



Corporate Overview

Developing New Therapies *for* Rare Respiratory Diseases

October 2024



Safe Harbor Statement

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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*

Braden Parker
Chief Commercial Officer

Ray Pratt, M.D. FACP
Chief Medical Officer

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

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

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

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



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Potential
U.S. Opportunity

aPAP and MOLBREEVI* (molgramostim inhalation solution)

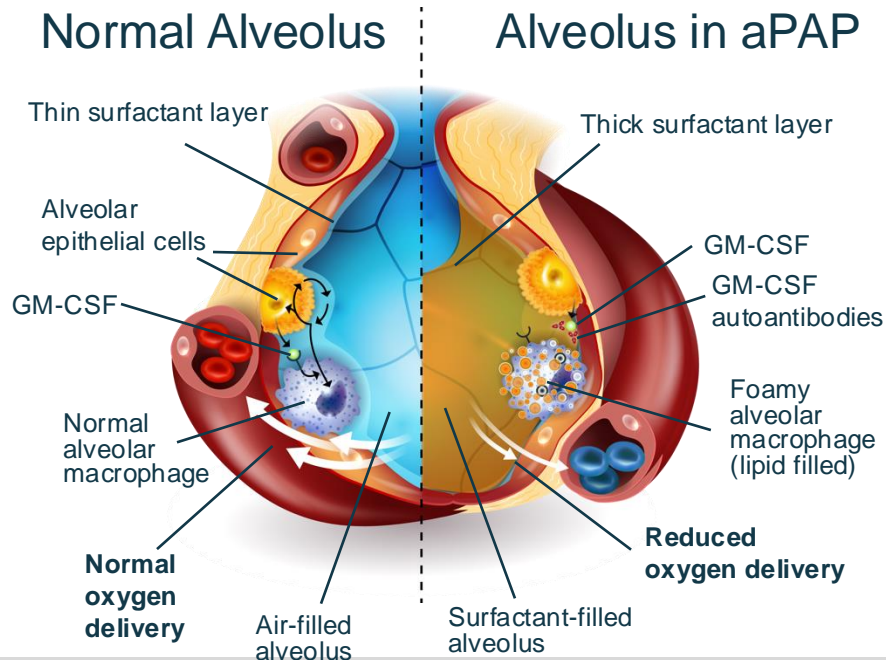
**FDA and EMA conditionally accepted trade name for molgramostim inhalation solution*

aPAP: An Autoimmune Disease of Alveolar Macrophage Dysfunction

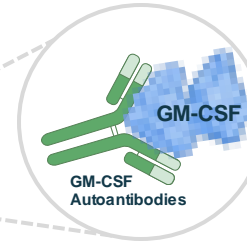
NORMAL LUNG FUNCTION

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



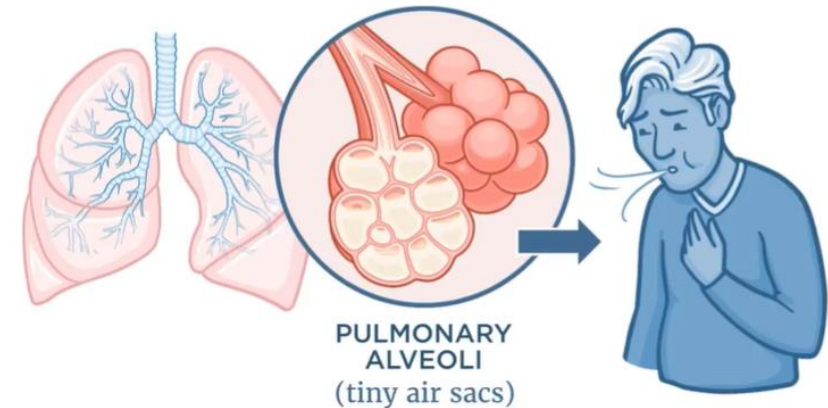
aPAP



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



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

Cough and Episodes of Fever



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

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

Fibrosis and Lung Transplant

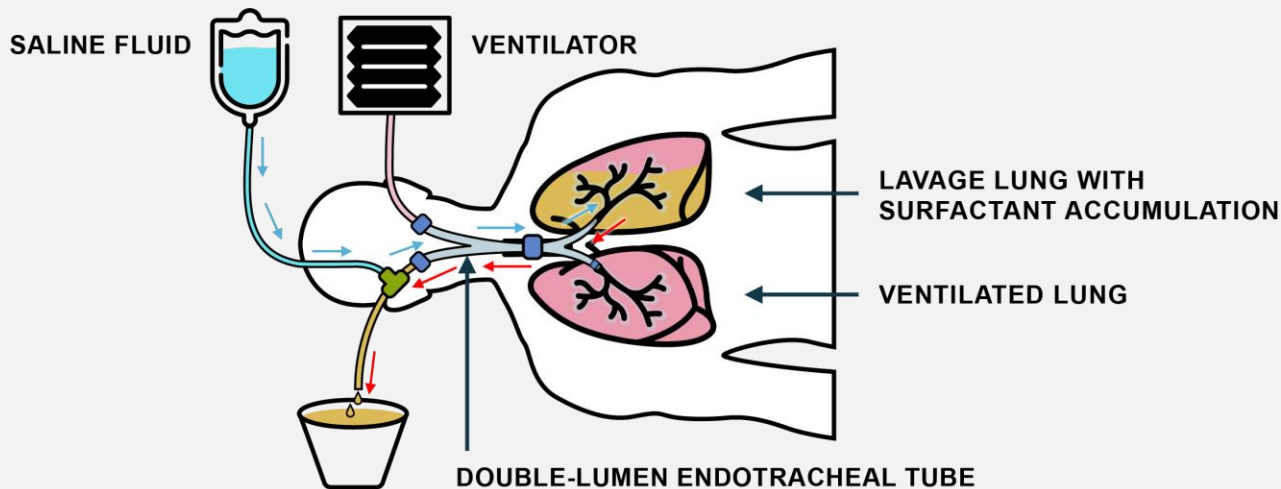


- In the long-term, the disease can lead to serious complications, including fibrosis, and may lead to the need for lung transplantation

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

- 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 μ g 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

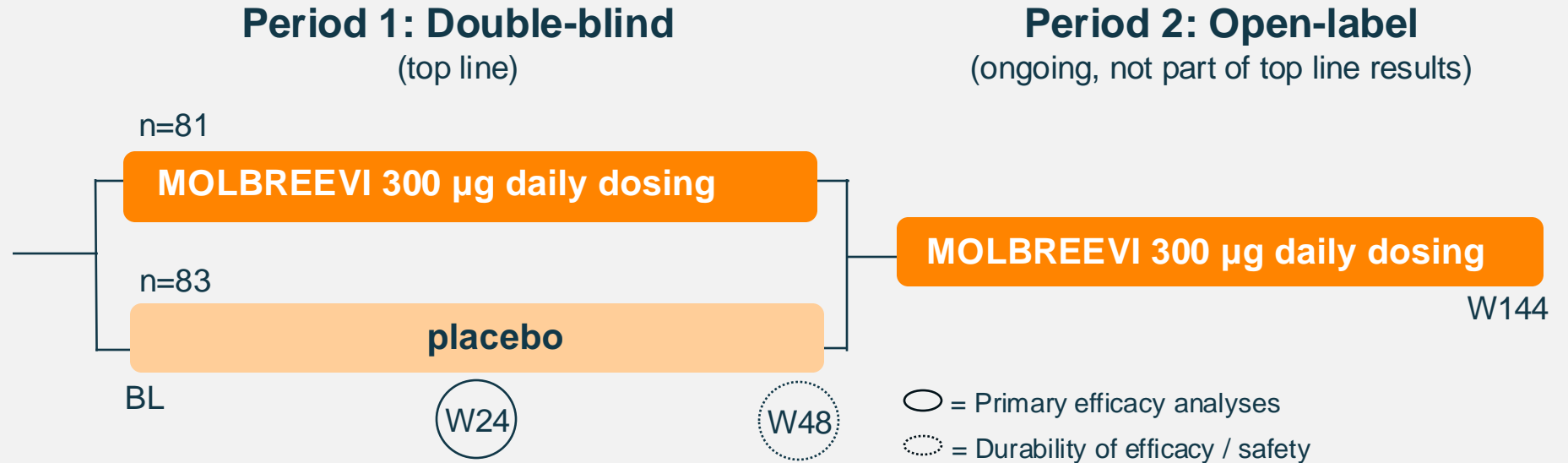


Phase 3 IMPALA-2 Top Line Results

Phase 3 IMPALA-2 Trial Design

6-Week Screening

- DLCO $\leq 70\%$ 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

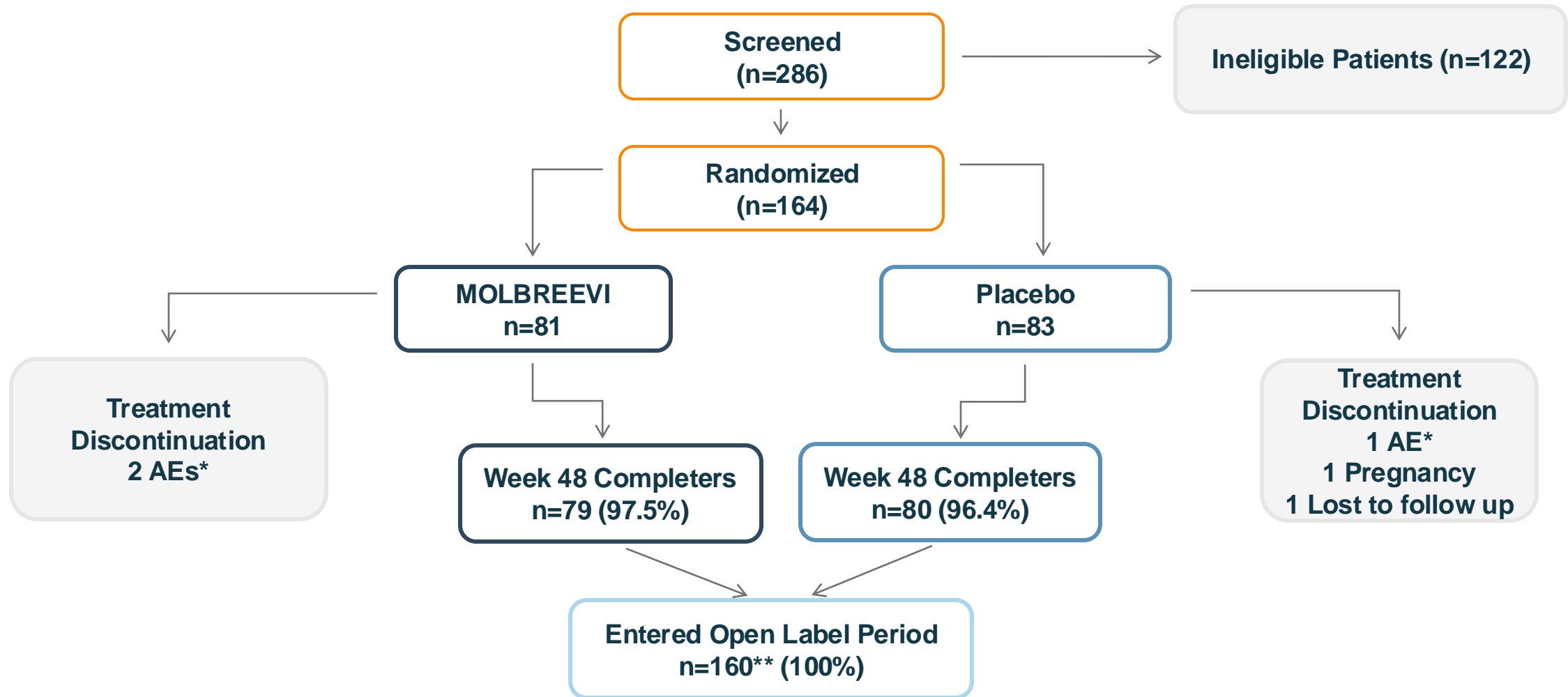
Change from baseline in:

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

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

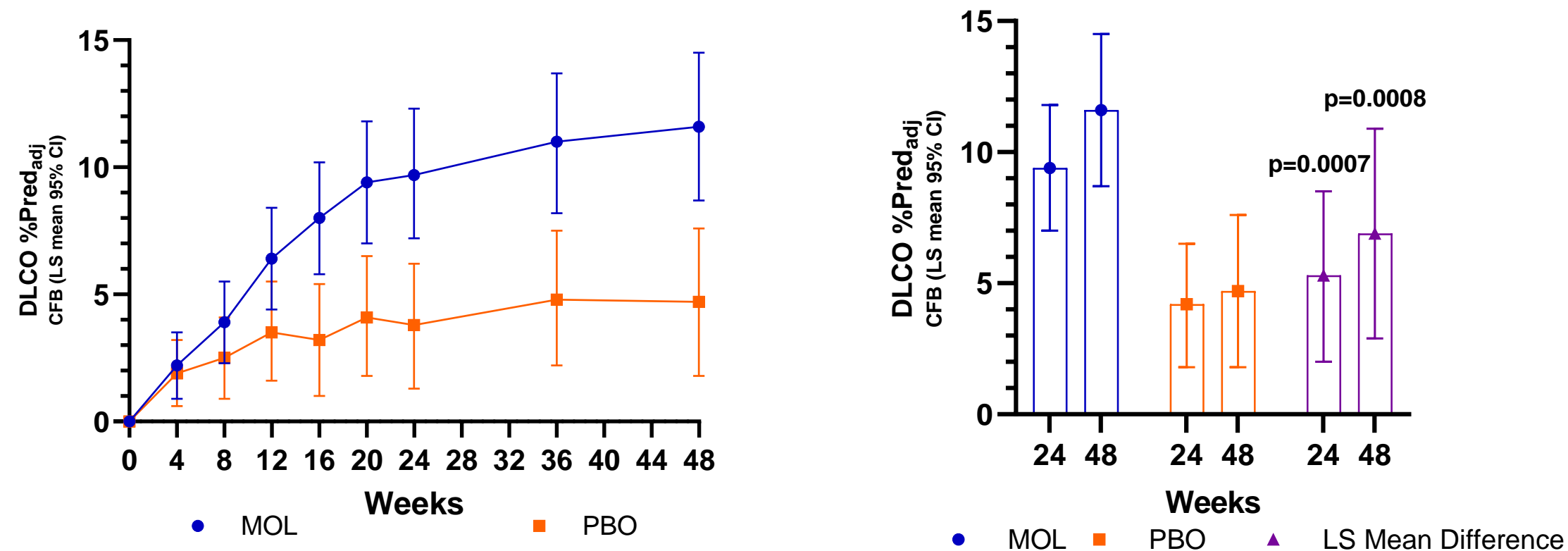
**One placebo patient stopped blinded trial drug but continued trial participation through Week 48 and entered the open label period

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	44 (54.3)	54 (65.1)
	Female	37 (45.7)	29 (34.9)
Race n (%)	White	38 (46.9)	40 (48.2)
	Asian	36 (44.4)	37 (44.6)
	Black or African American	3 (3.7)	2 (2.4)
	Other	4 (4.9)	4 (4.8)
DLCO at baseline	Mean (SD)	52.6 (11.71)	52.6 (10.39)
DLCO stratification group	≤ 50%	31 (38.3)	32 (38.6)
	> 50%	50 (61.7)	51 (61.4)

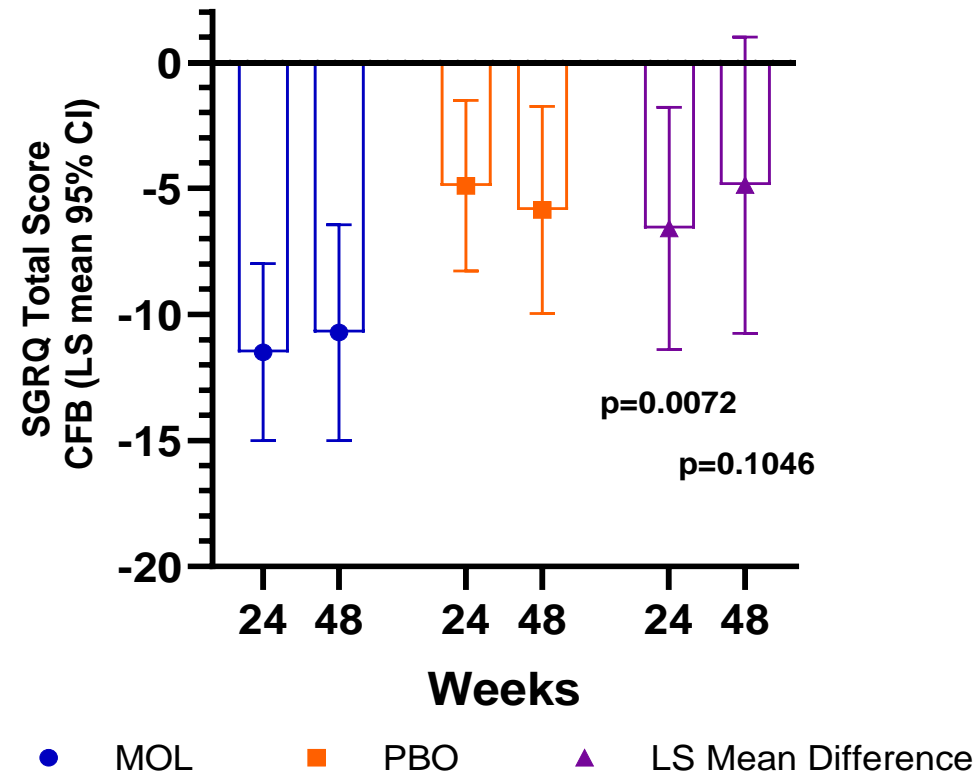
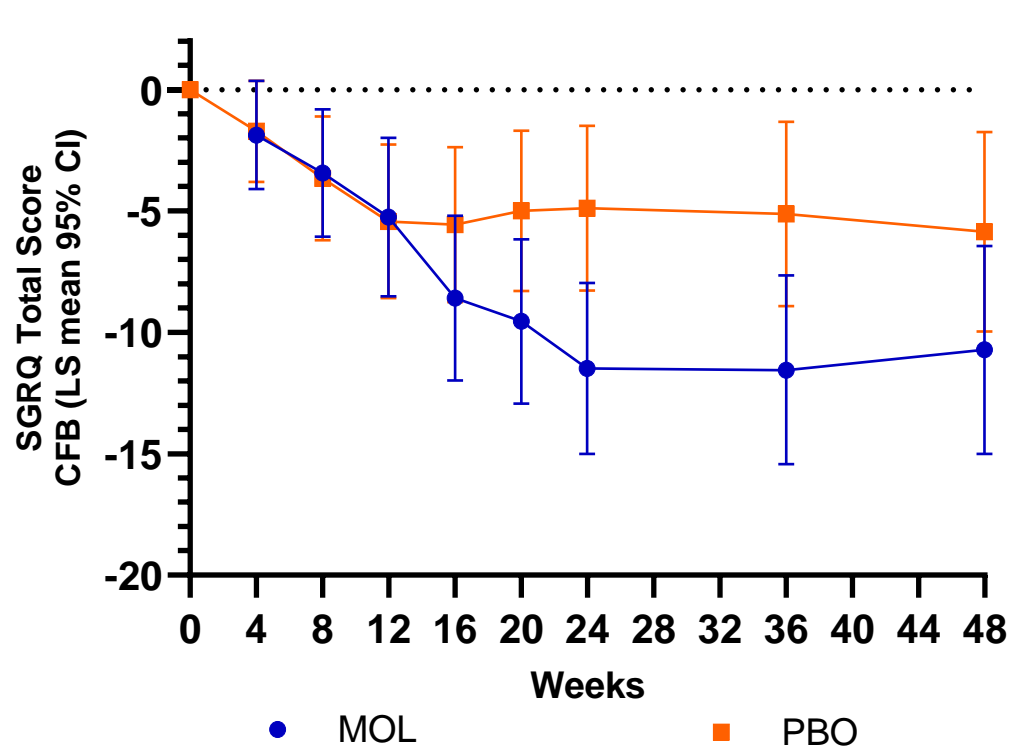
Primary Endpoint Met (DLCO): Achieved Statistical Significance

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



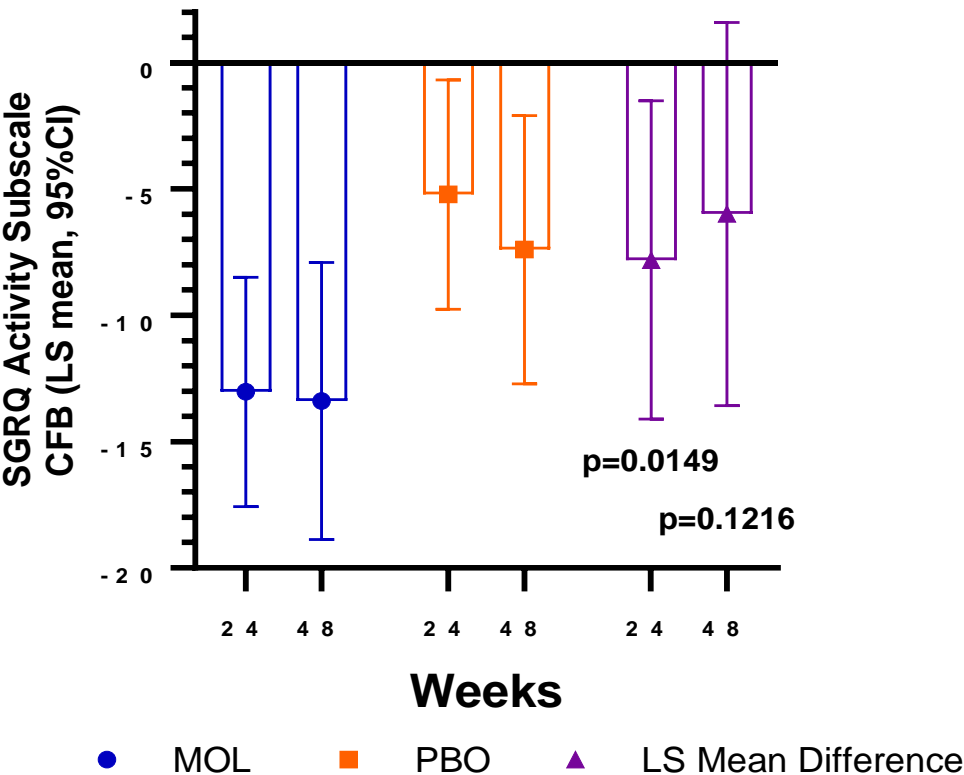
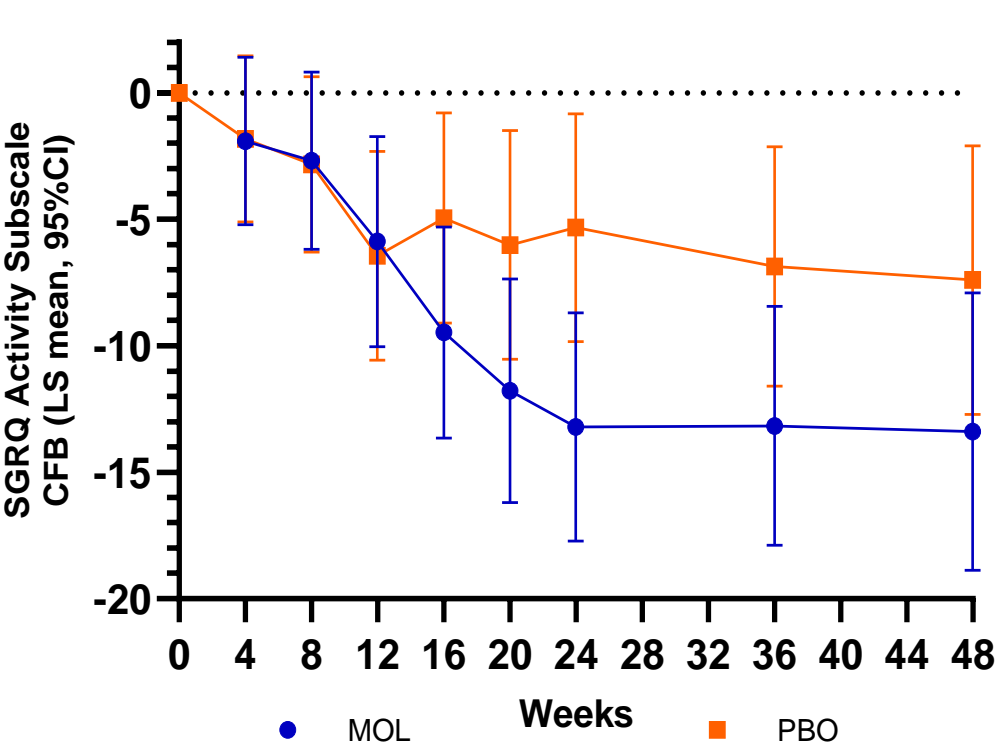
P-values are for Difference in LS Mean compared to PBO

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



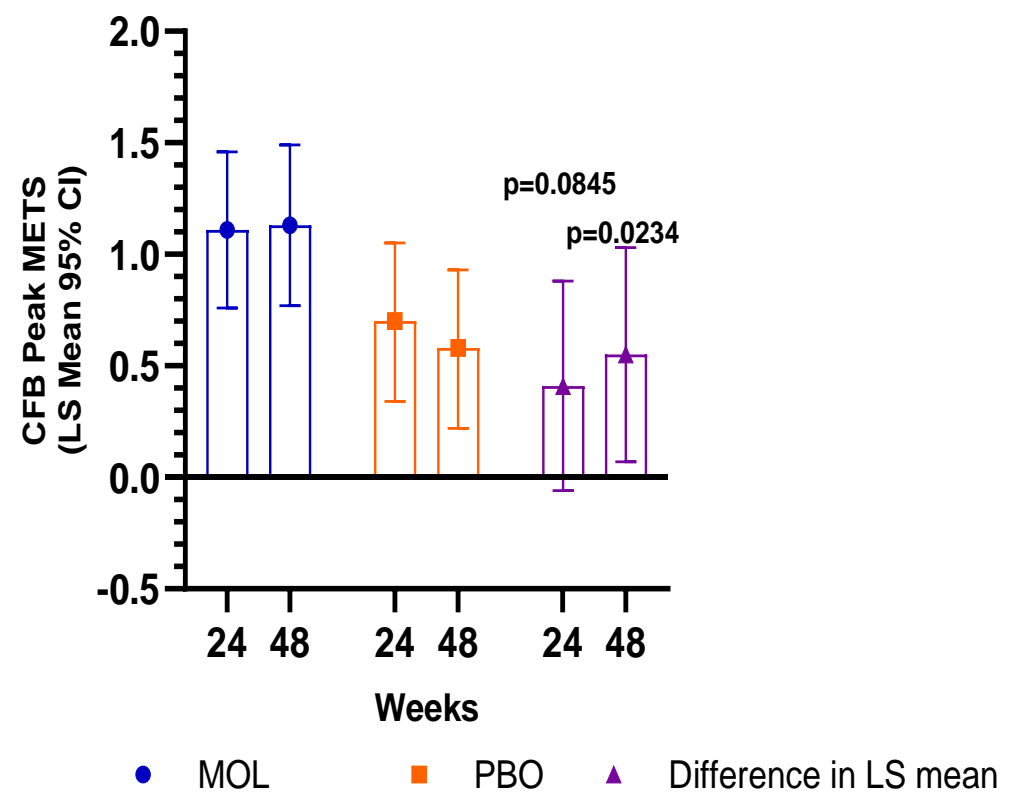
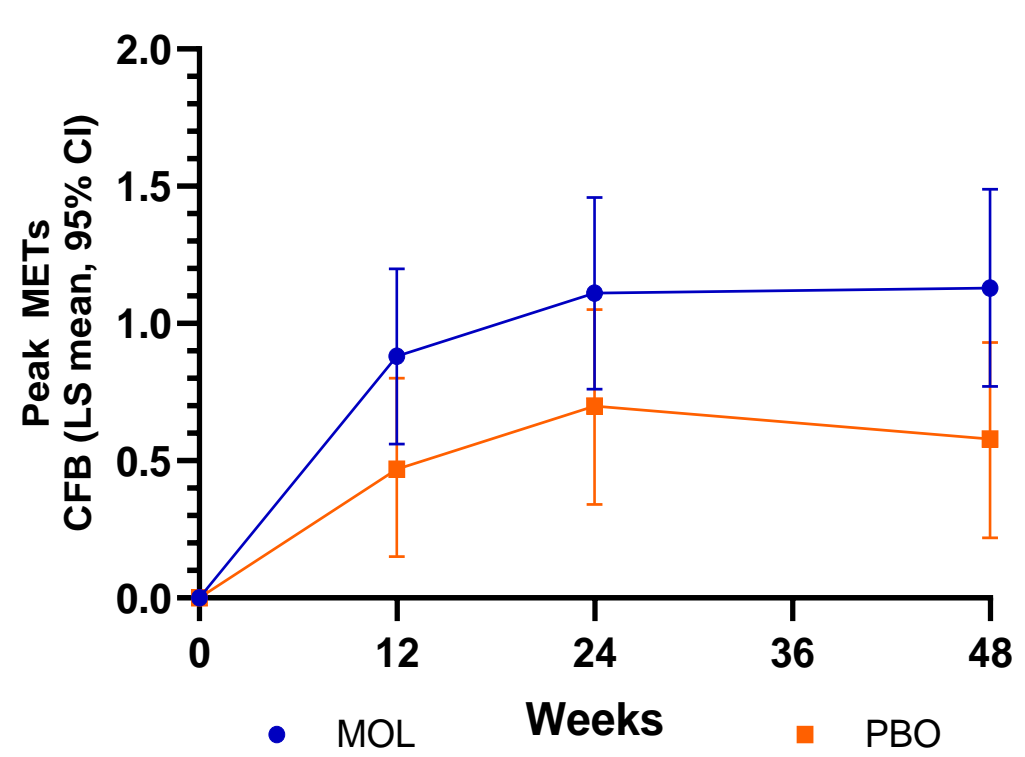
P-values are for Difference in LS Mean compared to PBO

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



P-values are for Difference in LS Mean compared to PBO

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



P-values are for Difference in LS Mean compared to PBO

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%)

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)

¹SAE 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.

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)

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

	Measure	Timeframe	P-Value / Results
Pulmonary gas exchange	DLco%	Week 24 Week 48	0.0007 0.0008
	Disease Severity Score (DSS)	Week 24 Week 48	0.0239* 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 Week 48	0.0072 0.1046
	SGRQ Activity Score	Week 24 Week 48	0.0149† 0.1216
	Responder Analysis – SGRQ Total	Week 24 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 Week 48	0.0845 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.

Regulatory and Intellectual Property

BLA Submission On Track for 1H 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

Commercial Outlook

U.S. Addressable Market is Sizeable with ~3,600 Diagnosed aPAP Patients

CONFIRMED DIAGNOSED aPAP PATIENTS¹



~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 aPAP¹

+1,400

Highly likely

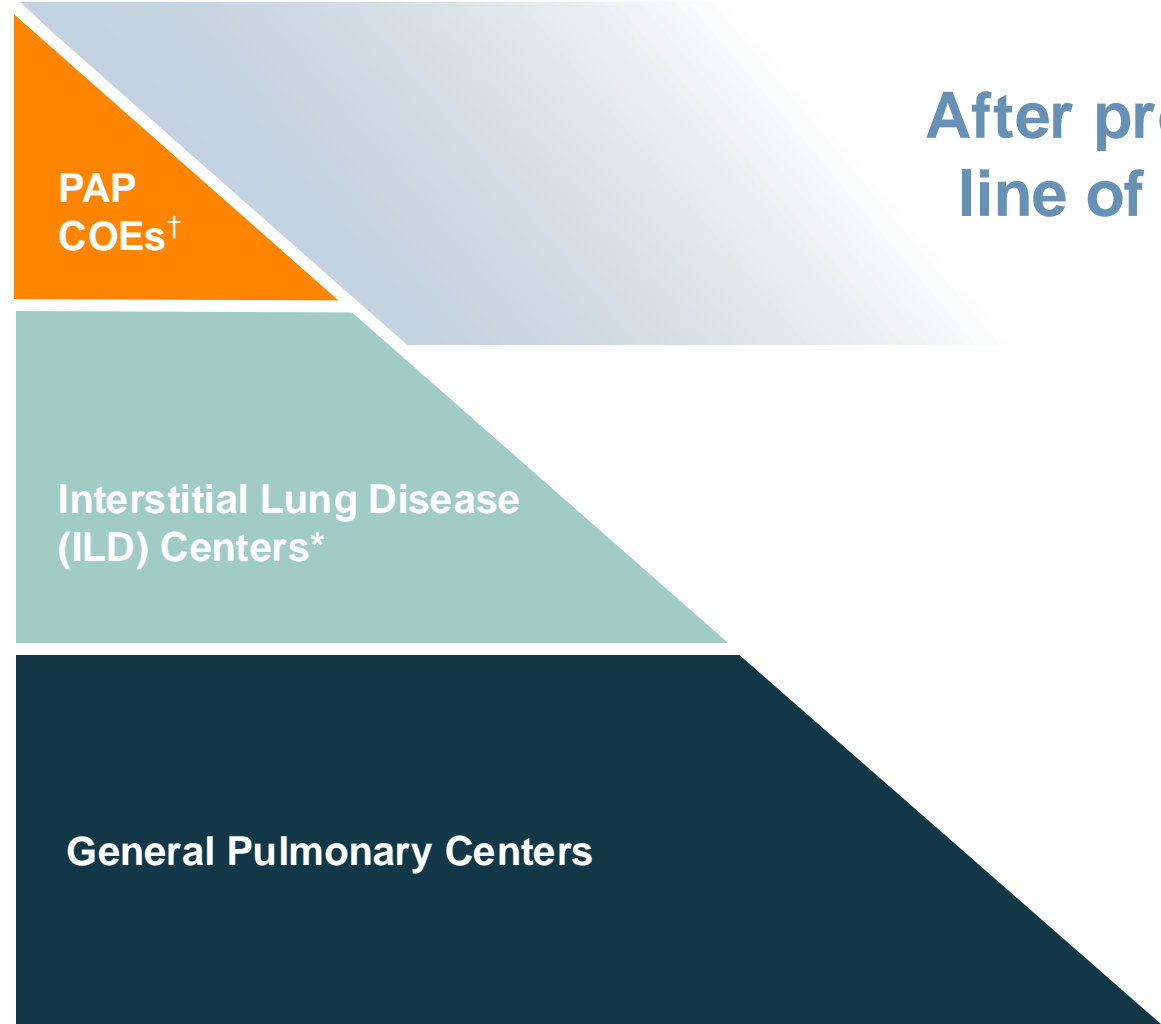
+2,300

Likely



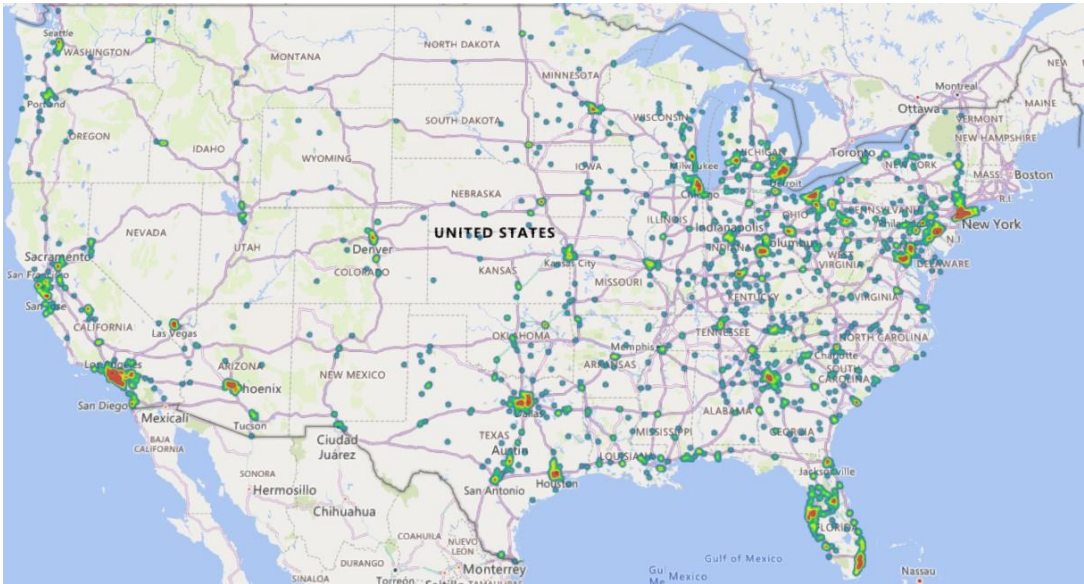
aPAP ClearPath Ab testing to confirm diagnosis

U.S. Centers Prioritized Based on Expertise and Experience Treating aPAP Patients



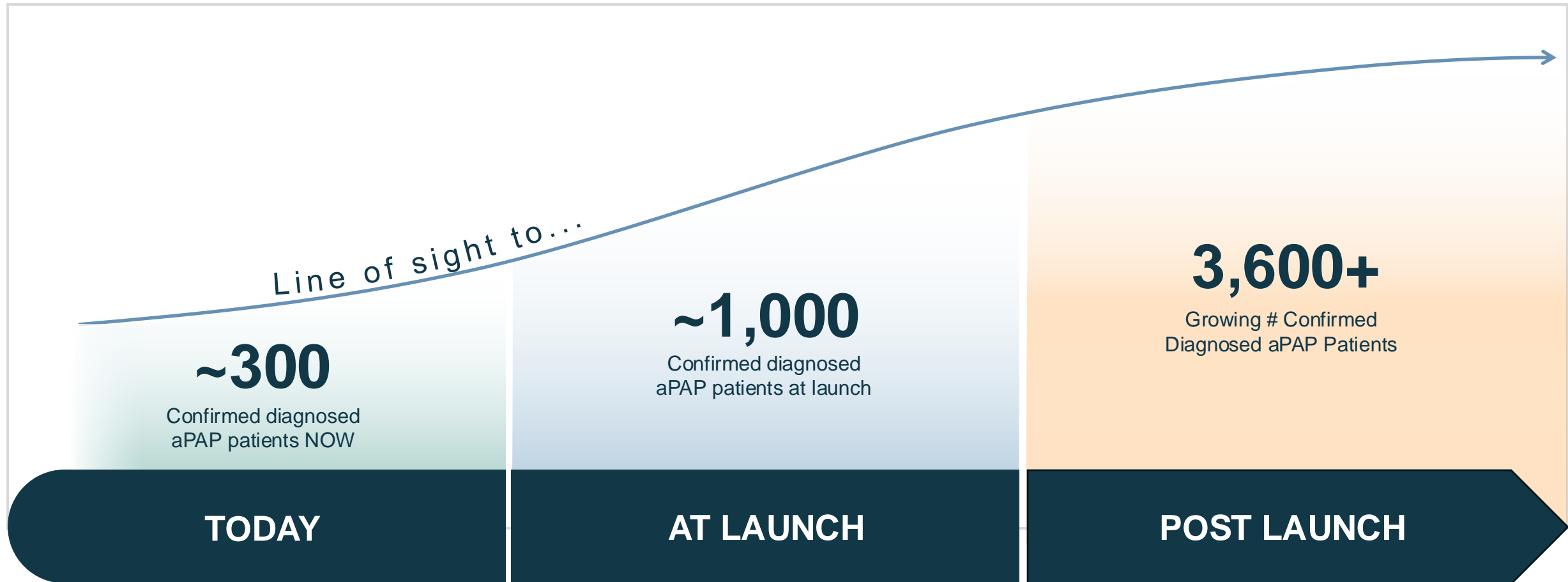
After profiling the first 29 centers, we have line of sight to ~300 aPAP patients today

U.S. PATIENTS/HCP HEATMAP¹



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

Goal: Line of Sight to ~1,000 U.S. Addressable aPAP Patients at Launch



Pulmonologists, Payers, and Patients Indicate Strong Interest in MOLBREEVI

U.S. PULMONOLOGISTS¹

83% Likely to prescribe MOLBREEVI

Willing to prescribe across severity segments

Rated performance of MOLBREEVI as superior to currently used treatments

U.S. PAYERS²

87% At \$300-500K annually, payers intend to cover MOLBREEVI with typical prior authorization criteria

Recognize aPAP disease burden as moderate to severe

Not concerned about impact on pharmacy budget

U.S. PATIENTS³

100% Think new, non-invasive PAP treatments are needed

Would ask their doctor to prescribe MOLBREEVI

Would take MOLBREEVI if doctor recommended it

Europe (EU4+UK) Market Development is Underway

aPAP TREATMENT CENTERS

Country	Target Centers (#) ¹	Estimated TAM ²
Germany	11	~1,100
UK	25	~900
France	24	~900
Italy	16	~700
Spain	12	~600
Total	88	~5,000

62 EU patients are currently enrolled in the IMPALA-2 open-label extension*

*Enrolled across 15 IMPALA-2 sites in the EU, UK, and Turkey

TREATMENT CENTER MAPPING¹



IDENTIFIED:
8 Tier-1 aPAP
Treatment
Centers

MOLBREEVI: Global Commercial Opportunity

Significant Unmet Need

- **High disease burden**
- **Strong market expansion potential** via disease awareness campaign, broad access to GM-CSF autoantibody testing

Rare Disease Infrastructure

- **Orphan disease-like infrastructure in U.S.** – field-based team of ~15-30
- **OUS commercial strategy optionality** – go-it-alone, regional partnerships, etc.



MOLBREEVI

- **WLL (standard of care) is invasive and not standardized**
- **Dosing expected to be chronic**, providing long-term revenue stream
- **Assumed pricing power consistent with recently approved orphan drug analogs** (i.e., in U.S. ~\$300-\$500K p/patient, p/year)

Long Term Exclusivity

- **12-year biologic exclusivity in the U.S. and biosimilar competition unlikely**

Financials

- **Cash runway through 2026**
 - ~\$215M in cash*
- **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

**Pro forma for cash, cash equivalents, and short-term investments as of 06/30/24, including July 2024 equity offering of \$94M (net).*

Financial Highlights

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
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Potential
U.S. Opportunity



Thank You

