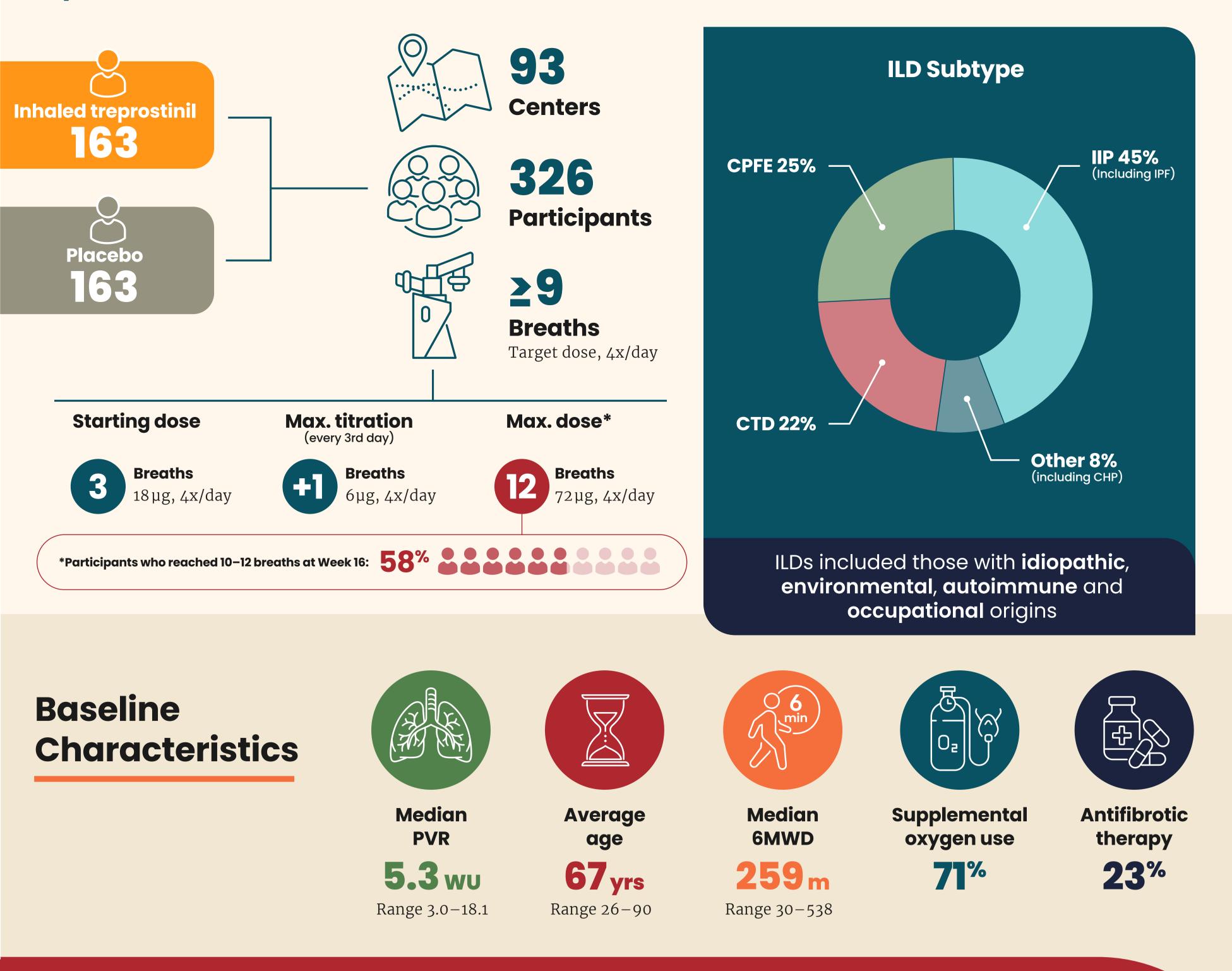
INCREASE: Inhaled Treprostinil in Pulmonary Hypertension Due to Interstitial Lung Disease

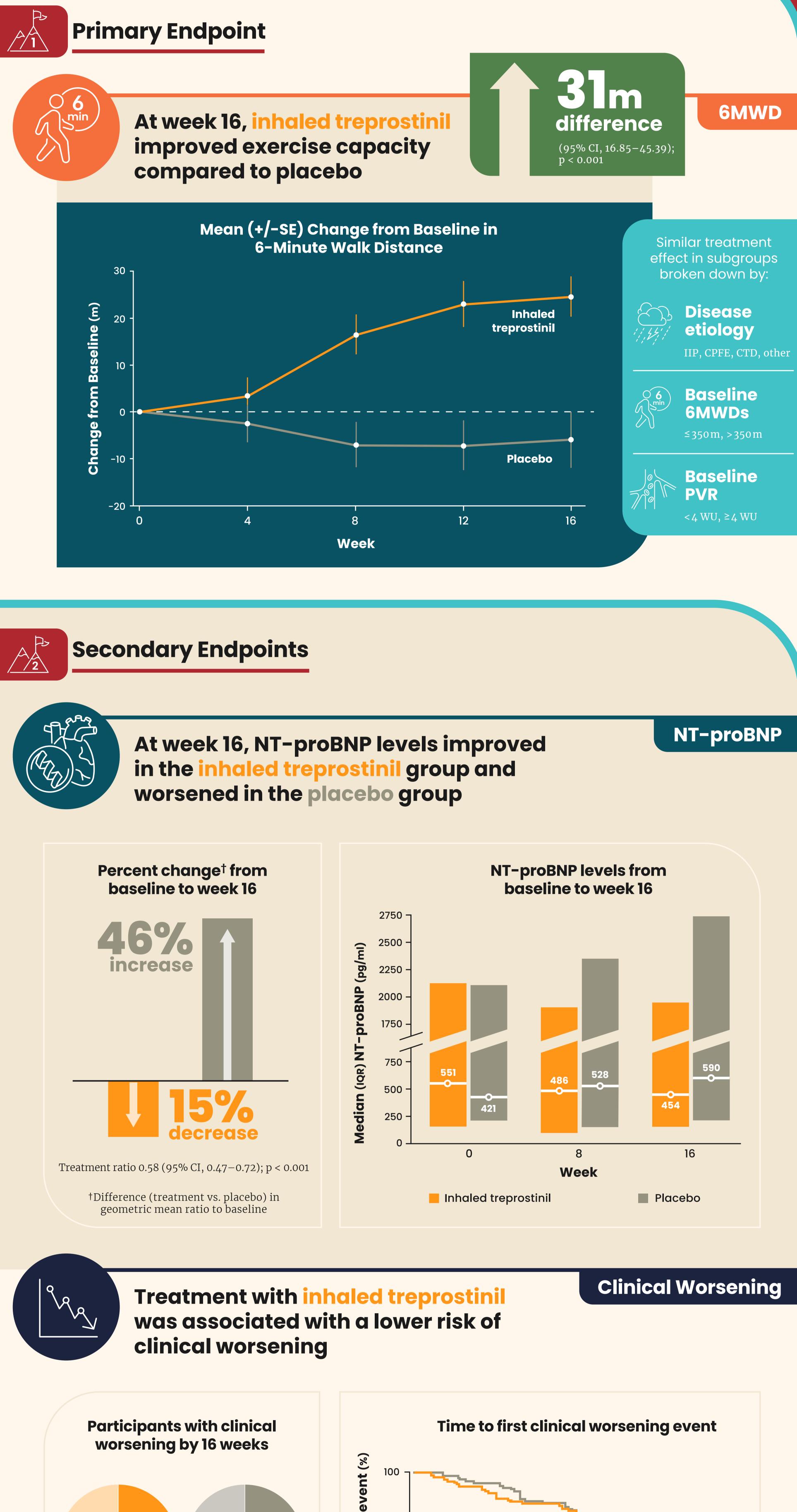
Phase III, multicenter, double-blind, randomized, placebo-controlled, parallel-group trial

Study Overview

A 16-week study evaluating the safety and efficacy of inhaled treprostinil in patients with PH-ILD



Results



Lowered risk of clinical worsening for inhaled treprostinil vs. placebo over 16 weeks

Some data is censored in the

event curve shown at right

33%

n = 54

Placebo



12

16



n = 37

Inhaled treprostinil

6MWD Decrease > 15% disease-related decline from baseline

Clinical worsening events

ithout

Patients **w**

75

0



Hospitalization for cardiopulmonary indication



HR: 0.61 (95% CI: 0.4, 0.92); p = 0.04

8

Week

4

Lung Transplant



Exacerbations**



26% Treprostinil

Fewer patients in the treprostinil group reported exacerbations of underlying lung disease

**Acute, clinically significant respiratory deterioration characterized by evidence of new widespread alveolar abnormality

The use of inhaled treprostinil was not associated with any decrement in lung function or oxygenation.



The safety profile of inhaled treprostinil was consistent with previous studies in people with pulmonary arterial hypertension (PAH).

| Variable | Inhaled treprostinil (n=163) | Placebo (n=163) |
|---|------------------------------------|--------------------|
| Most frequently occurring adverse events – no. of patients (%)‡ | | |
| Cough | 71 (44) | 54 (33) |
| Headache | 45 (28) | 32 (20) |
| Dyspnea | 41 (25) | 51 (31) |
| Dizziness | 30 (18) | 23 (14) |
| Nausea | 25 (15) | 26 (16) |
| Fatigue | 23 (14) | 23 (14) |
| Diarrhea | 22 (13) | 19 (12) |
| Throat irritation | 20 (12) | 6 (4) |
| Oropharyngeal pain | 18 (11) | 4 (2) |
| NT-proBNP increased | 9 (6) | 25 (15) |
| AEs leading to discontinuation | 16 (10) | 13 (8) |

[‡] Shown are the most frequently occurring adverse events occurring in more than 10% of patients in either group in the safety population, which comprised all patients who underwent randomization and received at least one dose of treprostinil or placebo

Conclusion



In people with PH-ILD, treatment with inhaled treprostinil can improve exercise capacity and lower risk of clinical worsening

6MWD, 6-minute walk distance; CHP, chronic hypersensitivity pneumonitis; CPFE, combined pulmonary fibrosis and emphysema; CTD, connective tissue disease; IIP, idiopathic interstitial pneumonia; IPF, idiopathic pulmonary fibrosis; NT-proBNP, plasma N-terminal pro-brain natriuretic peptide; PH-ILD, pulmonary hypertension due to interstitial lung disease; PVR, pulmonary vascular resistance



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