



Corporate Overview

Developing New Therapies *for* Rare Respiratory Diseases

February 2023



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Executive Leadership Team

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

Dave Lowrance
Chief Financial & Administrative Officer

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

Ray Pratt, M.D. FACP
Chief Medical Officer

Peter Clarke, Ph.D.
EVP, Global Technical Operations

Scott Wilhoit
EVP, Global Commercial

Anne Erickson
SVP, Head of Global Business Operations

Charles LaPree
*SVP, Global Regulatory Affairs
and Quality Assurance*

Kate McCabe, J.D.
SVP, General Counsel



Pursuing Transformative Therapies for Rare Respiratory Diseases

Focused on single Phase 3 program: molgramostim nebulizer solution (molgramostim) in autoimmune pulmonary alveolar proteinosis (aPAP)

- Recombinant form of human granulocyte-macrophage colony-stimulating factor (GM-CSF)
- Favorable efficacy and safety data generated from the first IMPALA trial
- Pivotal Phase 3 trial underway – builds on key learnings from IMPALA

Seasoned management team

- Deep experience in the development and commercialization of rare respiratory therapeutics and pulmonary medicines

Capitalized through major clinical and regulatory milestones

- ~\$134M* in cash expected to fund company ~18-months beyond Phase 3 data read-out, beyond BLA filing, and through potential approval

Quality investor base

Investment Thesis



The molgramostim in aPAP clinical program has a high probability of success



As a novel inhaled biologic, molgramostim has the potential for a long-term, durable revenue stream



Significant global commercial opportunity



Strong balance sheet –funded through 2025

Molgramostim Key Highlights



June 2019: IMPALA clinical trial results

- Randomized, double-blind, 24-week, placebo-controlled trial
- Primary endpoint of alveolar-arterial oxygen gradient (A-aDO₂) not met
- Improvements in St. George's Respiratory Questionnaire (SGRQ) suggest molgramostim may improve health status in patients with aPAP

Sept. 2020: IMPALA results published in *New England Journal of Medicine*



Data demonstrating synchronous improvement across multiple outcome measures that reflect physiological, clinical, radiologic, and biochemical disease manifestations provide strong support for a beneficial treatment effect of molgramostim in aPAP

June-Aug. 2022: UK's Medicines and Healthcare Products Regulatory Agency (MHRA) awarded molgramostim Innovation Passport and Promising Innovative Medicine Designations



End of 2Q 2021: First patient dosed in Phase 3 IMPALA-2 Trial

- Randomized, double-blind, 48-week, placebo-controlled trial
- Informed by key learnings from IMPALA trial

Dec. 2019: FDA granted molgramostim Breakthrough Therapy Designation for aPAP



May 2016: Phase 1 clinical trial of molgramostim:

May 2016, presented results from randomized, double-blind, 7-day, placebo-controlled trial at American Thoracic Society (ATS)

← 2016

2019

2020

2021

2022

Q1

Q2

Q3

Q4

Q1

Q2

Q3

Q4

Q1

Q2

Q3

Q4

Q1


Q2

Q3

Q4

IMPALA-2 Key Milestones

- Expect top line data readout end of 2Q 2024
- Upon a successful trial, Company plans to submit regulatory applications in the US, UK, EU, and Japan

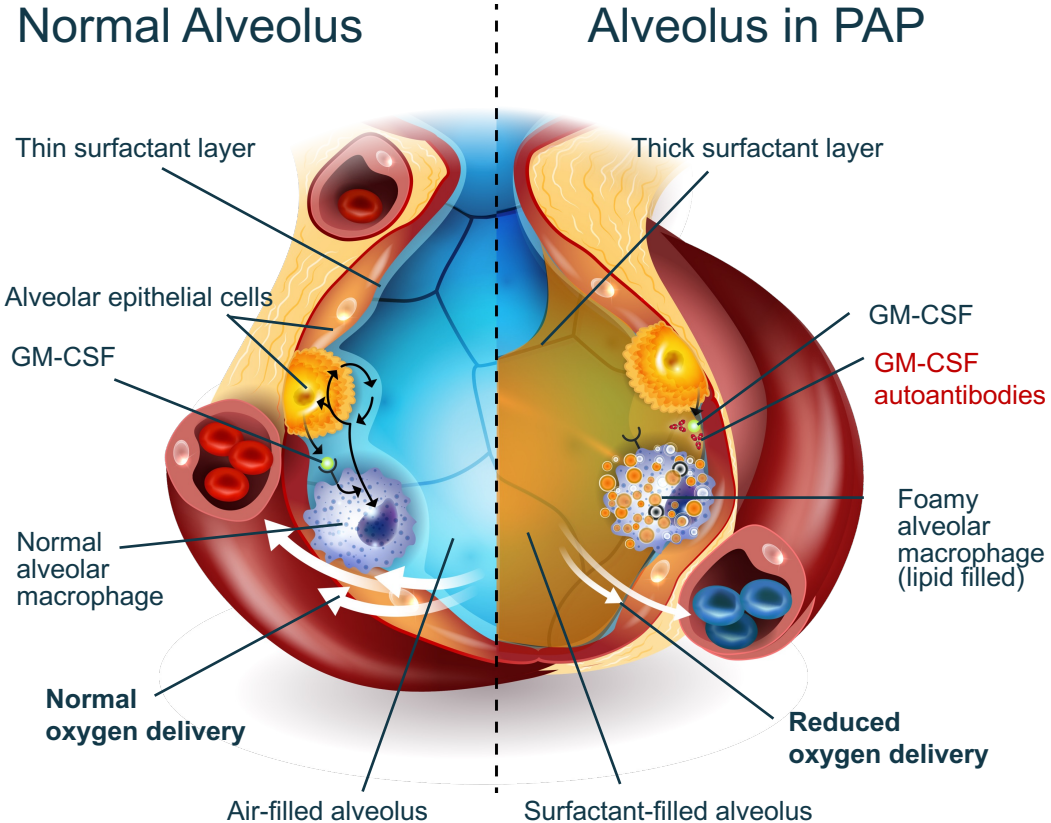


Company operations funded through 2025 (~18-months beyond anticipated IMPALA-2 top line results)

Molgramostim

Molgramostim for Autoimmune Pulmonary
Alveolar Proteinosis (aPAP)

aPAP: A Disease of Alveolar Macrophage Dysfunction



Alveolar macrophages

Need GM-CSF for maturation, expansion, and function (e.g., surfactant clearance)

GM-CSF

Critical to alveolar homeostasis, structure, function, and host defense

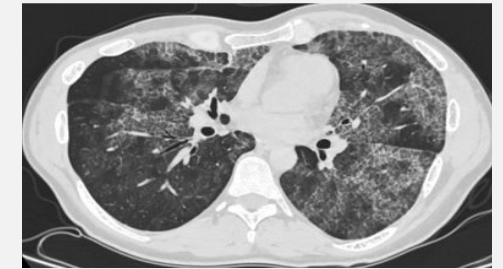
aPAP

Caused by GM-CSF autoantibodies which block GM-CSF signaling and reduce surfactant clearance

Surfactant accumulation causes altered gas exchange in the lung, reduced blood oxygenation and, ultimately, hypoxemic respiratory failure

aPAP PATIENT

Baseline
(Week 0)



After
Treatment
(Week 24)



From IMPALA trial

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

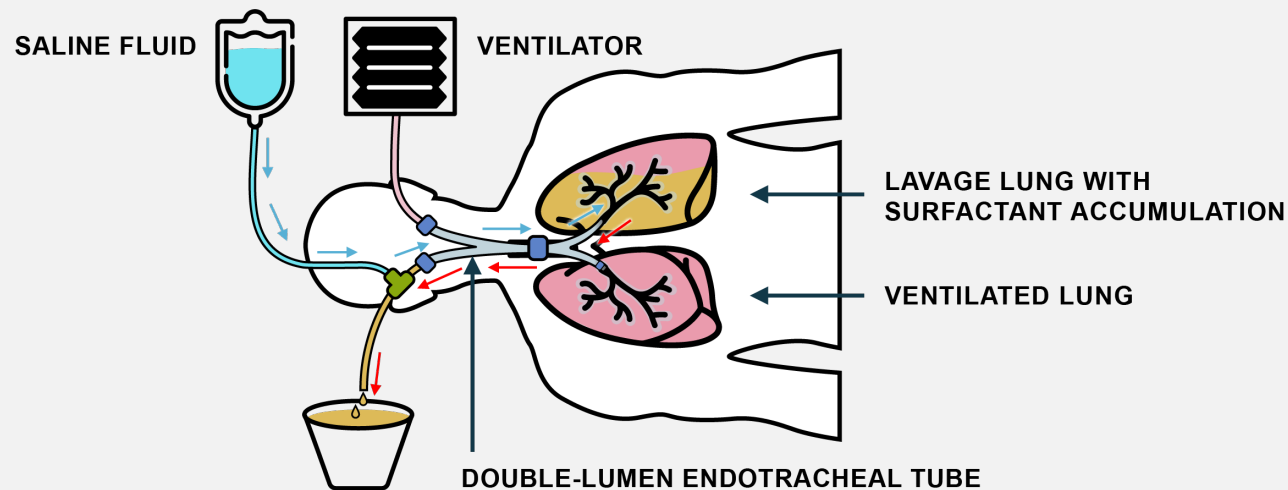
Fibrosis and Lung Transplant



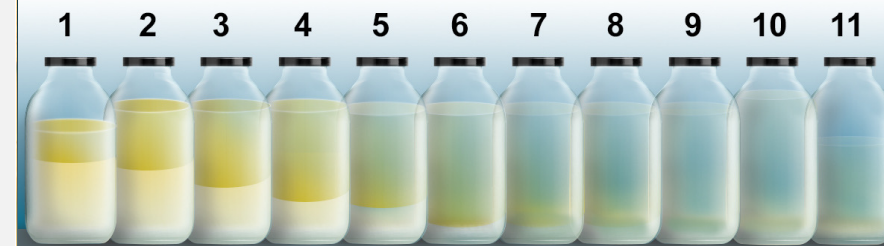
- In the long-term, the disease can lead to serious complications, including fibrosis, often leading to the need for lung transplantation

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

- Whole lung lavage is an invasive procedure to physically remove excess surfactant from the lungs and requires hospitalization
- Performed under general anesthesia by highly experienced physicians at certain sites



Whole Lung Lavage is a Highly 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.

Complications and Short-Comings of Whole Lung Lavage



Potential Complications

- Rib fracture
- Hypoxia
- Pneumothorax (collapsed lung)
- Hydrothorax (fluid in pleural cavity)
- Superimposed infection
- Acute Respiratory Distress Syndrome (ARDS)



Short Comings

- Treatment fails to address pathophysiology of disease
- Patients continue to experience symptomatic deterioration between procedures – and can require more than one whole lung lavage
- Rollercoaster ride of improvement and decline
- The procedure, performed under general anesthesia, is not standardized and remains highly operator-dependent

Journey to Diagnosis Can Be Long and Misdiagnosis is Common

Due to aPAP's rarity and associated non-specific symptoms, patients are often misdiagnosed with more common pulmonary illnesses (e.g., recurrent pneumonia, chronic bronchitis, COPD, asthma)

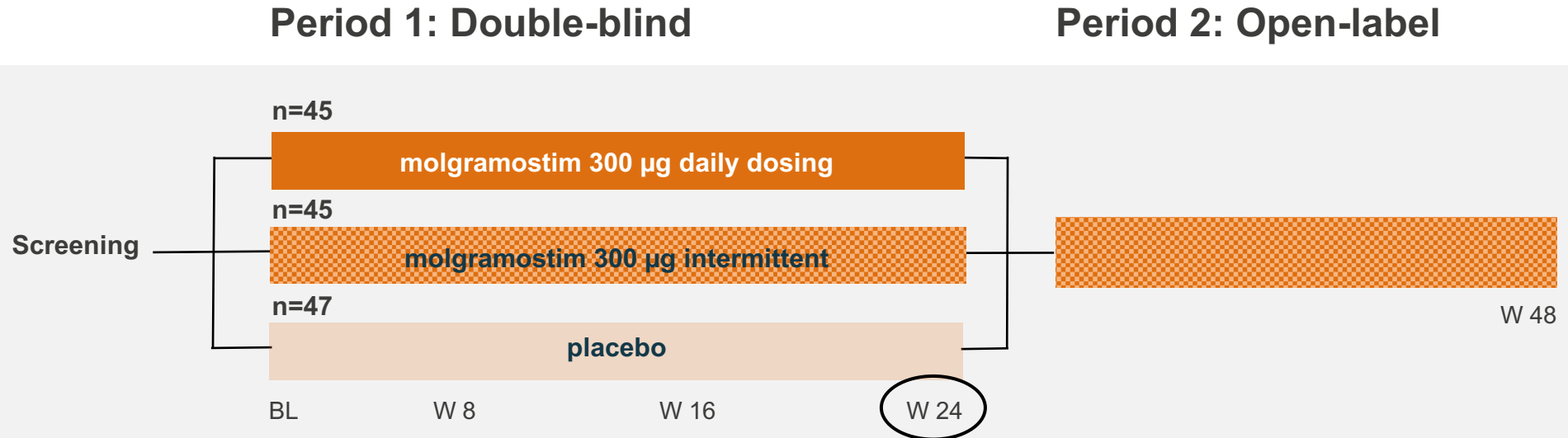


Diagnostic tests typically conducted to rule-out other more common pulmonary diseases:

- Imaging
- Pulmonary function tests
- Secondary PAP testing
- Transbronchial biopsy and cytological analysis of bronchoalveolar lavage fluid

IMPALA Clinical Trial Design

○ = Primary efficacy analyses



Primary Endpoint*

- Change from baseline in A-aDO₂

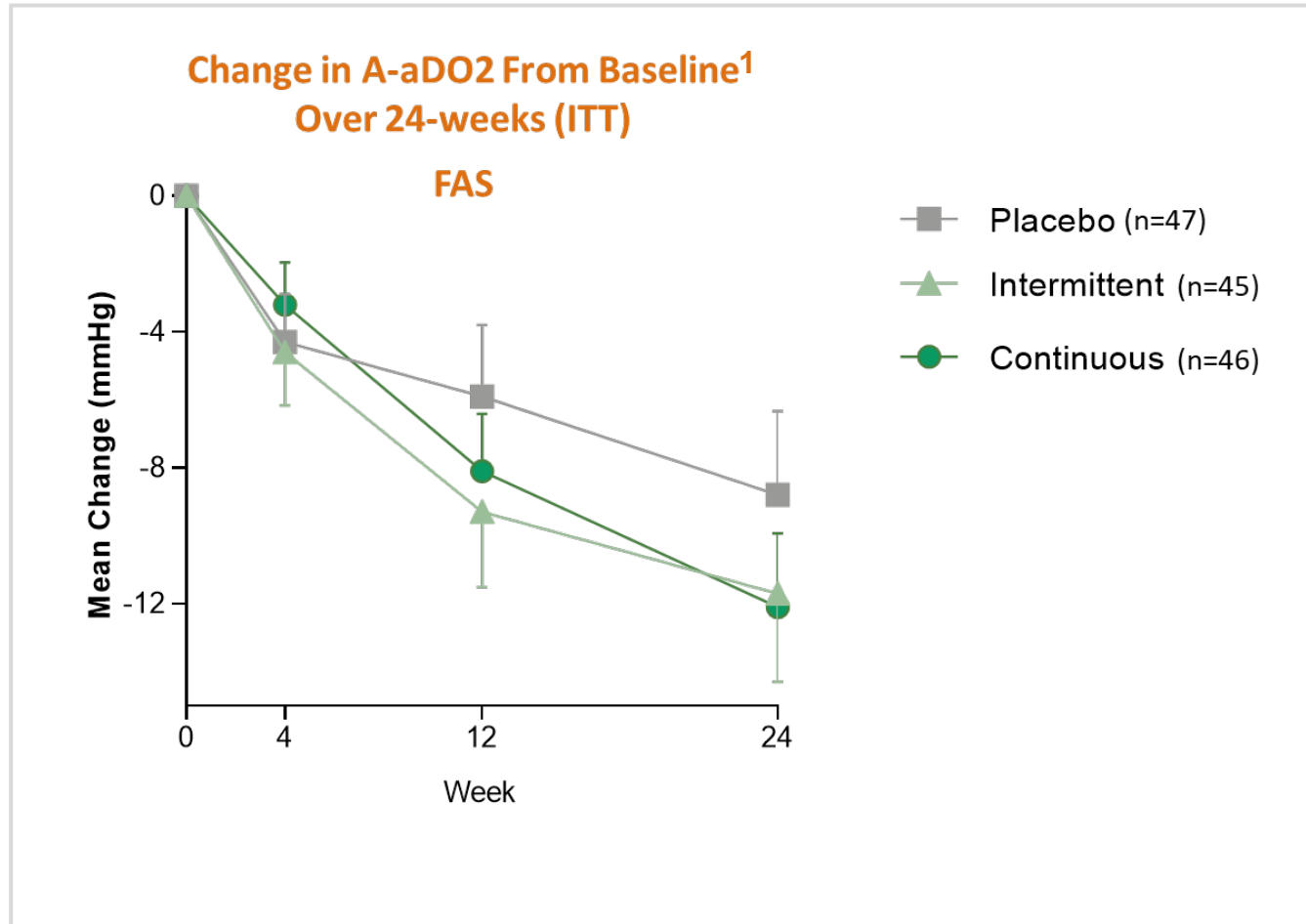
Secondary Endpoints**

- 6-minute walk distance
- SGRQ
- Time to whole lung lavage/requirement for whole lung lavage

*Primary analysis: Continuous dose vs. placebo

**Secondary endpoints: Analyzed in parallel and corrected for multiplicity

IMPALA Trial Did Not Meet the Primary Endpoint



1: Trapnell, Inhaled Molgramostim Therapy in aPAP, NEJM, 2020.

Continuous Once Daily Dosing Regimen (OD)

Full Analysis Set (FAS)*
Estimated treatment difference of
-4.6 mmHg (p=0.17)

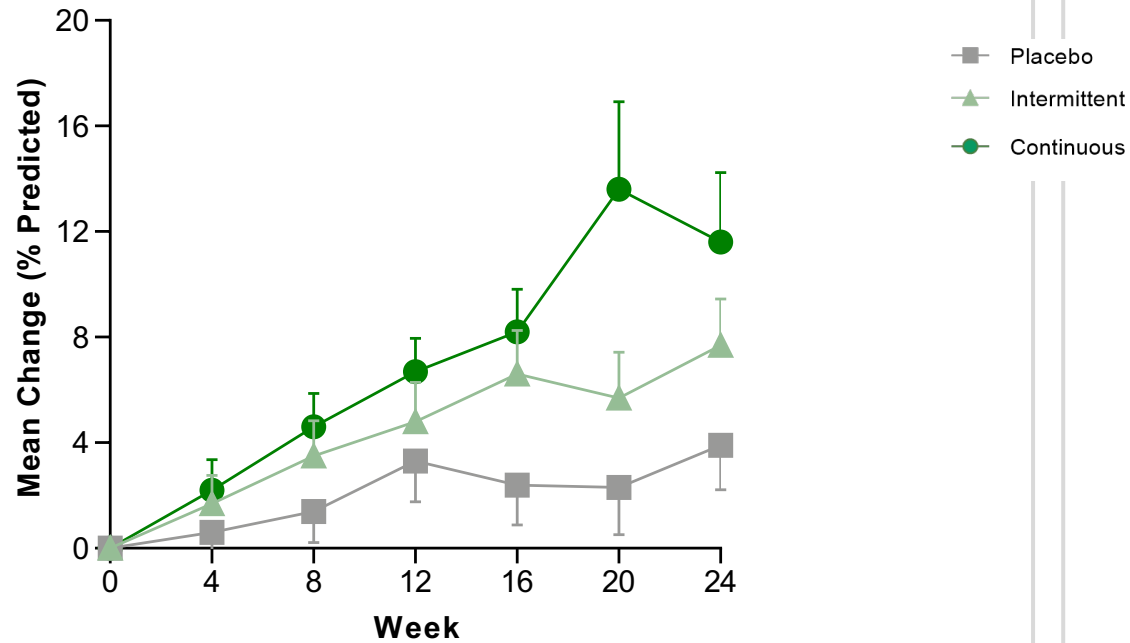
Revised FAS†
Estimated treatment difference of
-6.5 mmHG (p=0.025)

*Protocol specified analysis (ITT).

†Revised analysis excludes 4 patients using supplemental oxygen during testing (placebo: n=2, intermittent: n=1, continuous: n=1).

IMPALA: DLCO and SGRQ Showed Robust Improvement with Continuous Once Daily (OD) Dosing Regimen

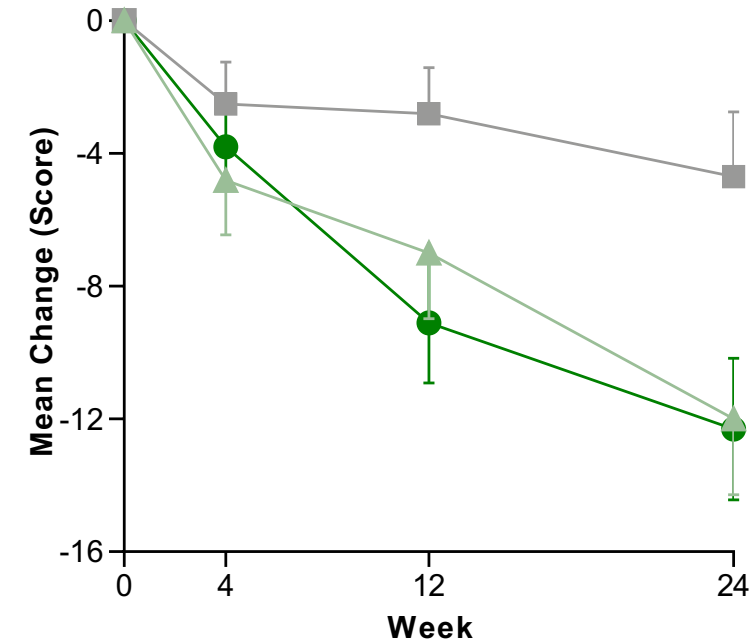
Change in Diffusion Capacity for Carbon Monoxide (DLCO) From Baseline Over 24-weeks¹ (FAS)



OD estimated treatment difference of 7.9% predicted (p=0.007)

IMPALA-2 Primary Endpoint

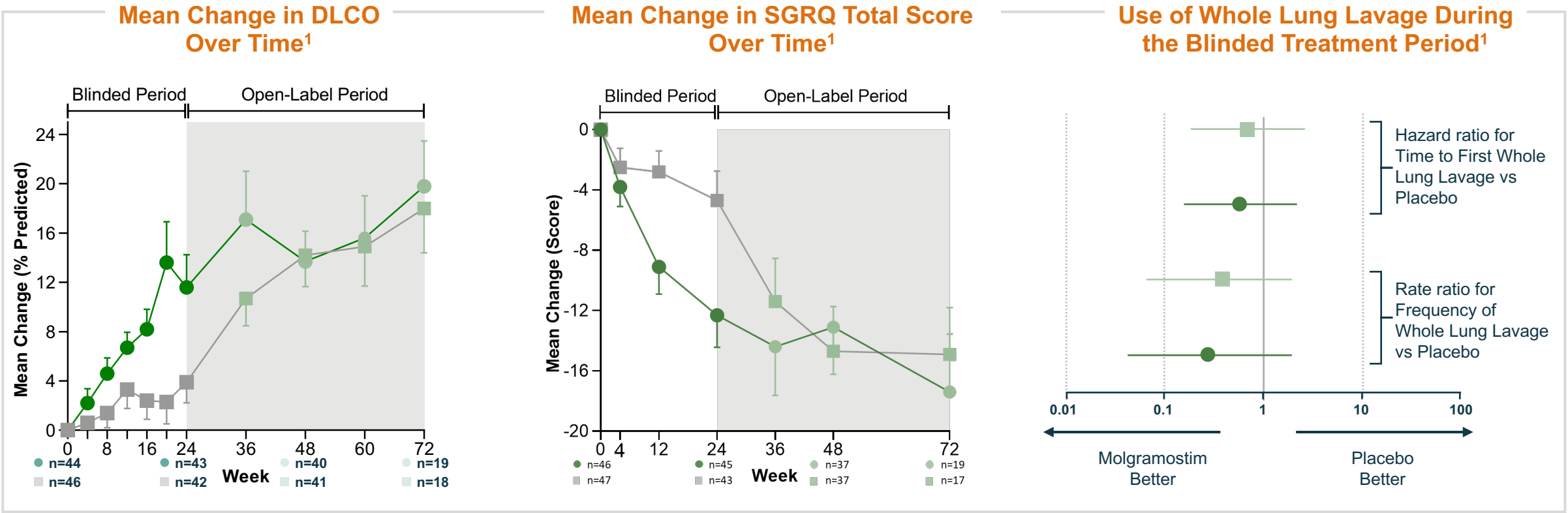
Change in St. George's Respiratory Questionnaire (SGRQ) From Baseline Over 24-weeks¹ (FAS)



OD estimated treatment difference of 7.6 points (p=0.01)

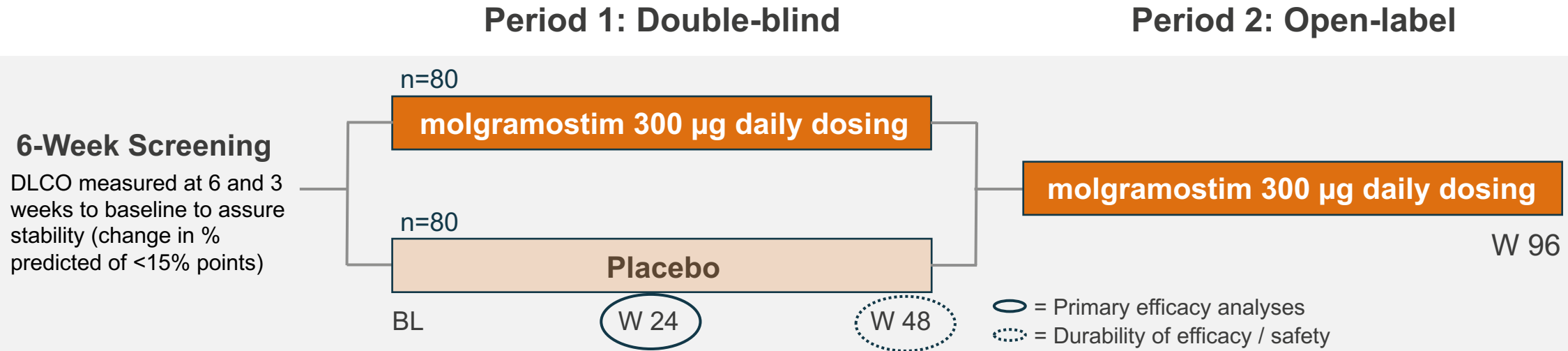
IMPALA-2 Secondary Endpoint

IMPALA Open-Label Data Show Sustained Effect, or Continued Improvement, after Longer-Term Drug Exposure



Dosing schedules for blinded and open-label periods were different.
All patients received intermittent molgramostim during open-label period.

Phase 3 IMPALA-2 Trial Design Leverages Key Learnings from IMPALA



Primary Endpoint

- Change from baseline in DLCO
 - 90% powered to detect 5.7% predicted difference with standard deviation of 11

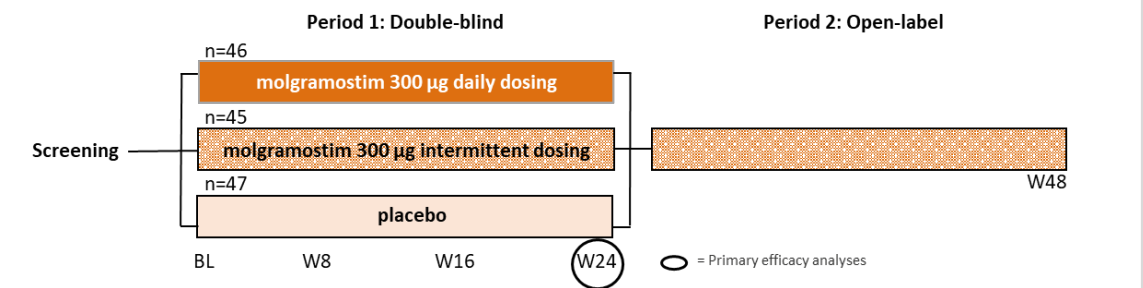
Secondary Endpoints

- SGRQ Total Score
- SGRQ Activity Score
- Exercise capacity using treadmill test

IMPALA-2 is being conducted at ~50 sites across ~18 countries. Patients needing whole lung lavage will have procedure prior to screening.

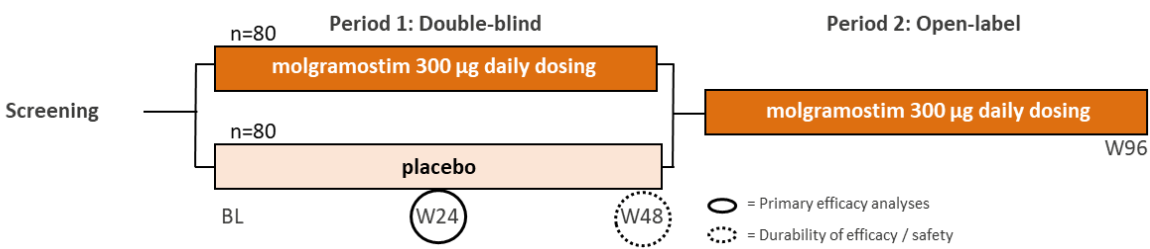
Clinical Trial Design: IMPALA vs. IMPALA-2

IMPALA



PRIMARY ENDPOINT: (surrogate endpoint)	Gas Exchange: A-aDO ₂
SECONDARY ENDPOINTS: (direct patient benefit)	SGRQ Total 6-minute walk distance Whole lung lavage
DEVICE:	Pari e-Flow Nebulizer System
NUMBER OF TRIAL SITES:	34
GEOGRAPHIES:	18 countries N. America, Europe, Japan, S. Korea
ENROLLMENT DURATION:	~32 months
SUPPLEMENTAL OXYGEN:	Allowed as background and during efficacy measure (n=4)
DISEASE SEVERITY:	Stable moderate to severe disease

IMPALA-2



PRIMARY ENDPOINT: (surrogate endpoint)	Gas Exchange: DLCO
SECONDARY ENDPOINTS: (direct patient benefit)	SGRQ Total SGRQ Activity Exercise capacity test using treadmill
DEVICE:	Pari e-Flow Nebulizer System
NUMBER OF TRIAL SITES:	~50
GEOGRAPHIES:	~18 countries N. America, Europe, Japan, S. Korea
ENROLLMENT DURATION:	~20 months
SUPPLEMENTAL OXYGEN:	Allowed as background, NOT during efficacy measure
DISEASE SEVERITY:	Stable moderate to severe disease

Molgramostim Regulatory Landscape

MOLGRAMOSTIM IN aPAP REGULATORY DESIGNATIONS

- Orphan Drug Designation, Europe (eligible for 10 years exclusivity)
- Orphan Drug Designation, US (eligible for 7 years exclusivity)
- Fast Track Designation, US
- Breakthrough Therapy Designation, US
- Innovation Passport Designation, UK
- Promising Innovative Medicine Designation, UK

IMPALA-2

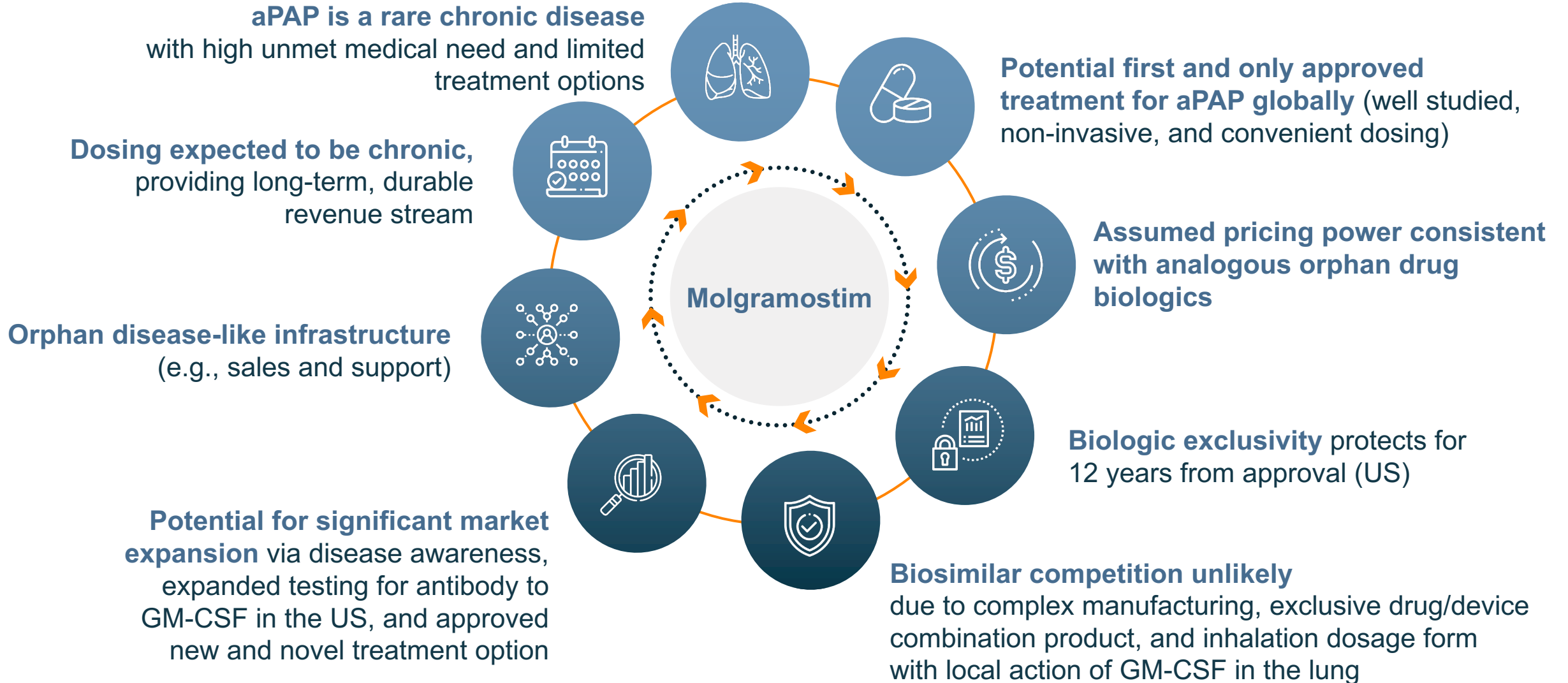
- Trial design endorsed by regulatory authorities in the US, Canada, Japan, South Korea, and the countries in Europe where the trial is being conducted

BIOLOGIC EXCLUSIVITY

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

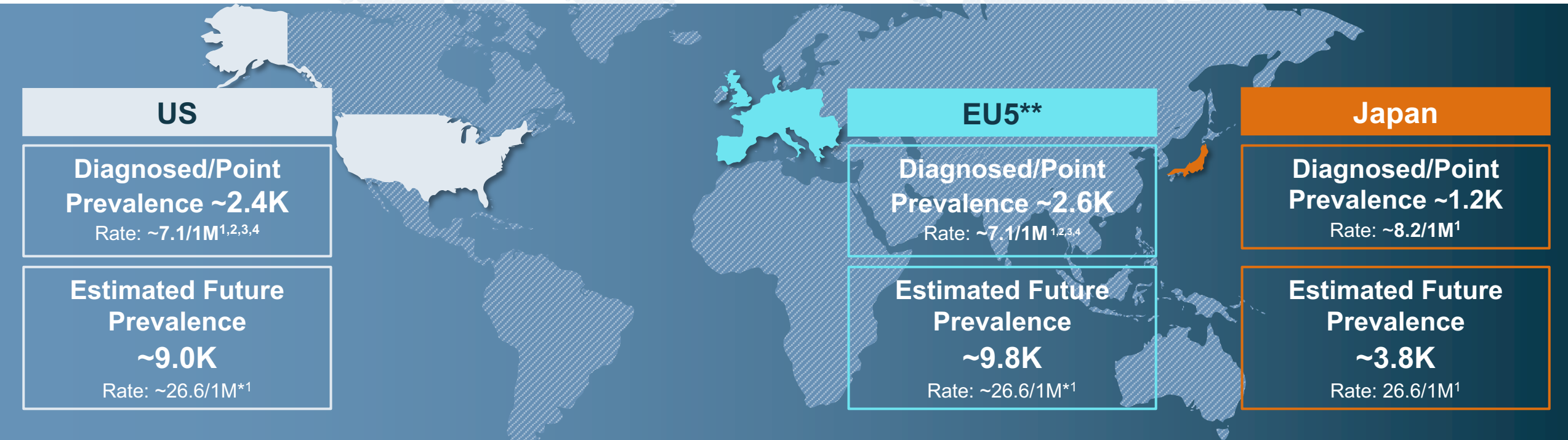
Commercial Outlook

Significant Global Commercial Opportunity



Current Market Opportunity is Robust and has Significant Potential for Growth

Current projected patient population is **~6K**. With increased anti-GM-CSF antibody testing, the potential addressable population could be **greater than 20K**



Diagnosed prevalence expected to grow given anticipated increased awareness and market shaping efforts with a new approved agent

Sources: 1. Kitamura et al (2019); 2. McCarthy et al, (2018); 3. Medicare FFS and IBM MarketScan (2019) - Trinity EvidenceFirst Analysis; 4. Campo et al, (2013); *High diagnosed prevalence rate in the Niigata region (Kitamura et al., 2019 - 26.6/1M) of Japan can be used as a proxy for true prevalence given high rates of GM-CSF antibody testing

**EU5: France, Germany, Italy, Spain, UK

In Japan, a Simple Blood Antibody Test is Routinely Performed to Diagnose aPAP



- Research advances have led to the development of a highly effective, simple blood test that can diagnose aPAP
- 100% sensitivity and 100% specificity
- Distinguishes aPAP from other respiratory diseases
- Not yet widely available in the US and EU
- Once widely available in the US and EU, it could improve accuracy and reduce time to diagnosis

Analog: Pulmozyme® (dornase alpha)

Pulmozyme®

- Prototype inhaled biologic
- Approved by the FDA in 1993
- No biosimilar available

Pulmozyme is a registered trademark of Genentech

Financials

- **Well capitalized**
 - ~\$134M in cash (as of 9/30/22)
 - Cash **runway extends ~18-months** beyond anticipated IMPALA-2 top line results
- **Strong investor support with coverage from 6 equity research analysts**

ANALYST COVERAGE

Evercore ISI	Liisa Bayko, MSC, MBA
H.C. Wainwright	Andrew Fein
Jefferies	Suji Jeong, PhD
Ladenburg Thalmann & Co.	Michael Higgins
Oppenheimer	Francois Brisebois
Piper Sandler	Yasmeen Rahimi, PhD

Financial Highlights

Investment Thesis



The molgramostim in aPAP clinical program has a high probability of success



As a novel inhaled biologic, molgramostim has the potential for a long-term, durable revenue stream



Significant global commercial opportunity



Strong balance sheet –funded through 2025



Thank You

