Molgramostim for the Treatment of Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP): Long-term Efficacy and Safety Results from the Open-Label Period of the IMPALA-2 Phase 3 Clinical Trial

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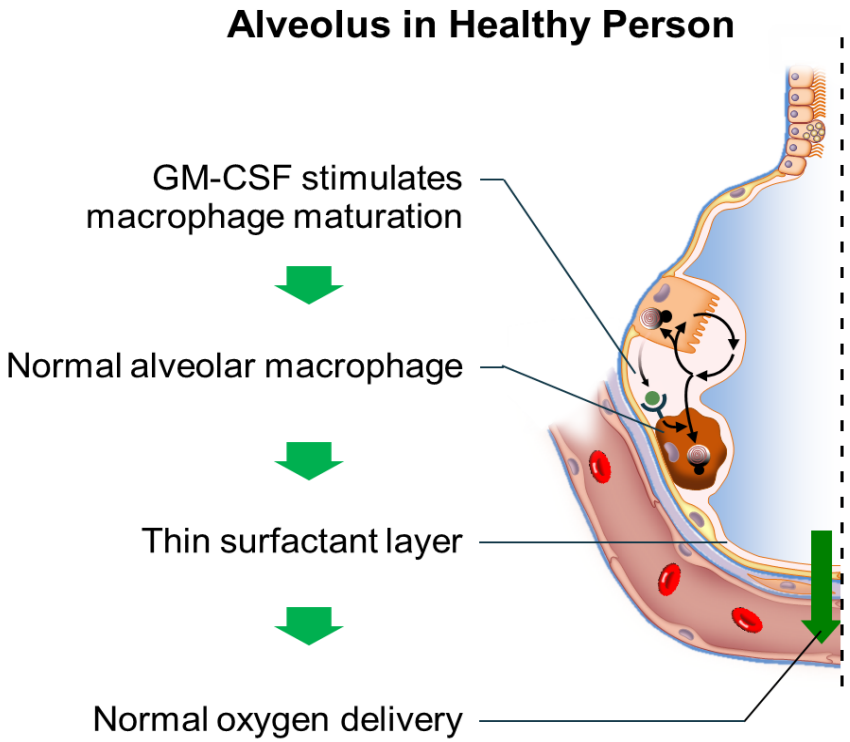
- I have been a consultant for Partner Therapeutics and Savara Inc.
- I have an unpaid role as a Scientific Director and Board Chairman at the PAP Foundation.
- The IMPALA-2 clinical trial is sponsored by Savara Inc.

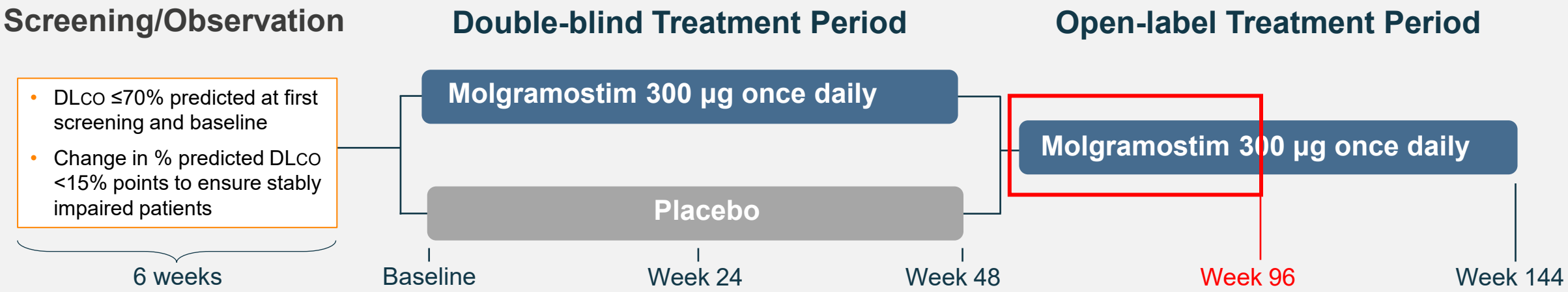
Autoimmune Pulmonary Alveolar Proteinosis (aPAP): Pathogenesis



Molgramostim inhalation solution is a recombinant human GM-CSF in development for the treatment of aPAP

GM-CSF, granulocyte-macrophage colony-stimulating factor.

IMPALA-2: Phase 3 Clinical Trial of Molgramostim in aPAP



Here we report data from the first 48 weeks of the 96-week open-label treatment period

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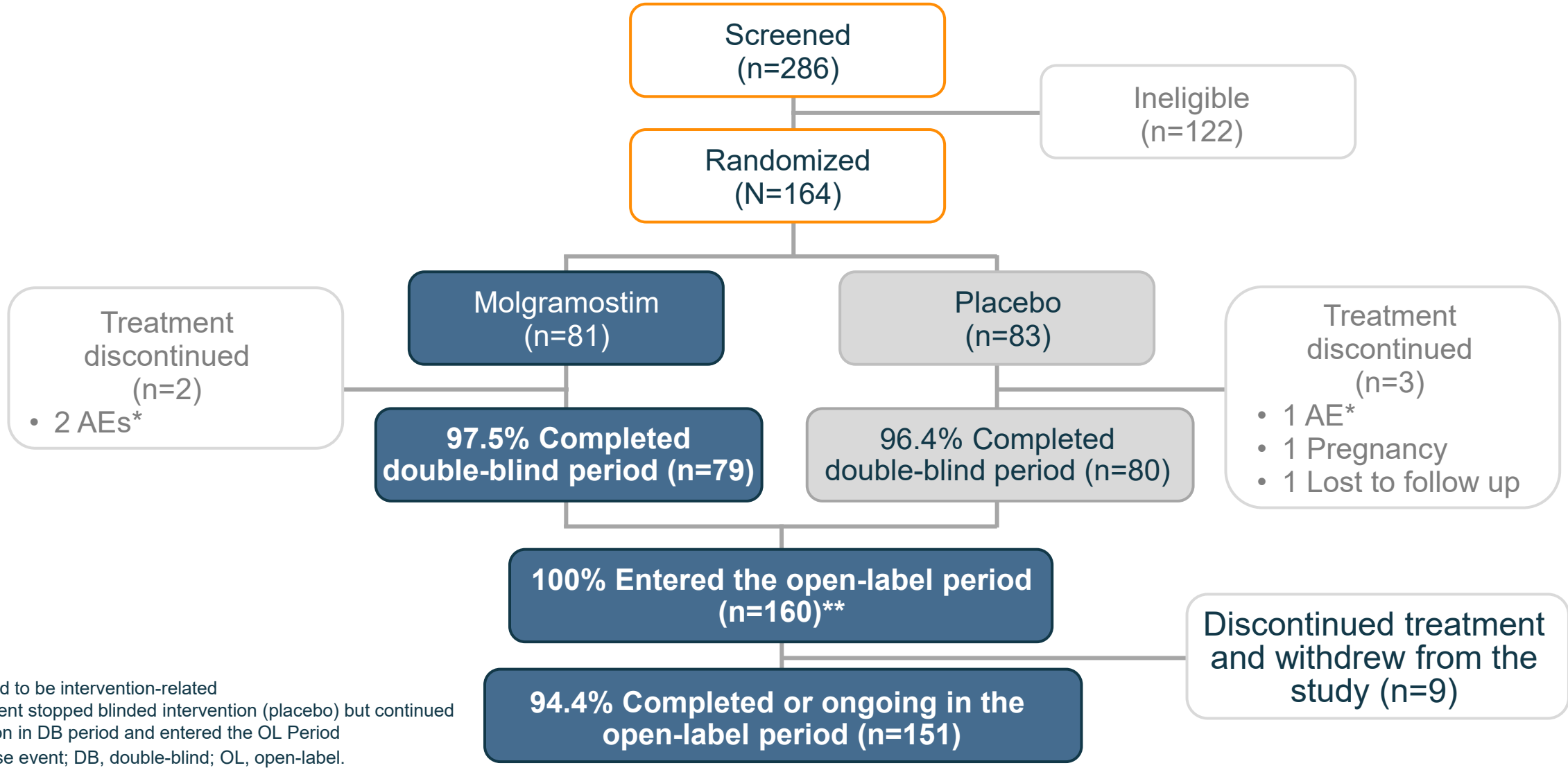
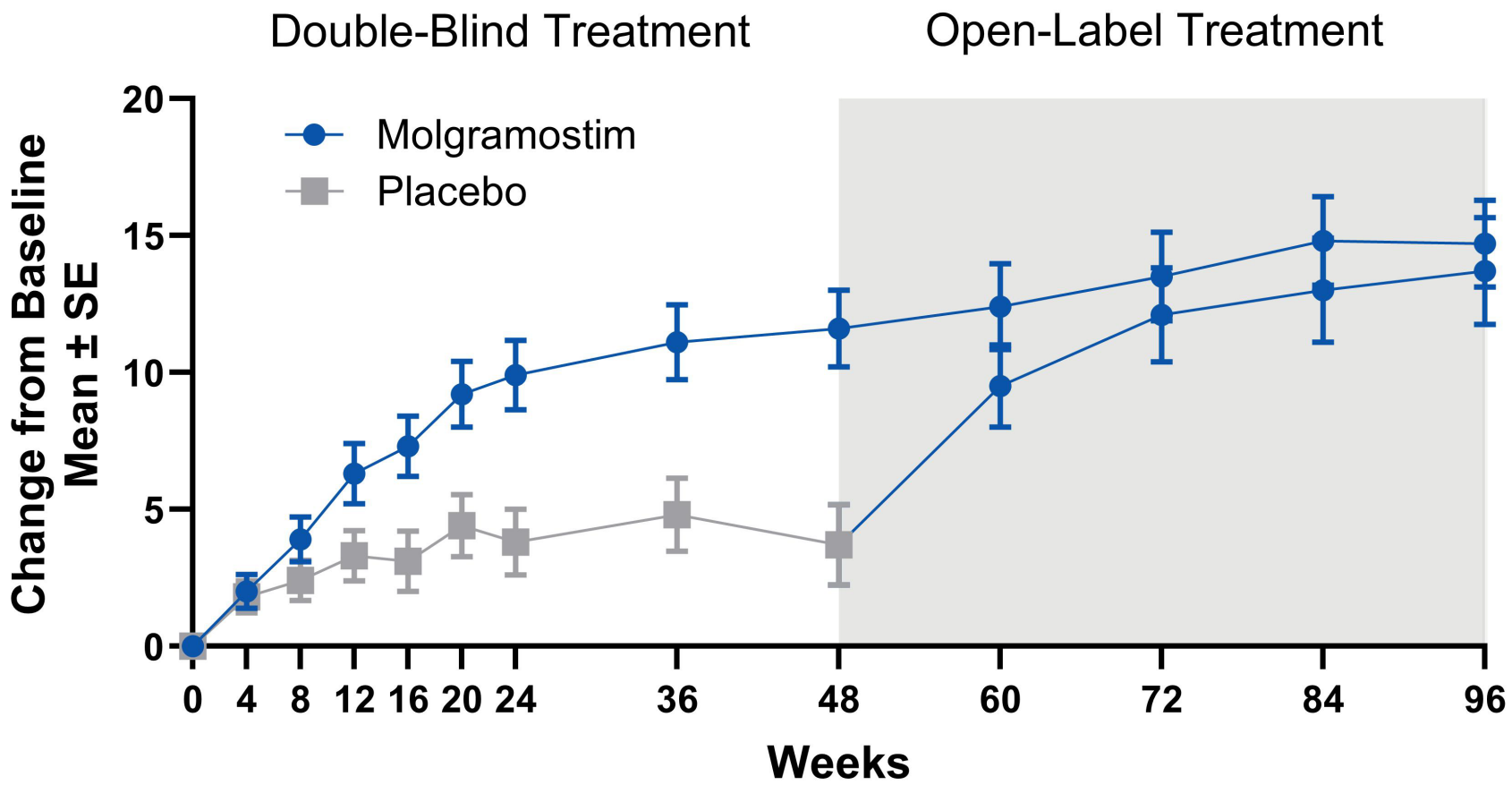
DLCO%, percent predicted diffusing capacity of the lungs for carbon monoxide adjusted for hemoglobin; SGRQ, St. George's Respiratory Questionnaire.

IMPALA-2 Patient Disposition



*Not judged to be intervention-related
**One patient stopped blinded intervention (placebo) but continued participation in DB period and entered the OL Period
AE, adverse event; DB, double-blind; OL, open-label.

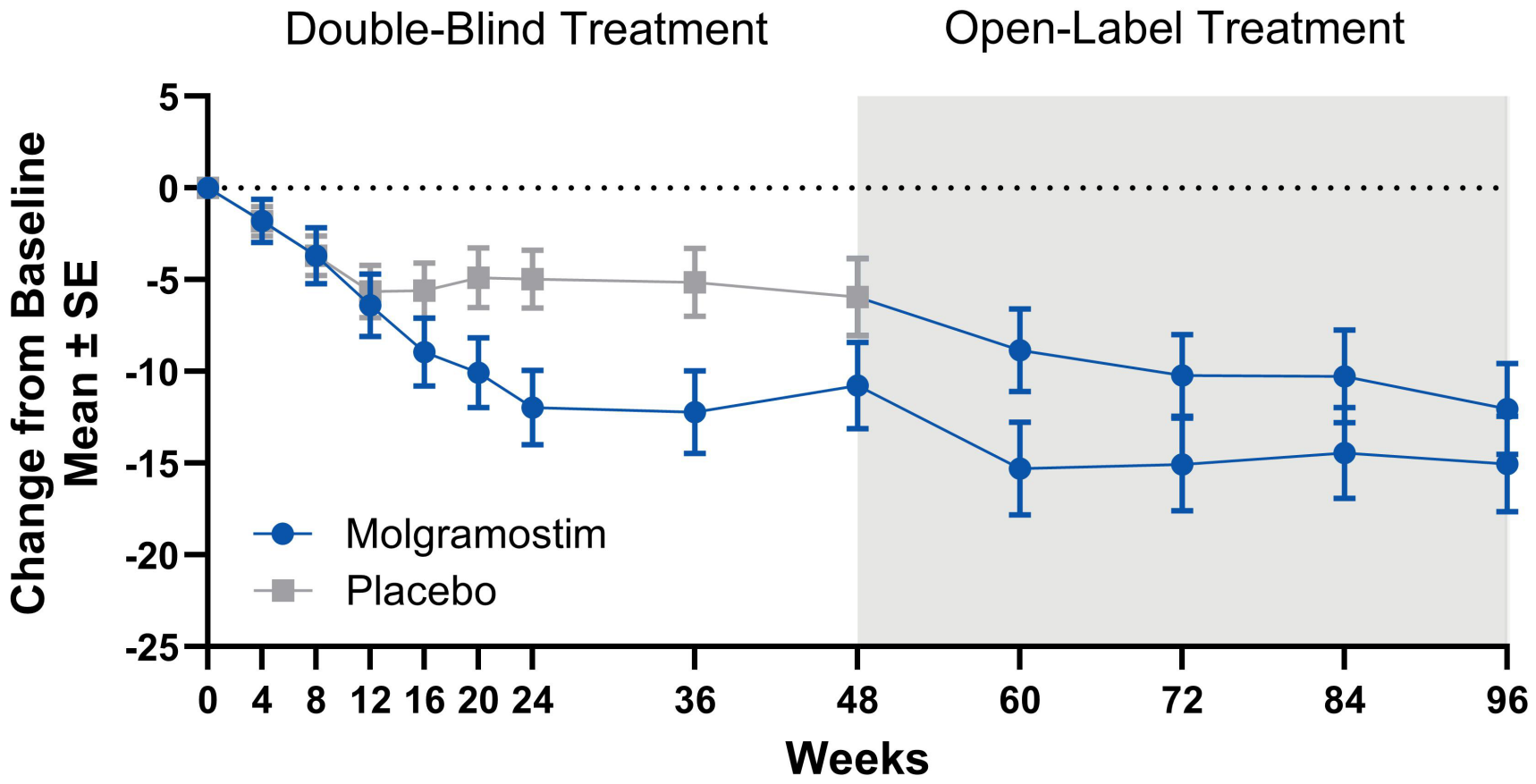
DLCO% Improved Through Week 96 with Continued Molgramostim and Increased After Placebo Crossover*



Molgramostim/Molgramostim	79	74	71	74	77	77	75	77	76	70	77	75
Placebo/Molgramostim	81	77	78	82	79	81	82	78	77	77	72	71

*Arithmetic mean changes from baseline for observed data.
DLCO%, percent predicted diffusing capacity of the lungs for carbon monoxide adjusted for hemoglobin; SE, standard error.

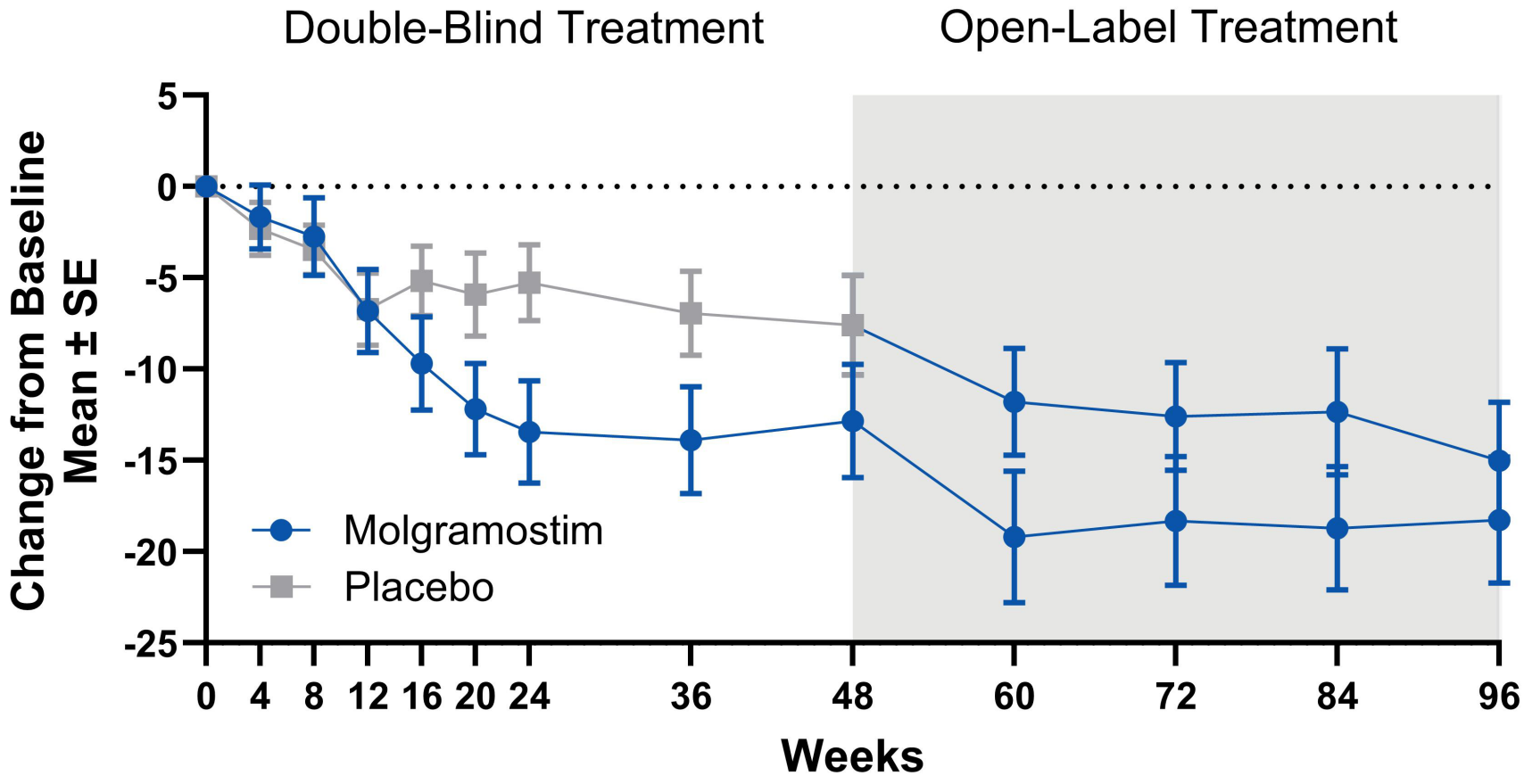
St. George's Respiratory Questionnaire (SGRQ) Total Score Improved Through Week 96 with Continued Molgramostim and After Placebo Crossover*



Molgramostim/Molgramostim	72	72	72	71	71	72	70	71	70	70	72	71
Placebo/Molgramostim	76	76	73	76	74	75	75	76	75	76	74	72

*Arithmetic mean changes from baseline for observed data.
SE, standard error; SGRQ, St. George's Respiratory Questionnaire.

St. George's Respiratory Questionnaire (SGRQ) Activity Score Improved Through Week 96 with Continued Molgramostim and After Placebo Crossover*



Molgramostim/Molgramostim	72	72	72	71	71	72	70	71	70	70	72	71
Placebo/Molgramostim	76	75	73	75	74	75	75	76	75	76	74	72

*Arithmetic mean changes from baseline for observed data.
SE, standard error; SGRQ, St. George's Respiratory Questionnaire.

No Treatment-Related Discontinuations Through Week 96; Safety Consistent with the Double-Blind Period*

Treatment-Emergent AEs	MOL-MOL n=79 (%)	PBO-MOL n=81 (%)
Any adverse event	**72 (91)**	**70 (86)**
Severe adverse events	11 (14)	15 (19)
Treatment related	**10 (13)**	**9 (11)**
Serious adverse events	**17 (22)**	**23 (28)**
Not treatment related	16 (20)	23 (28)
Treatment related	1 (1)	0
Leading to death	**1 (1)**	**2 (2)**
Leading to drug discontinuation	**1 (1)**	**3 (4)**
Special interest	**12 (15)**	**10 (12)**
Serious special interest	1 (1)	0

Treatment-Emergent AEs	MOL-MOL n=79 (%)	PBO-MOL n=81 (%)
Most common (>10% of patients in either treatment group)		
Nasopharyngitis	19 (24)	17 (21)
COVID-19	15 (19)	11 (14)
Cough	13 (16)	10 (12)
Influenza	13 (16)	8 (10)
Upper respiratory tract infection	12 (15)	11 (14)
Alveolar proteinosis	7 (9)	12 (15)
Dyspnea	5 (6)	9 (11)

- The safety and tolerability of molgramostim during the OL period were consistent with the DB period
- There were no study discontinuations due to treatment-related adverse events (AEs)

*Safety data represent all available open-label data through the data cutoff date of 03Jul2025.
DB, double-blind; MOL-MOL, patients who received molgramostim during both DB and OL periods; PBO-MOL, patients who received placebo during the DB period and crossed over to molgramostim in the OL period; OL, open-label.

Conclusions (IMPALA-2 Open-Label Treatment Period)

- Long-term treatment with molgramostim *continuously* improved pulmonary gas transfer and respiratory health-related quality of life (HRQoL) in aPAP patients
- After crossing over to molgramostim in the open-label period, placebo patients experienced improvement in pulmonary gas transfer and HRQoL
- Patient retention was high (94%)
- No study discontinuations occurred due to treatment-related AEs
- Safety and tolerability were consistent with results observed in the DB Period

Thank you!

We thank our patients and the investigators who participated in the IMPALA-2 trial