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ASPIRE, a global, double-blind, randomized, placebo-controlled Phase 2b trial of buloxibutid, an angiotensin II type 2 receptor agonist, in idiopathic pulmonary fibrosis: trial design and patient characteristics

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Buloxibutid is an Oral Small Molecule AT2R Agonist Designed to Support Tissue Repair Through Alveolar Epithelial Type 2 cells (AEC2)

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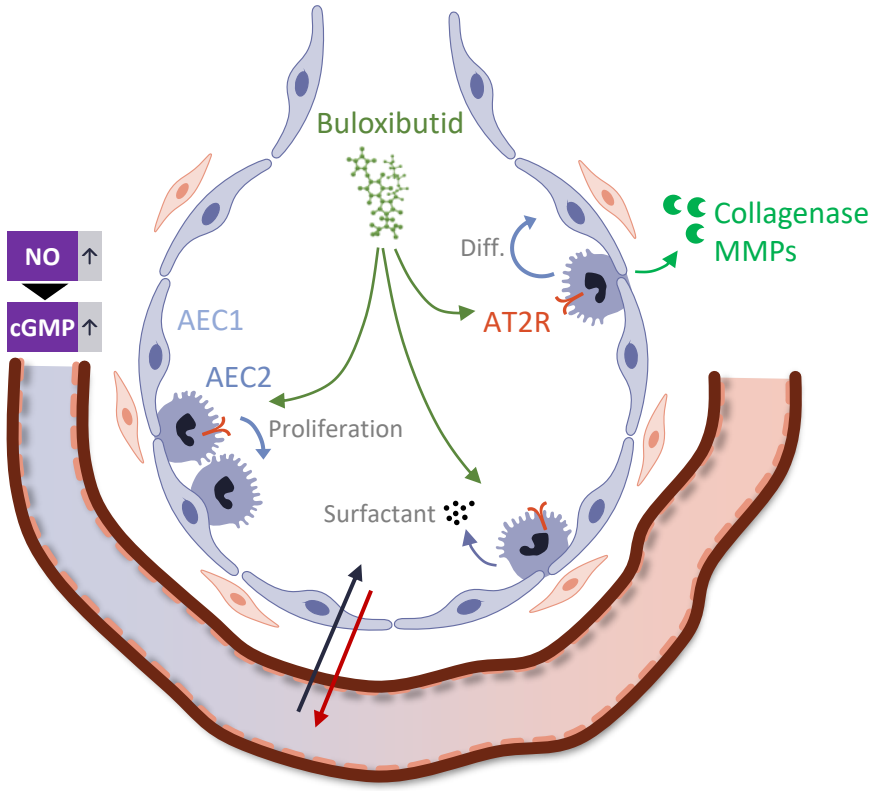
Buloxibutid is designed to target AT2R on AEC2[1,2]



Buloxibutid: Expected effects in IPF[1,2]

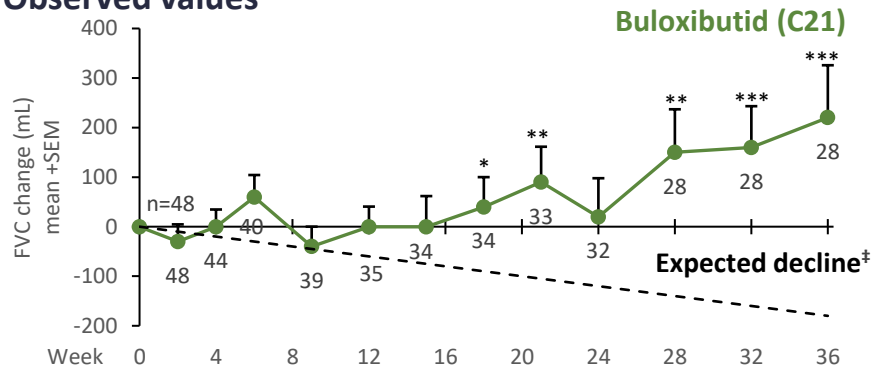
Increased AEC2 viability and surfactant production

Reduced TGF-β1 production, EMT, and collagen accumulation

Anti-remodeling and vasodilatation (NO release)

Stabilization and improvement of FVC in the open label Phase 2a AIR study [3–5]

Observed values



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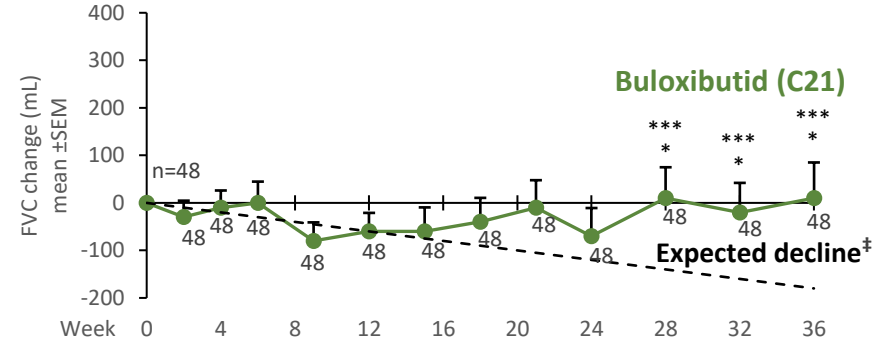

‡ Expected average decline of 180 mL/36 weeks for untreated patients based on published placebo data.[4,5]
*p<0.05, **p<0.01, ***p<0.001, t-test versus expected untreated decline.
n=48 patients with 2-week FVC change from baseline data.

AEC2: alveolar epithelial type 2 cell; AT2R: angiotensin II Type 2 receptor; C21: compound 21; cGMP: cyclic guanosine monophosphate; EMT: epithelial-mesenchymal transition; FVC: forced vital capacity; IPF: idiopathic pulmonary fibrosis; MMP: matrix metalloproteases; NO: nitric oxide; SEM: standard error of the mean; TGF-β1: transforming growth factor beta 1.

1. Steckelings UM, et al. *Pharmacol Rev.* 2022; 74:1051–135; 2. Nalbandyan A et al. *FASEB* 2018; 32(S1):829.7; 3. Vicore data on file. ;4. Noble PW et al. *Eur Respir J.* 2016; 47: 243–53; 5. Richeldi L et al. *N Engl J Med.* 2014; 370:2071–82.

The ASPIRE Trial in Patients with IPF was Designed to Assess Changes in FVC over 52 Weeks

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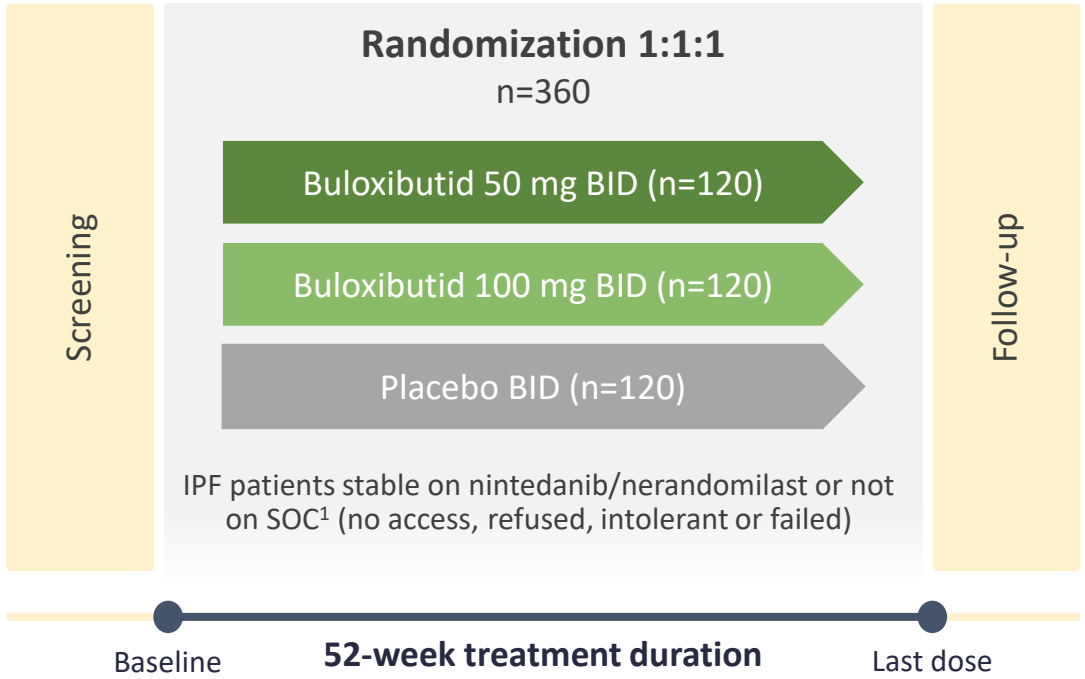
Trial design



Enrollment complete: n=378

Primary endpoint
Absolute change from baseline in FVC at Week 52

Select secondary endpoints
Proportion of participants with ≥10% FVCpp decline, a respiratory-related hospitalization, or death

Quality of life and IPF symptoms

Quantitative HRCT

Key inclusion and exclusion criteria

- Age ≥ 40 years
- Diagnosed with IPF within the last 7 years
- FVC ≥ 50% predicted
- DLCO ≥ 30% predicted
- UIP – prob. UIP on HRCT scan < 36 months
- Stable dose of approved IPF therapy

- Treatment with pirfenidone within 8 weeks
- FEV_1/FVC ratio <0.7
- Heart failure NYHA Class IV
- PH with syncopal episode
- Acute IPF exacerbation within 3 months

AV: atrioventricular; BID: twice daily, DLCO: diffusing capacity of the lungs for carbon monoxide; FEV_1: forced expiratory volume in 1 second; FVC: forced vital capacity; FVCpp: FVC percent predicted; HRCT: high-resolution computed tomography; IPF: idiopathic pulmonary fibrosis; NYHA: New York Heart Association; PH: pulmonary hypertension; QTcF: corrected QT interval; SOC: standard of care; UIP: usual interstitial pneumonia.

ASPIRE is a Global Trial Representing a Broad IPF Patient Population

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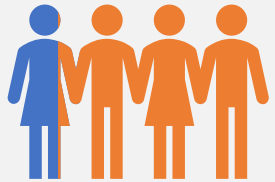
Characteristics, N=377*

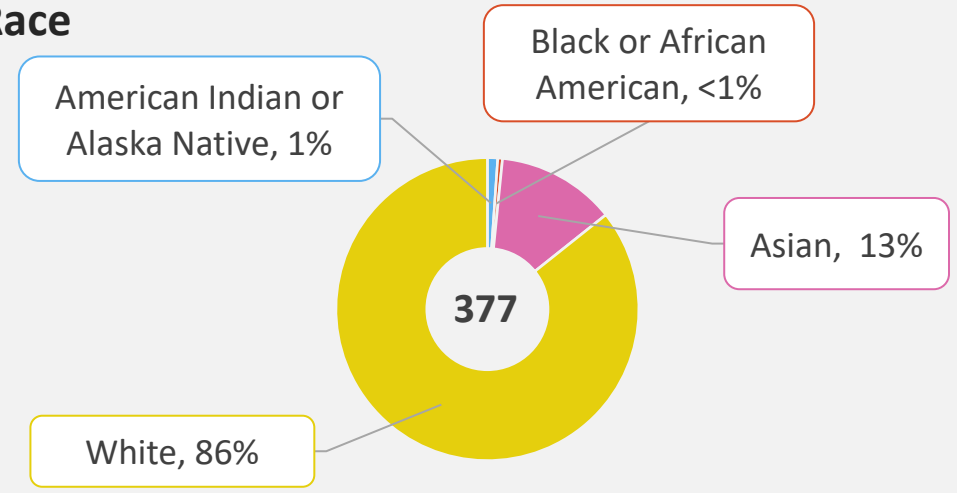


21.8% female
78.2% male

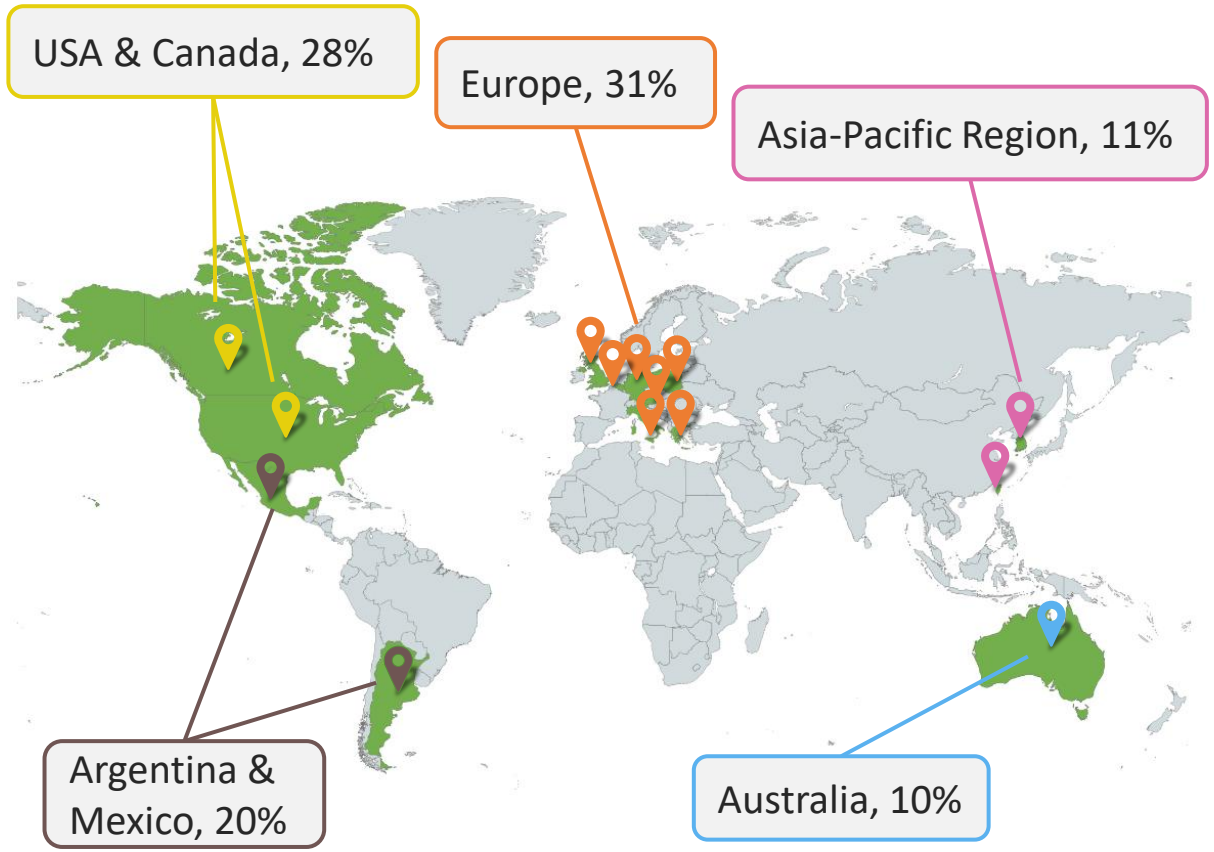
Mean (SD) age at study entry:
71.1 (7.5) years

Mean (SD) BMI:
27.9 (4.8) kg/m^2

Race



> 100 study sites across 14 countries



BMI, body mass index; SD, standard deviation. *Total randomized participants exposed to at least one dose of IMP

Preliminary data, reflecting 16 June 2026 database extract

ASPIRE Baseline Patient Data are Reflective of a Typical Cohort of Patients with IPF

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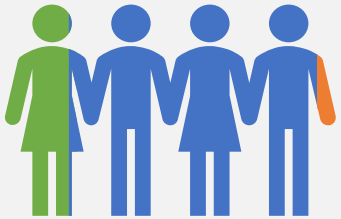
Time since diagnosis

2.4 (1.7) years

Smoking status



36.9% never smoked

61.5% former smokers

1.6% current smokers

FVC, mean (SD)

2.9 L (0.8)

FVCpp, mean (SD)

81.3% (17.6)

FEV_1/FVC ratio, mean (SD)

0.8 (0.06)

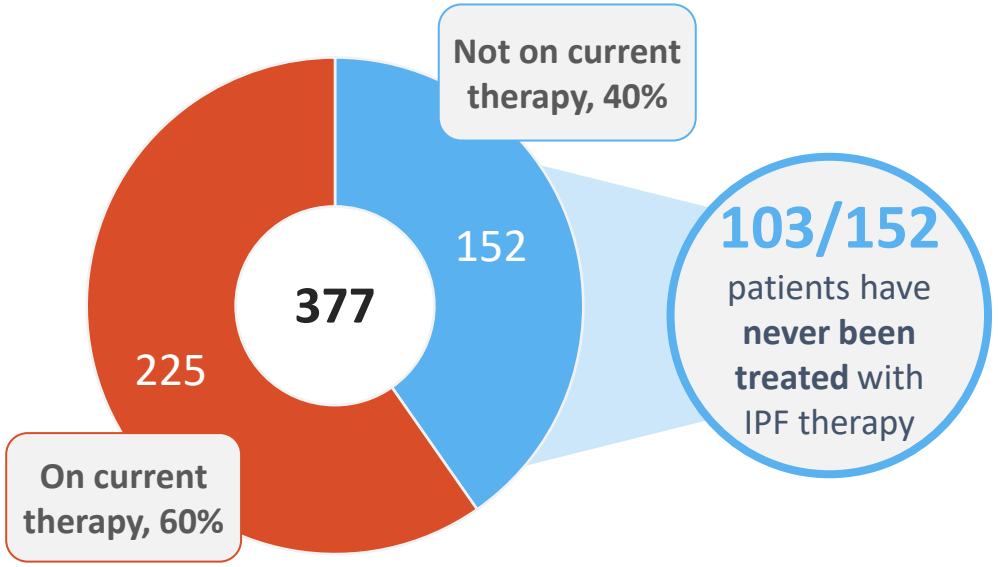
DLCOpp, Hb corrected, mean (SD)

54.1% (15.7)

Oxygen saturation, mean (min – max)

96.0% (86% – 100%)

Previous and current IPF therapy at study entry



DLCO: diffusing capacity of the lungs for carbon monoxide; FEV_1: forced expiratory volume in 1 second; FVC: forced vital capacity; FVCpp: FVC percent predicted; Hb: haemoglobin; HRCT: high-resolution computed tomography; IPF: idiopathic pulmonary fibrosis; SD: standard deviation.

Preliminary data, reflecting 16 June 2026 database extract

Conclusions

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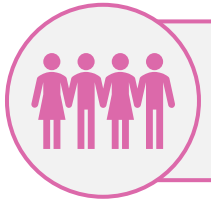
Buloxibutid is an **angiotensin II type 2 receptor agonist** designed to support tissue repair through alveolar epithelial type 2 cells

ASPIRE is an ongoing randomized, placebo-controlled Phase 2b study that is designed to assess the efficacy and safety of **two doses of buloxibutid over 52 weeks** in patients with IPF



Patients enrolled in ASPIRE are **generally representative of the IPF population**, with a mean time since diagnosis of 2.4 years and 40% of participants not receiving background therapy

The global distribution of enrolled participants demonstrates that ASPIRE successfully captured a **geographically diverse IPF population**, supporting the relevance and applicability of the study across regions

IPF: idiopathic pulmonary fibrosis.

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