ERS CONGRESS | 2026
5-9 September | Barcelona, Spain

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

B. Trapnell (Cincinnati, United States), Y. Inoue (Osaka, Japan), F. Bonella (Essen, Germany), C. McCarthy (Dublin, Ireland), T. Wang (Los Angeles, United States), A. Ataya (Gainsville, United States), B. Robinson (Langhorne, United States), R. Fleming (Langhorne, United States), R. Pratt (Langhorne, United States), Y. Wasfi (Langhorne, United States)

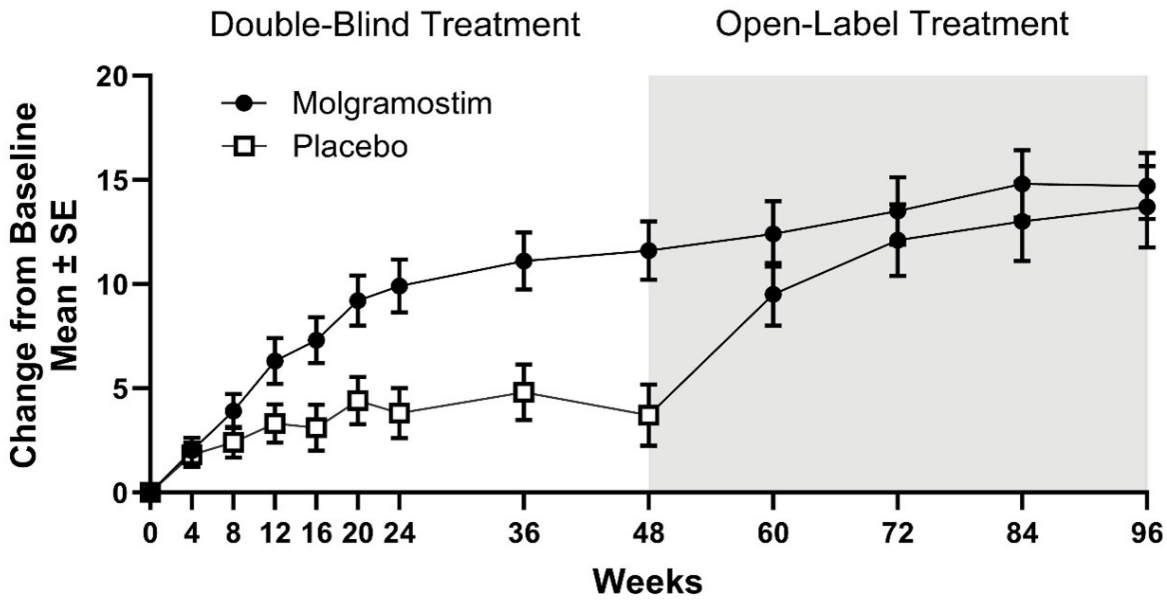
Aims and objective: IMPALA-2 is a randomized, double-blind, placebo-controlled trial assessing molgramostim (MOL) in aPAP. The trial consists of a 48-week double-blind treatment (DB) period (completed) followed by a 96-week open-label treatment (OL) period (ongoing). We report results from the first 48 weeks of the 96-week OL period.

Methods: During the DB period, patients received daily inhaled MOL (300 µg) or placebo (PBO); all patients receive daily MOL in the OL period. Efficacy was assessed by change from baseline in % predicted diffusing capacity of the lungs for carbon monoxide (DLco%) and the St. George's Respiratory Questionnaire (SGRQ).

Results: Of 164 aPAP patients who completed the DB period, 160 (98%) entered the OL period. At Week 48, the mean (SE) changes from baseline in DLco% were 11.6 (1.4) for MOL and 3.7 (1.5) for PBO (P=0.0008). During the OL period, patients receiving MOL in both DB and OL periods (MOL-MOL) showed improvement in DLco% through Week 96; the mean increase during Weeks 48-96 was 2.8 (1.2) with an overall increase from baseline (Weeks 0-96) of 14.7 (1.6) (Figure). In PBO patients crossing over to MOL (PBO-MOL), the mean increase in DLco% during Weeks 48-96 was 8.8 (1.6). Similar continued improvements in SGRQ were observed. Safety/tolerability were consistent with the DB period.

Conclusions: Long-term MOL treatment continuously improved pulmonary gas transfer (DLco%) and health-related quality of life (SGRQ) in aPAP patients. In addition, PBO-MOL patients showed improvements.

DLco%


Double-Blind Treatment
Open-Label Treatment
Molgramostim
Placebo
Change from Baseline
Mean ± SE
20
15
10
5
0
0 4 8 12 16 20 24 36 48 60 72 84 96
Weeks