

**+1,400** Highly likely

**+2,300** Likely

aPAP ClearPath™

**aPAP ClearPath Ab testing to confirm diagnosis**

[1] Data from 2023 U.S. Insurance Claims Analysis conducted by Savara



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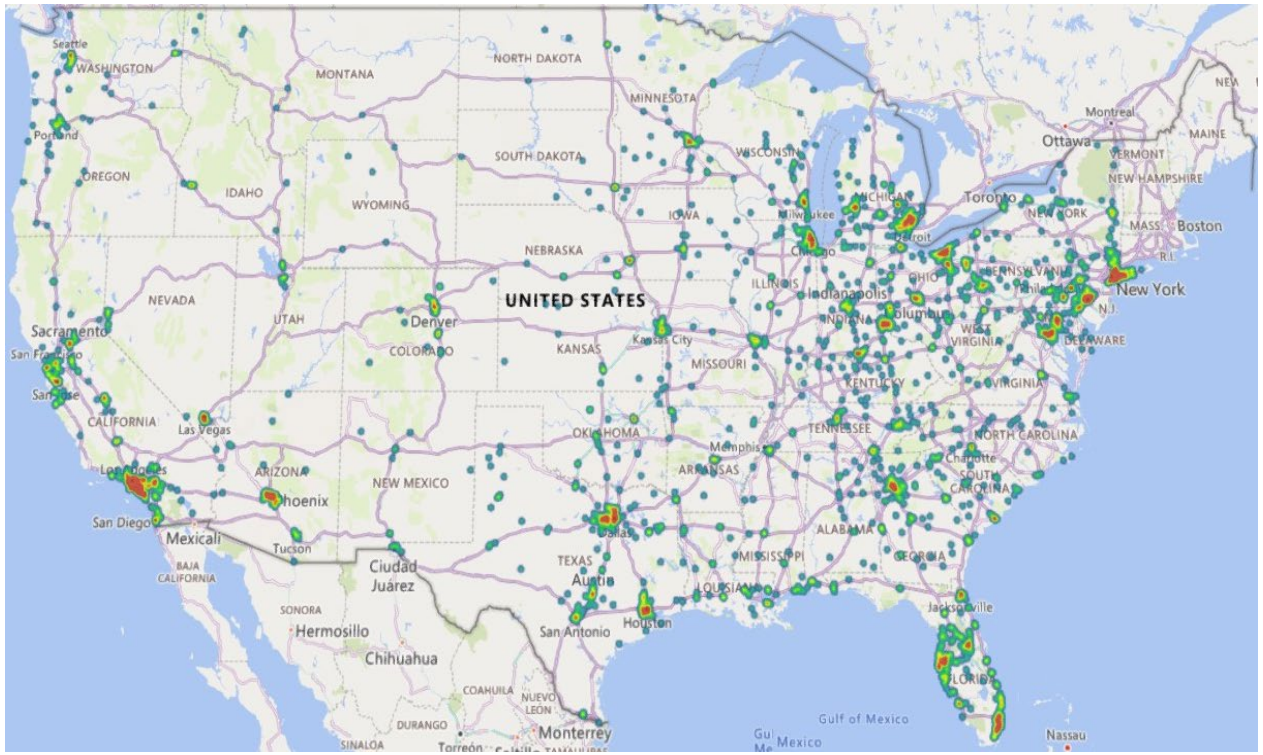
# U.S. Centers Prioritized Based on Experience Treating aPAP Patients

## U.S. PATIENTS / HCP HEATMAP[1]




[1] Data from 2023 U.S. Insurance Claims Analysis conducted by Savara

**PAP COEs†**

**ILD Centers***

**General Pulmonary Centers**

**Account Profiling Initiated**

- Disease Awareness
- Practice Size
- Patient Management
- Testing Education



†PAP Center of Excellence (COE) includes healthcare organizations listed on PAP Foundation website, IMPALA-2 clinical trial sites, and other sites of expertise
*ILD clinics are dedicated to the management of patients with a wide variety of interstitial lung diseases that can range from pulmonary fibrosis to rare lung diseases

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# Overwhelming Support for MOLBREEVI Across Stakeholders

## U.S. PULMONOLOGISTS

**83%**

Likely to prescribe **MOLBREEVI regardless of severity** of disease

**Perceived MOLBREEVI as superior** to current options based on:

- Overall efficacy
- Simple, standard nebulizer
- Favorable safety profile
- FDA approval

Savara 2024 Qualitative Research: N=10 US KOLs and high-volume pulmonologists; Quantitative research: N=78 HCPs

## U.S. PAYERS

**87%**

**Intend to cover MOLBREEVI with typical Prior Authorization criteria** when priced between $300-500K annually

**Not concerned about impact** on pharmacy budget

**Recognize the significant disease burden** associated with aPAP

Savara 2024 U.S. payer pricing and reimbursement research: N=10 representing ~88M covered lives

## U.S. PATIENTS

**100%**

**Think new, non-invasive PAP treatments are needed**

**WOULD ask their doctor to prescribe** MOLBREEVI

**WOULD take MOLBREEVI** if their doctor recommended it

Savara 2024 Patient Advisory Board meetings: N = 7 aPAP patients



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# Claims Data Analysis Suggests U.S. Market May Be 2x Larger

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# Europe (EU4+UK) Market Development is Underway

## TREATMENT CENTER MAPPING[1]

| Country | Key Centers[1] | Est. TAM[2] |
|---|---|---|
| Germany | 11 | ~1,100 |
| UK | 25 | ~900 |
| France | 24 | ~900 |
| Italy | 16 | ~700 |
| Spain | 12 | ~600 |
| **Total** | **88** | **~5,000** |

aPAP Centers of Excellence identified (8)

aPAP ClearPath™ antibody test expected to launch in Europe by end of 2024

62 EU patients enrolled in IMPALA-2 open label extension study*

[1] Savara 2024 EU4+ UK Primary (N= 6 EU4+ UK Principal Investigators, 5 EU4+UK Lab Directors) and Secondary Market Research;
[2] Data from 2023 U.S. Insurance Claims Analysis conducted by Savara and extrapolated based on geographic population
[3] Enrolled across 15 IMPALA-2 sites in the EU, UK, and Turkey



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# MOLBREEVI: Commercial Opportunity

## Significant Unmet Need

- High disease burden
- No FDA approved therapies
- Whole lung lavage is invasive, not standardized, and minimally used


## MOLBREEVI

- Clinically meaningful benefit
- Strong stakeholder interest
- Orphan drug pricing potential
- Chronic dosing

## Efficient Rare Disease Model

- Small customer facing footprint
- Exclusive pharmacy network
- Regional expansion optionality (go-it-alone, partnership, etc.)

## Long Term Exclusivity

- 12-year biologic exclusivity (U.S.)
- Biosimilar competition unlikely



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# Financials

# Financial Highlights

- **Cash runway through 2Q 2027**
  - ~$219M in cash, cash equivalents and short-term investments*
- **Strong investor support with coverage from 7 equity research analysts**

## ANALYST COVERAGE

| | |
|---|---|
| Jefferies | Andrew Tsai |
| Piper Sandler | Yasmeen Rahimi, PhD |
| Guggenheim Securities | Vamil Divan, MD, MBA |
| Oppenheimer | Francois Brisebois |
| JMP | Jonathan Wolleben |
| H.C. Wainwright | Andrew Fein |
| Evercore ISI | Liisa Bayko, MSC, MBA |

**As of 9/30/24*





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# Near- and Long-Term U.S. Market Opportunity in aPAP is Sizeable

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| **~3,700** | Large pool of likely patients that are currently undiagnosed |
| **Multiple** | Patents currently being prosecuted |
| **12-years** | Biologic exclusivity in U.S. upon approval |
| **Long-term** | Durable revenue stream with biosimilar competition unlikely |

**>$1B**

Potential
U.S. Opportunity

TAM = Total addressable market



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# Thank You

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