



Reimagining the Future of Rare Lung Disease Treatment

Corporate Overview

Nasdaq: AVLN

May 2026

■ TARGETED THERAPIES FOR RARE LUNG DISEASES



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Our Approach Reimagines the Future of Rare Lung Disease Treatment



Clinical-stage portfolio of inhaled therapies targeting multi-billion dollar total addressable market



Multiple clinical catalysts expected in 2026 and beyond



Well-capitalized with \$345M raised in upsized IPO in April 2026, providing cash runway into 2029

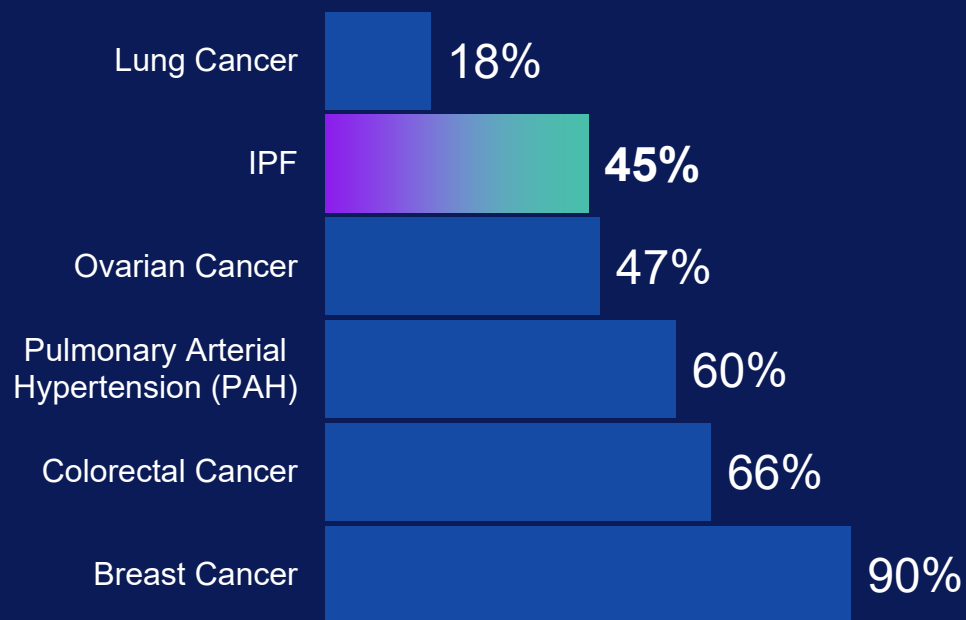


Expert team with deep experience developing & commercializing inhaled therapies

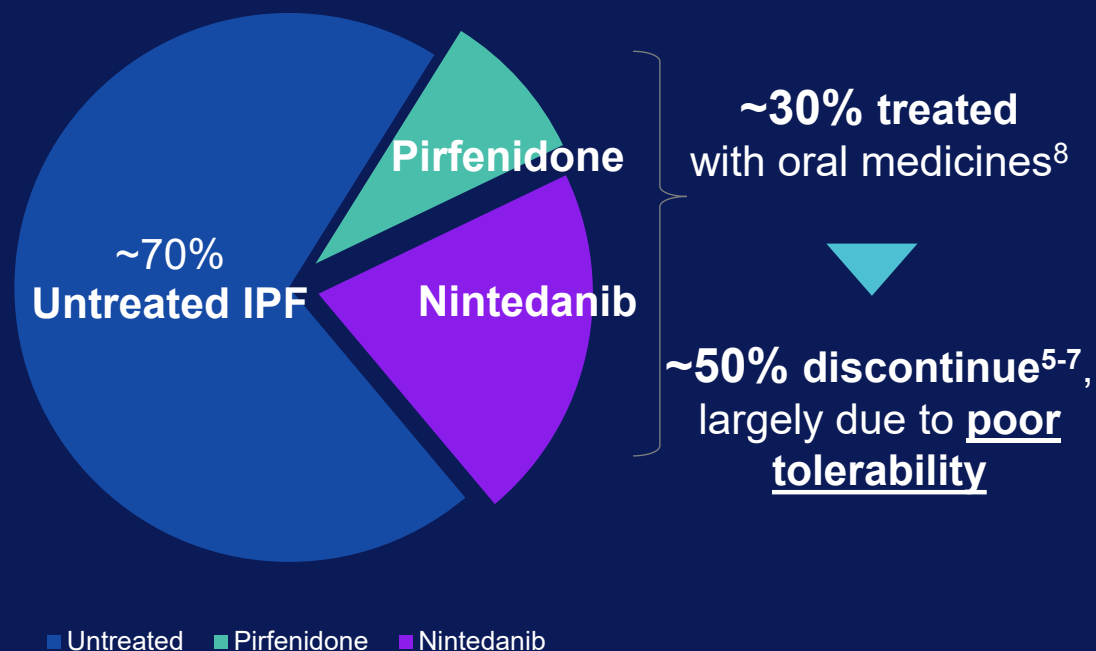


Pulmonary Fibrosis: Deadly Disease with Limited Approved Agents

3-5 year survival rate – worse than most forms of cancer¹⁻⁴



~70% of IPF patients are not on therapy⁵





Inhaled Delivery Has Potential to Improve Efficacy and Tolerability of Approved Oral Agents

AVALYN'S TREATMENT APPROACH



Increases lung exposure
even at >10x lower dose than oral



Decreases systemic exposure



Dramatic improvement to existing product profiles



Advancing a Clinical-Stage Portfolio That We Believe Will Transform Treatment of Pulmonary Fibrosis

AP01

Inhaled pirfenidone: 375 patient global Phase 2b MIST-PPF trial ongoing with enrollment completion expected mid-2026 with data expected 2H27

- >150 patients with pulmonary fibrosis studied in Phase 1 and open label extension studies
 - Substantially better activity compared to historic oral data with potential for disease modification
 - Generally well-tolerated with fewer AEs vs historic oral pirfenidone

AP02

Inhaled nintedanib: Phase 2 global AURA-IPF trial initiated with data expected late 2027

- Significantly higher lung exposure than orals demonstrated in Phase 1 trial
- Generally well-tolerated in Phase 1 with no bronchospasm or diarrhea observed

AP03

Inhaled pirfenidone + nintedanib fixed-dose combination: evolving the treatment algorithm

- We believe combining mechanisms is only tolerable with inhaled delivery
- Phase 1 study to begin late 2026 with data expected in 2H27



We Believe Avalyn is Positioned to Evolve the Treatment Algorithm in PF

Asthma and COPD treatments now include many combinations

GENERATION 1 (1960s+)

Oral Molecules

Prednisone
Tablets USP
Theo-dur®
Theophylline
Primatene®

GENERATION 2 (1990s+)

Inhaled Molecules

FloVent Diskus
Serevent Diskus®
Pulmicort®
SPIRIVA® RESPIMAT™
(tiotropium bromide) INHALATION SPRAY

GENERATION 3 (2000s+)

Dual FDCs

ADVAIR
BREO ELLIPTA
Symbicort®

GENERATION 4 (Today)

Triple FDCs

TRELEGY ELLIPTA
BREZTRI AEROSPHERE®

Rapid evolution of PF treatment options

GENERATION 1 2014 - Today

Oral Molecules

Esbriet®
(pirfenidone) tablets
Jascayd®
nerandomilast tablets
OFEV®
nintedanib

GENERATION 2

Inhaled Molecules

avalyn pharma
AP01 **AP02**

GENERATION 3

Dual FDCs

avalyn pharma
AP03

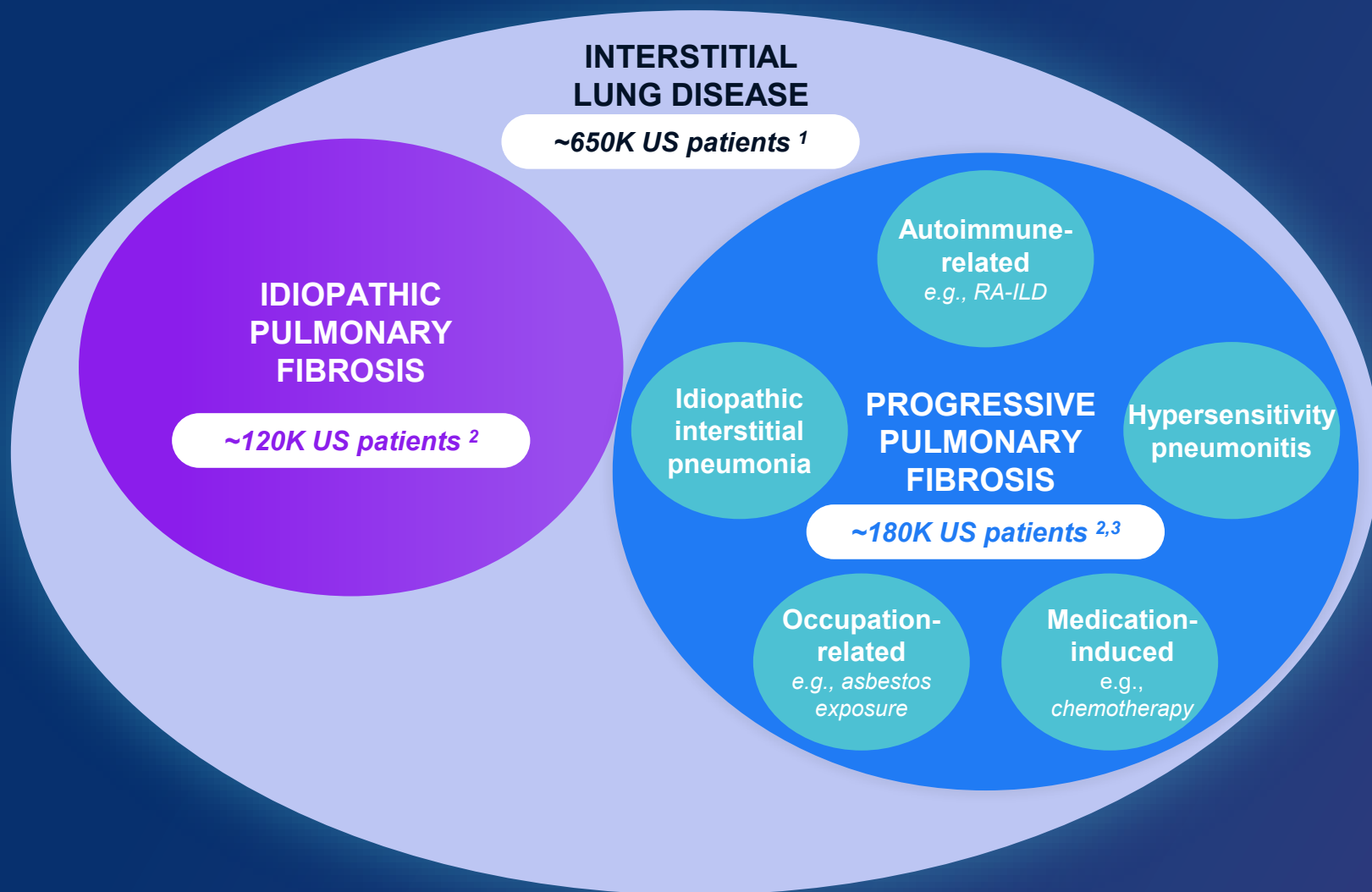
GENERATION 4 → Future

Triple FDCs

avalyn pharma
undisclosed



IPF and PPF Are Two Key Types of Interstitial Lung Disease



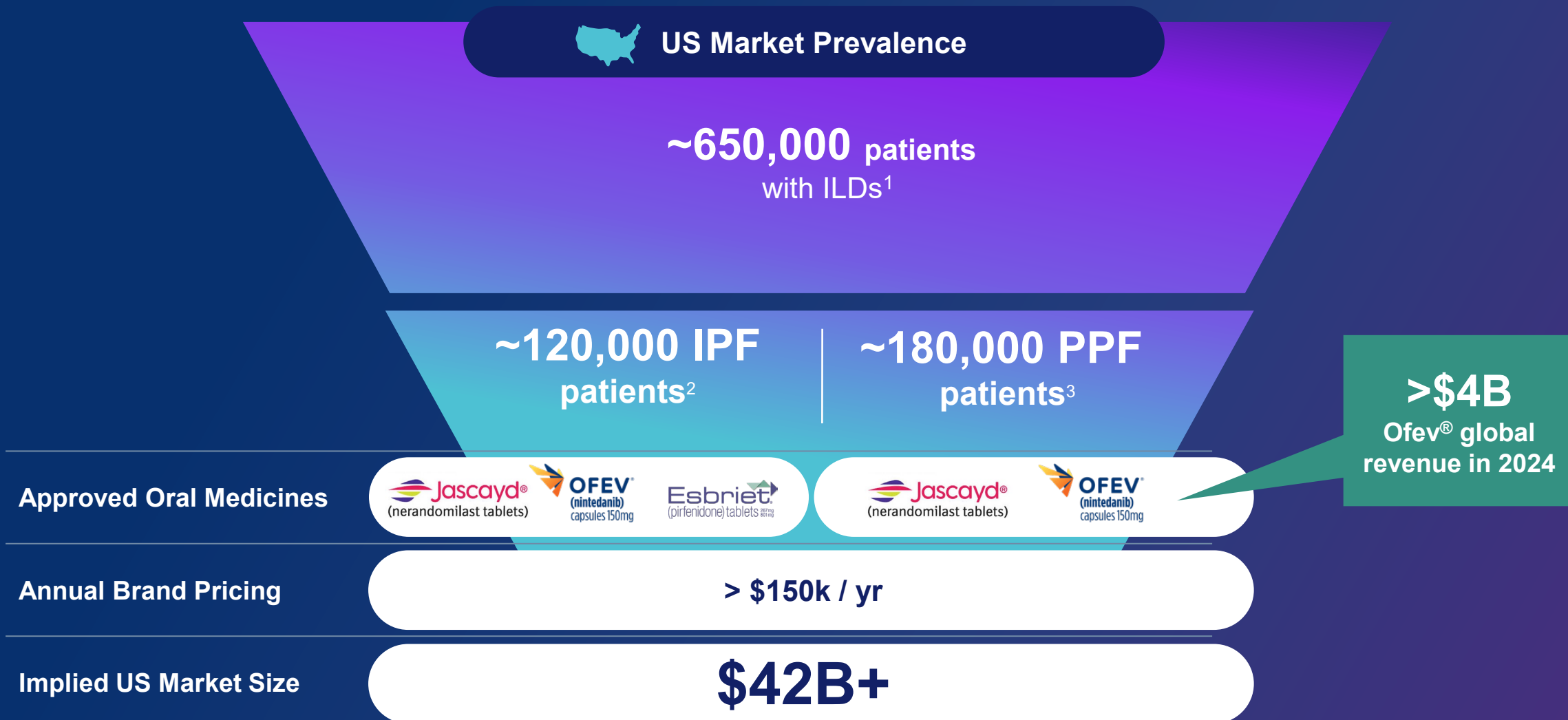
>200 types¹ of interstitial lung diseases (ILDs)

ILD-associated inflammation can lead to fibrosis, damaging the lung's ability to absorb oxygen

- Idiopathic Pulmonary Fibrosis (IPF) is the **most well-known form of ILD**
- **Progressive Pulmonary Fibrosis (PPF)** is a **larger** and poorly served segment of the ILD market



Pulmonary Fibrosis Represents a Large Market Opportunity in the US





Avalyn's Anticipated Near-Term Value Inflection Points

Program	1H26	2H26	1H27	2H27	Anticipated Milestones
AP01 (Inhaled pirfenidone)		MIST Phase 2b Enrollment Completion		MIST Phase 2b Study Readout	- Ph2b trial enrollment completion expected mid 2026 - Ph2b top line data expected 2H27
AP02 (Inhaled nintedanib)	AURA Phase 2 Initiation			AURA Phase 2 Study Readout	- First patient dosed in Ph2 trial 1Q26 - Ph2 top line data expected late 2027
AP03 (Inhaled pirfenidone + nintedanib fixed-dose combination)		AP03 Phase 1 Initiation		AP03 Phase 1 Study Readout	- Ph1 trial initiation expected late 2026 - Ph1 top line data expected 2H27



Optimized Drug/Device Combination for Treatment of PF



Handheld nebulized formulation delivered by proprietary, patented, 510(k) cleared PARI eFlow[®] device.



Device would be included in FDA label. The same device configuration is used in other commercial products, including Inmed's Arikayce[®] and Gilead's Cayston[®]



Avalyn has licensed device with exclusivity in molecules



Administration averages less than 10 minutes, twice a day



Aerosol particle size designed to achieve optimal deposition in peripheral airways and alveolus

AP01: Inhaled Pirfenidone



Inhaled Pirfenidone (AP01): Phase 1b ATLAS Trial

Open-Label Extension (OLE) / Compassionate Use Trials Include IPF and PPF

COMPLETED

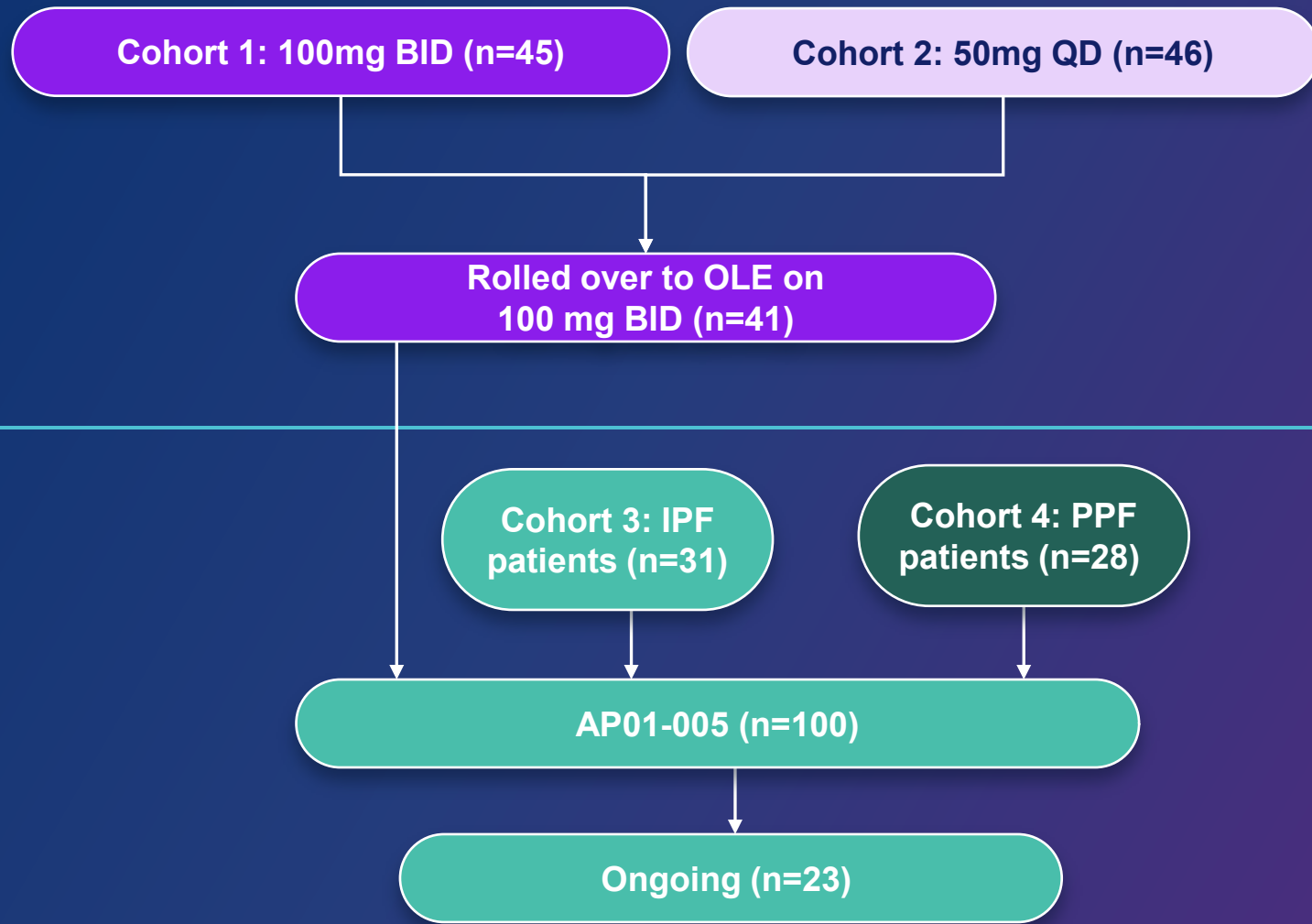
ATLAS Trial in IPF Patients

- ✓ Study complete
- ✓ Data published in *Thorax* in March 2023¹

ONGOING

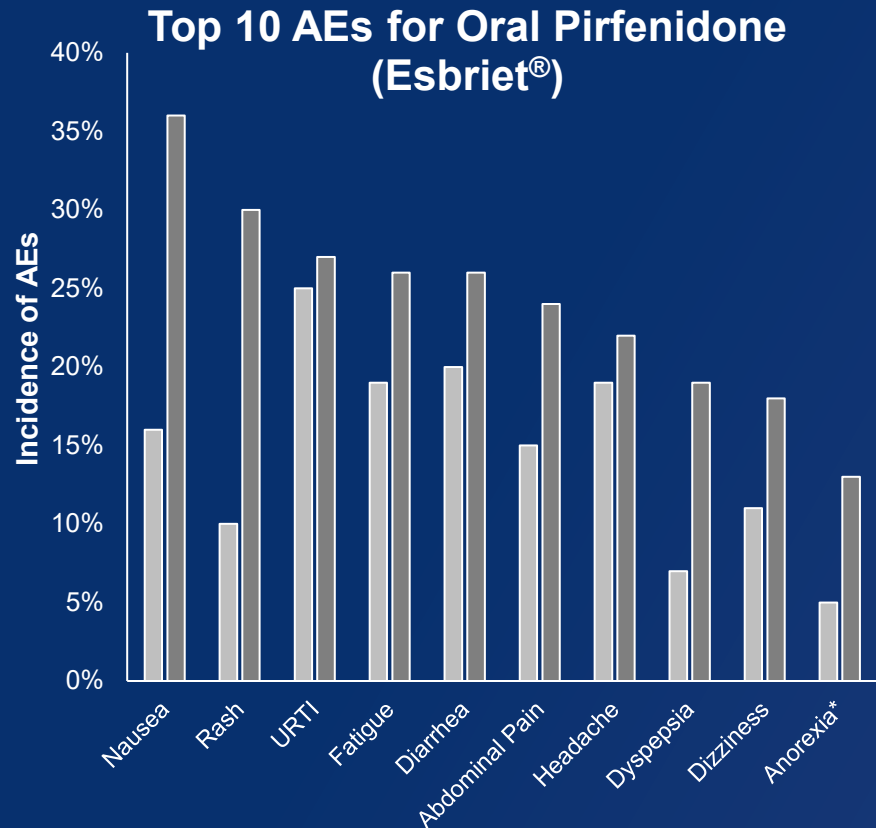
Open-Label Extension (OLE) / Compassionate Use IPF & PPF Trial

- All patients on 100 mg BID dose
- Initiated June 2021
- 4.5 years of lung function stabilization and tolerability data for roll-over patients announced May 2025
- Some patients from ATLAS on AP01 for 5+ years



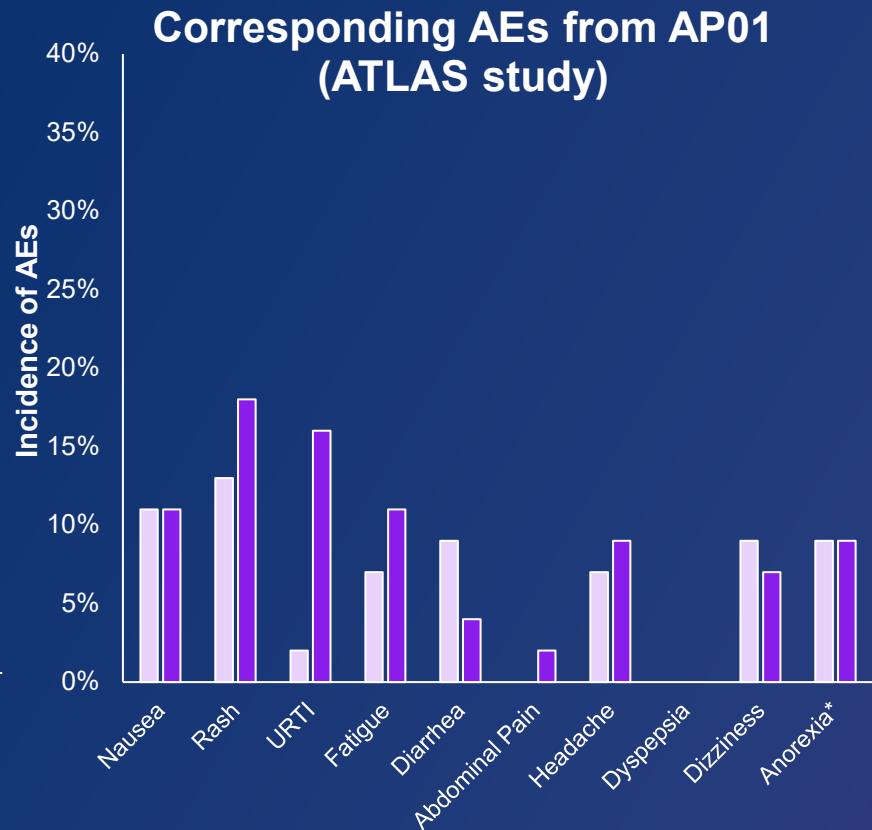


AP01 Showed Improved Tolerability in ATLAS



Pooled Historic Data¹

	Oral Placebo (n=624)
	Oral Pirfenidone, 801mg TID (n=623)



AP01-002 ATLAS Trial²

	AP01 (Inhaled Pirfenidone), 50mg QD (n=46)
	AP01 (Inhaled Pirfenidone), 100mg BID (n=45)

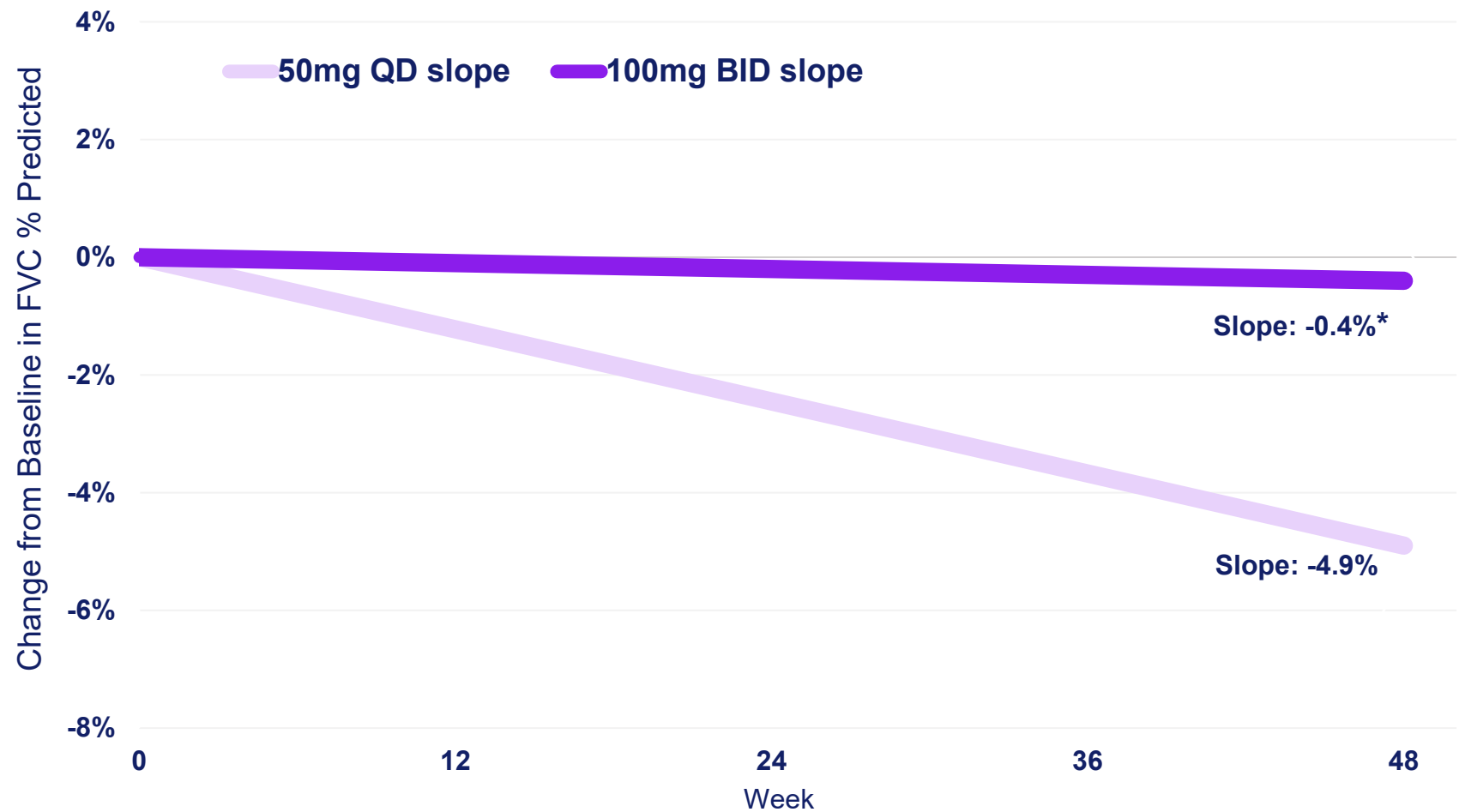
- Gastrointestinal and skin AEs are common reasons for discontinuing oral pirfenidone
- Compared to the historic pooled data on oral pirfenidone, patients in the ATLAS trial were:
 - Older
 - Generally lower FVC
 - Longer time since diagnosis

These cross-study comparisons are provided for illustrative purposes only as there are no head-to-head comparison available. Comparing the results from different trials may be unreliable due to factors such as protocol design and trial objectives varying between the trials. Therefore, cross-study comparisons provide limited information about the effectiveness of a product candidate and should not be relied on.

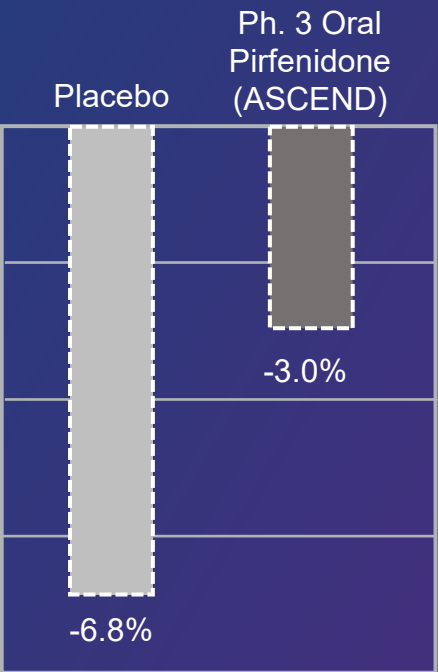


AP01 100mg Achieved Near Stabilization in ATLAS Exhibiting Significant Dose-Dependent Improvement in Lung Function

Lung function (FVC) with AP01 100 mg BID vs. 50 mg QD dosing in 48-week ATLAS trial¹



Historical data of oral
pirfenidone (52 wks)²



These cross-study comparisons are provided for illustrative purposes only as there are no head-to-head comparison available. Comparing the results from different trials may be unreliable due to factors such as protocol design and trial objectives varying between the trials. Therefore, cross-study comparisons provide limited information about the effectiveness of a product candidate and should not be relied on.

*Through 48 weeks, 100 mg BID vs. 50 mg QD p=0.0222 (24-week p=0.133). Historic oral and AP01 data are non-imputed;
¹West et al., *Thorax* 2023 ²King et al., *N Engl J Med* 2014



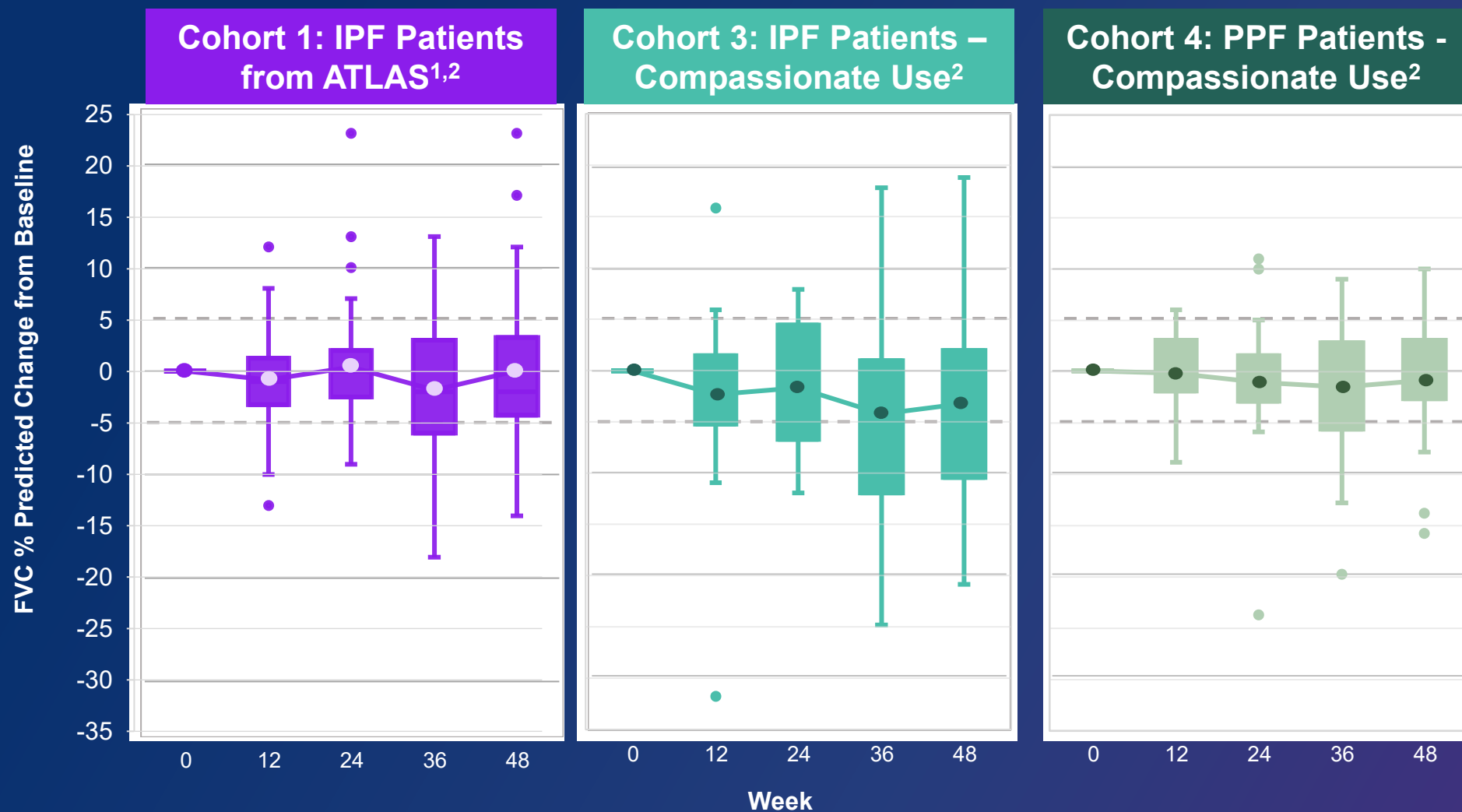
Average rate of decline in lung function due to aging is 20-50mL/year after age 40^{8, 9}

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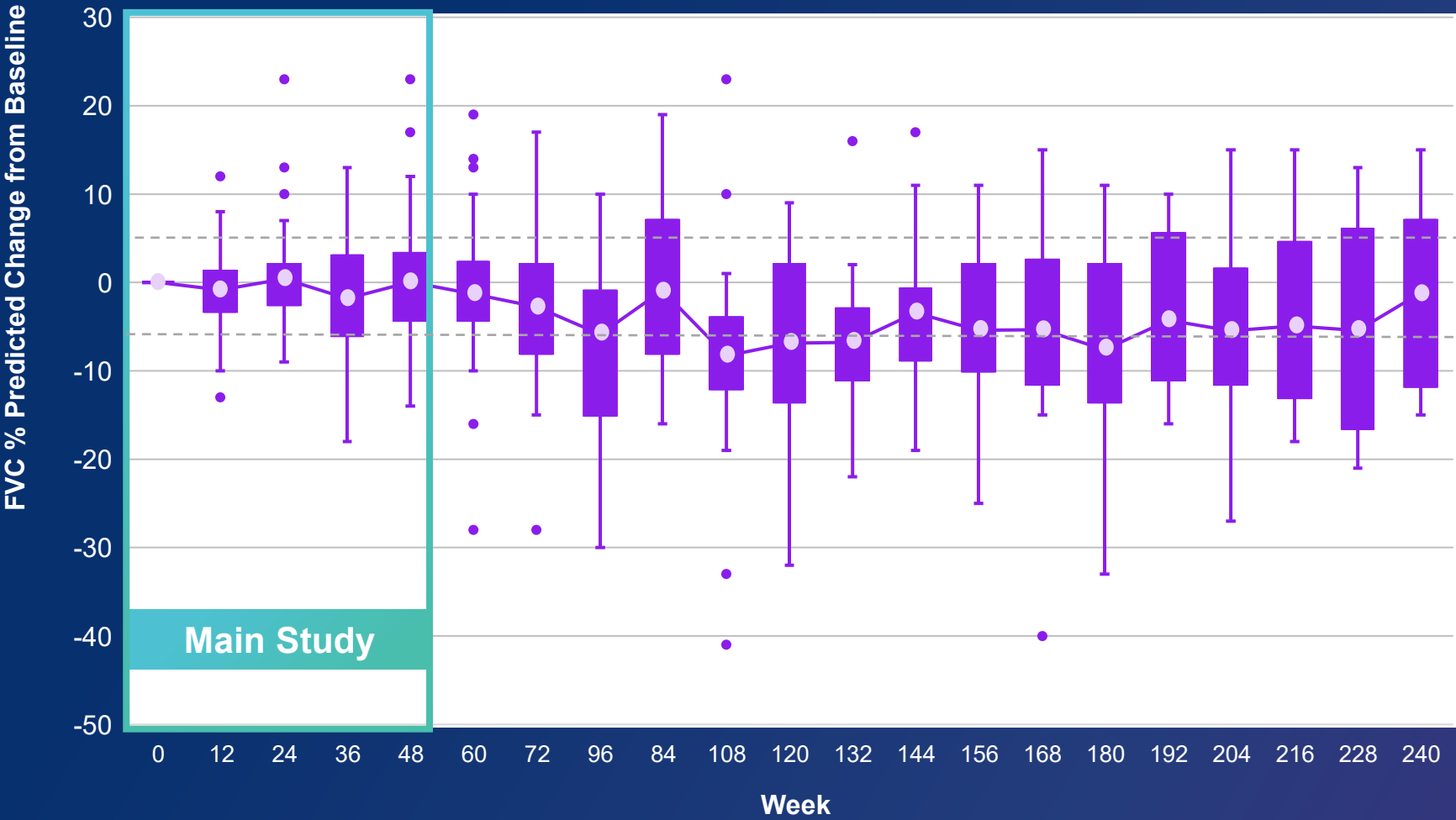
AP01 Activity in Compassionate Use Cohorts Similar to IPF Patients in ATLAS over 48 weeks





Open Label Extension Trial Has Demonstrated Disease Stabilization Over 4.5 Years

Cohort 1: ATLAS Study 100mg BID Patients Rolled Over Into OLE Study



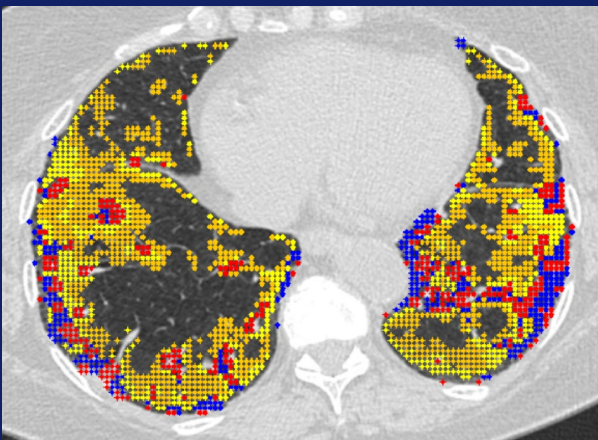
- Cohort 1 is the longest running of four cohorts in existing OLE
- This cohort has been on a stable 100 mg BID dose



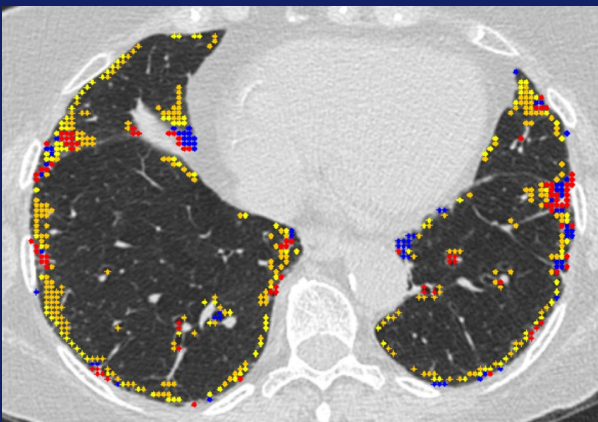
ATLAS Showed Promising Potential for Disease Modification: Imaging Correlated with FVC Data

Axial HRCT Images

BASELINE



24 WEEKS



QLF using HRCT imaging after 6 mo treatment with AP01

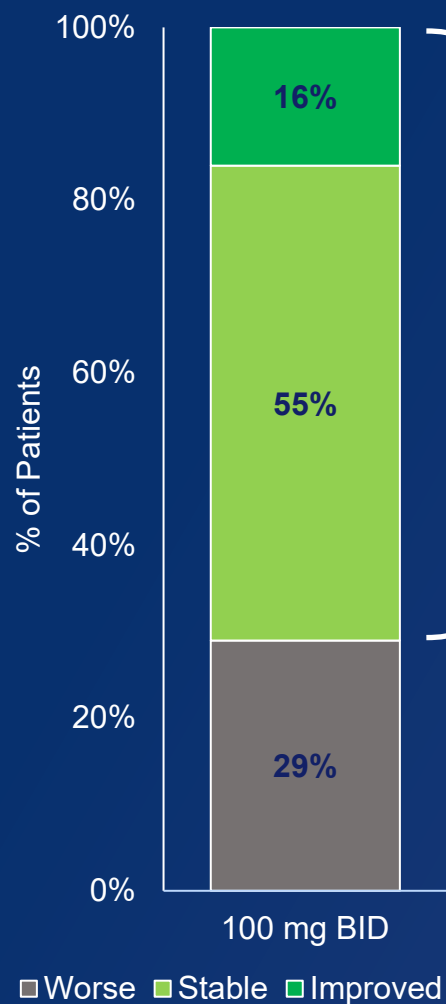
- **>70% of patients in ATLAS showed stabilization or reversal of fibrosis on 100 mg BID^{1,2}**
- Signals of disease course reversal seen, especially with early intervention
- Routine imaging (HRCT) is used to measure and quantify lung fibrosis using AI technology to calculate Quantitative Lung Fibrosis (QLF)
- Data has shown **correlation between lung function (FVC), fibrosis quantification (QLF), and quality of life (QOL)**

● Ground Glass (QGG) ● Reticulation (QLF) ● Honeycombing (QHC)

Different types of fibrosis

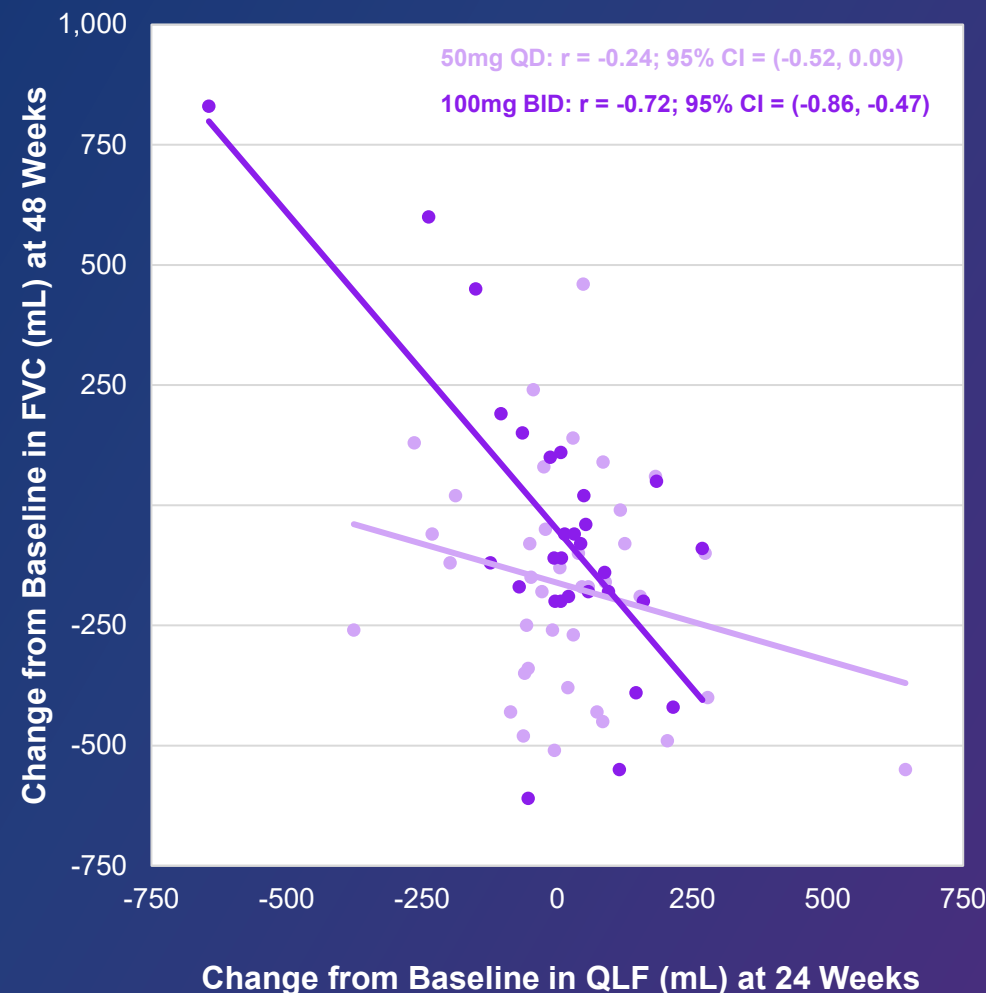


Stabilization or Reversal of Fibrosis Seen in Majority of Patients on 100mg BID Dose, with Correlation between Lung Function, Fibrosis, and QoL



>70% of Patients Demonstrate Stabilization or Reversal of Fibrosis¹⁻²

Correlation between FVC and QLF³





Phase 2b PPF MIST Study is Designed to Support Registration



Patient Population Key Criteria

- PPF patients with recent downward decline in FVC (INBUILD criteria)
- Background SOC allowed:
 - Immunosuppressants
 - Oral nintedanib or nerandomilast (capped at 50%)



Complete enrollment anticipated mid-2026; topline data anticipated 2H 2027

AP02: Inhaled Nintedanib



AP02: Inhaled Nintedanib for the Treatment of IPF Patients



Nonclinical program completed



Phase 1 SAD / MAD trials in healthy volunteers & IPF patients completed demonstrating:

- PK comparable between IPF patients & healthy volunteers
- Dose-related increase in systemic exposure
- Demonstrates preferential lung exposure with inhalation vs oral administration
- Generally well-tolerated with no bronchospasm or diarrhea observed



Phase 2 underway

First patient dosed in Phase 2 AURA-IPF study in 1Q 2026



First AP02 Phase 1 SAD Study (2023) Results Supported Dose Escalation

Phase 1 Study Design

	SAD Cohorts	Lung Exposure Cohorts	IPF Cohort
Cohorts	1-3	4-5	6
Subject	NHVs	NHVs	IPF
Dose (Single)	0.5, 1.0, 2.0 mg AP02	150 mg oral 2.0 mg AP02	2.0 mg AP02
Measurements	• Safety • Plasma PK • Airway tolerance measures (FEV₁, oximetry, cough)	• Single BAL / ELF timepoint • Safety • Plasma PK • Airway tolerance measures (FEV₁, oximetry, cough) • Estimated ELF PK	• Safety • Plasma PK • Airway tolerance measures (FEV₁, oximetry, cough)

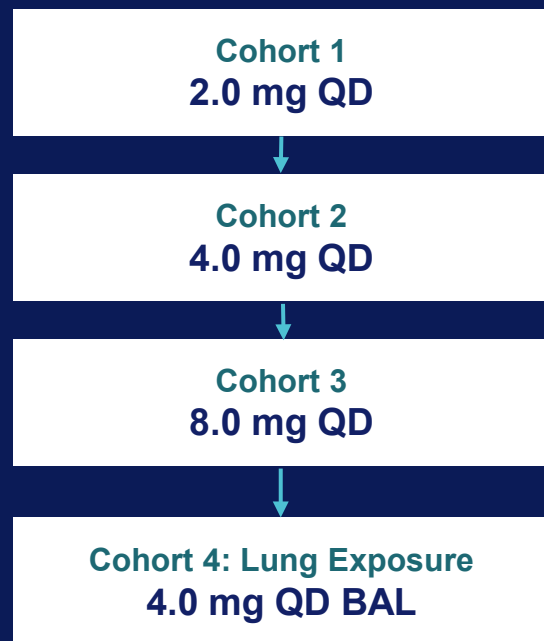
Safety & Tolerability

- ✓ **No** SAEs, bronchospasm or decreased oxygen saturation
- ✓ **All** TEAEs classified as mild; except for 1 moderate headache. All resolved within 48h
- ✓ Tolerability **supported advancement to higher doses**



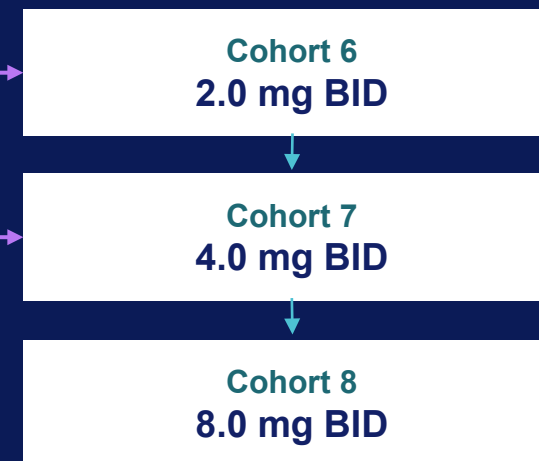
Second AP02 Phase 1 SAD / MAD Study Design Included Epithelial Lining Fluid Samples

Phase 1 Part A: Healthy Volunteer SAD



- Single inhalation dose in Healthy Volunteers
- Cohorts 1-3: N=8 (6 active vs 2 placebo per cohort)
- Cohort 4 (lung exposure): BAL / ELF; N=12 (n = 4 at each of 3 timepoints)
- Endpoints: Safety, PK

Phase 1 Part B: Healthy Volunteer MAD (7 days)



- Multiple inhalation doses in Healthy Volunteers
- N=8 (6 active vs 2 placebo per cohort)
- Endpoints: Safety, PK

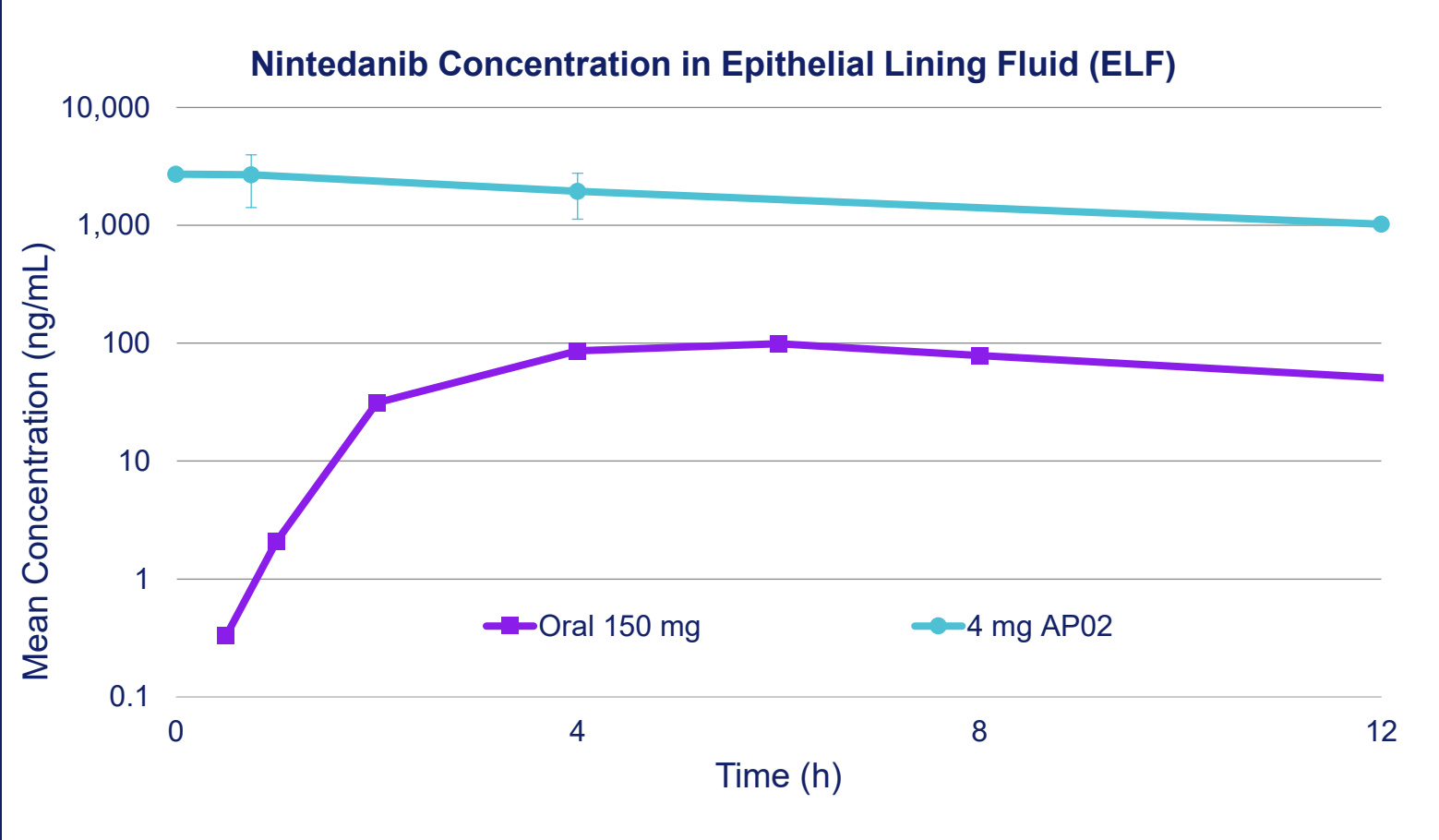
→ Safety Review Committee (SRC) Review

→ May be conducted following completion of specified Cohort

BAL: bronchoalveolar lavage; ELF: epithelial lining fluid



AP02 Significantly Improved Nintedanib Lung Exposure



Inhaled at 4mg vs oral 150 mg*

C_{max}

+27x

(2,720 ng/mL vs 99 ng/mL)

AUC_{0-24h}

+27x

(20,900 ng*h/mL vs 779 ng*h/mL)

Inhalation improved nintedanib lung exposure vs serum concentration

Lung exposure, measured as ELF, was evaluated using cross-trial comparative analysis against the ELF data from the first Phase 1 trial of 150 mg nintedanib. The second Phase 1 trial did not include a direct head-to-head comparison of the 4 mg AP02 dose to the approved oral product. A cross-trial comparative analysis against the first Phase 1 study with the same product formulations and patient population criteria was conducted, which may not be reliable as the dosing occurred under two separate protocols.



Inhaled Delivery of AP02 Avoided Systemic Exposure with No TEAEs at 4mg BID

Inhalation Results in Lower Plasma Exposure vs Oral

Inhaled at 4mg vs oral 150 mg

$C_{\max}$

-17x

(1.94 ng/mL vs 31.95 ng/mL)

AUC_{0-24h}

-26x

(14.1 ng*h/mL vs 363 ng*h/mL)

Generally Well Tolerated

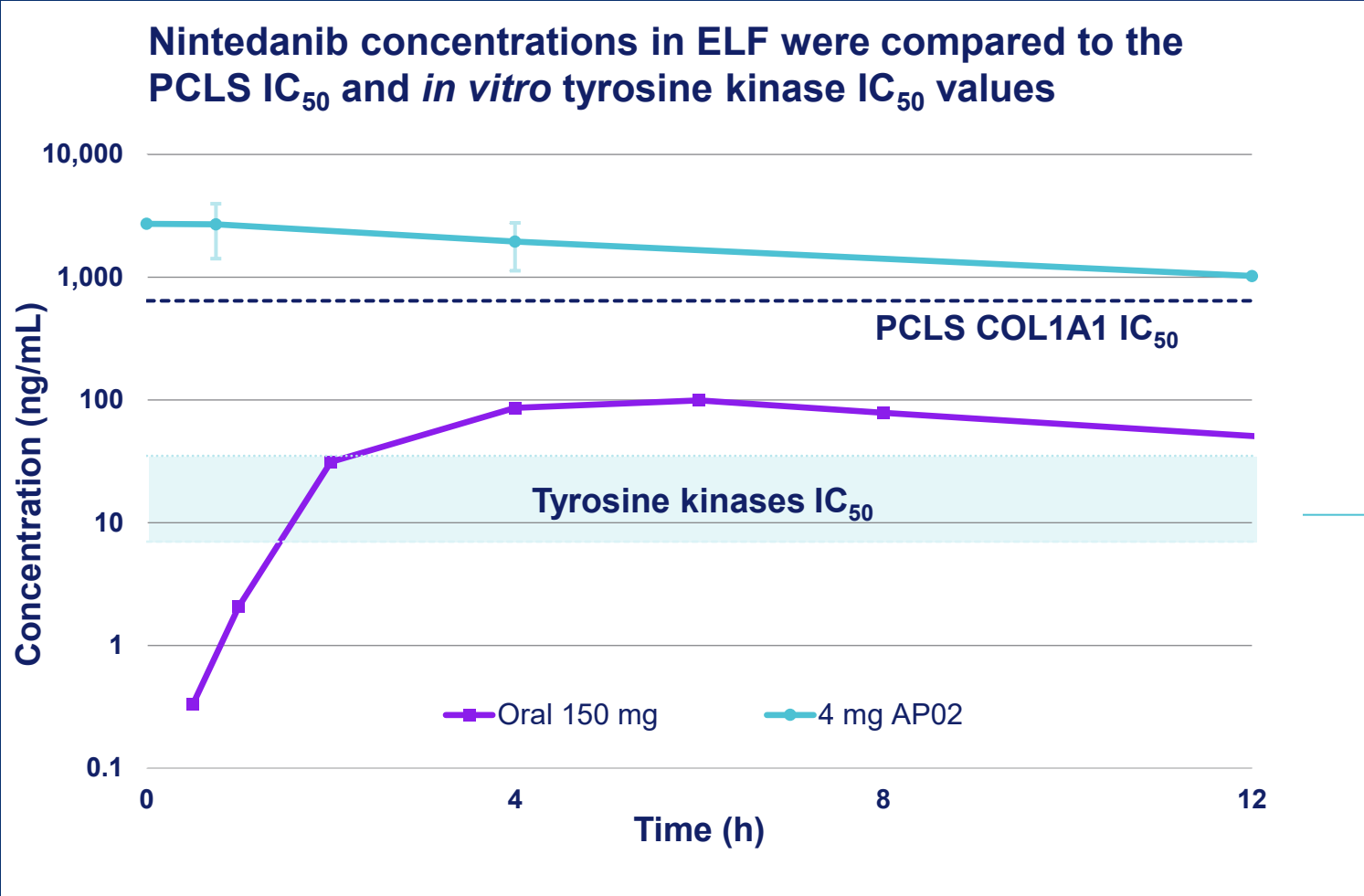
No drug-related AEs at 4 mg BID

No bronchospasm or cough

No diarrhea



Inhaled AP02 Concentration Exceeded IC₅₀ For Key Markers of Fibrosis



Select nintedanib *in vitro* kinase inhibition profile¹

Kinase	IC ₅₀ (ng/mL)
VEGFR-1	18
VEGFR-2	11
VEGFR-3	7
FGFR-1	37
FGFR-2	20
PDFGR-a	32
PDFGR-b	35

Precision cut lung slice (PCLS) model system uses IPF patient derived tissue explants to assess biomarker response.





Now Enrolling: AP02 Phase 2 AURA IPF Study Design

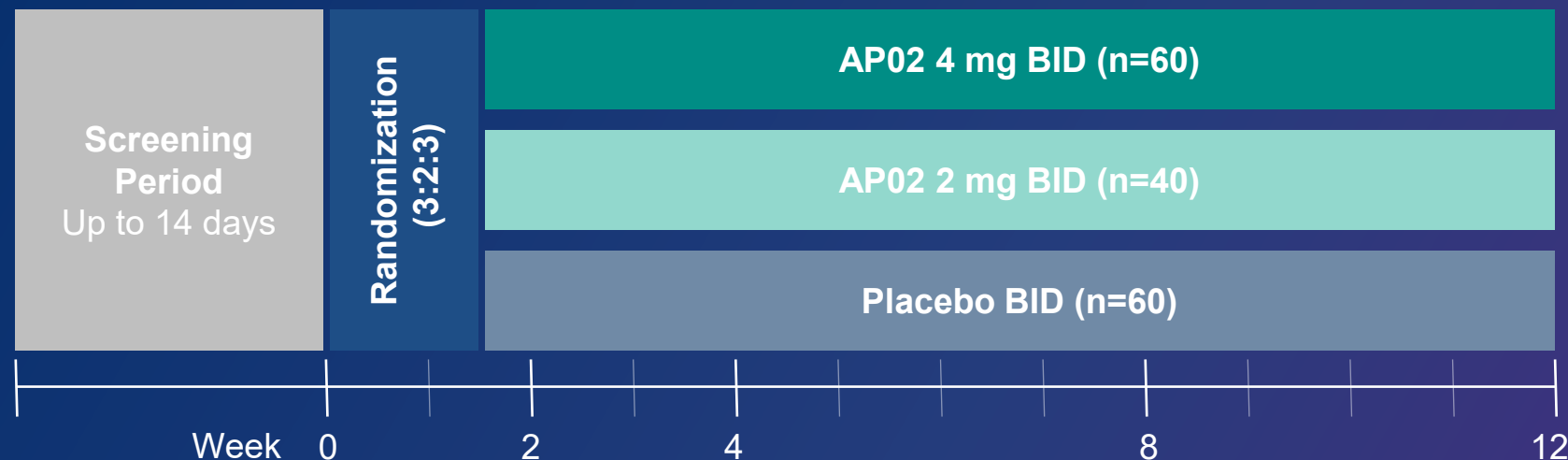
A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Trial Evaluating the Safety and Efficacy of AP02 in IPF



Patient Population Key Criteria

- Male or female ≥ 40 years
- Patients with IPF not actively on background antifibrotics
 - Patients may have been on oral nintedanib or pirfenidone previously but were intolerant to orals

***note:** Subjects will have 1 week of open-label nebulized saline to establish a baseline for cough



Primary Efficacy Endpoint: Change from baseline FVC over 12 weeks

Key Secondary Efficacy Endpoints:

- Change from baseline quantitative analysis on HRCT
- Time to disease progression

AP03: Fixed Dose Combination



AP03 Fixed Dose Combination: Advancing Toward Phase 1 Readiness

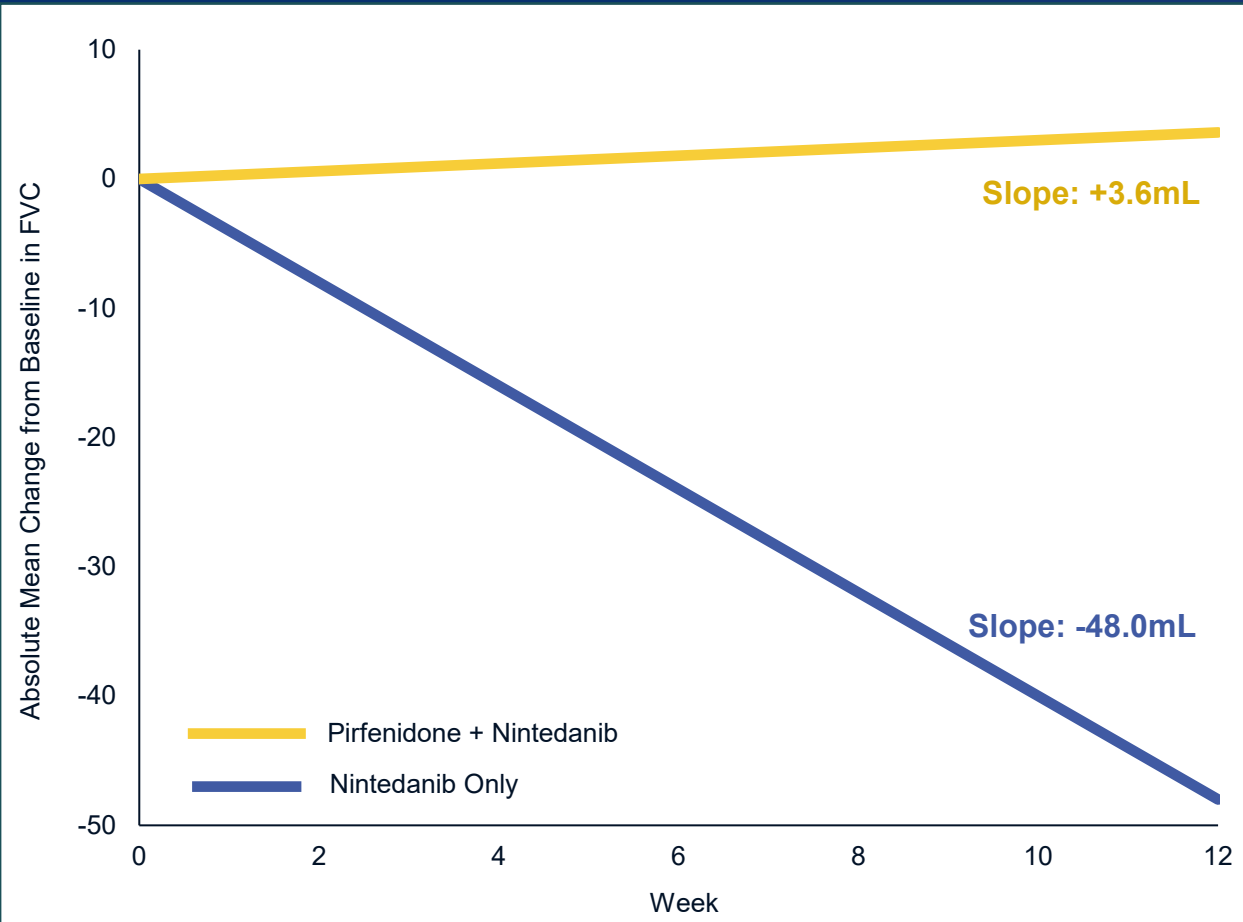
- ✓ CMC fixed dose formulation identified that supports full dose range potential
- ✓ CMC engineering batches manufactured
- ✓ Completed IPF patient-derived Precision Cut Lung Slice (PCLS) pharmacology studies to help guide AP03 Phase 1 dose selection
- Clinical supply manufacturing anticipated for 1H 2026

Initiation of Phase 1 study anticipated in late 2026

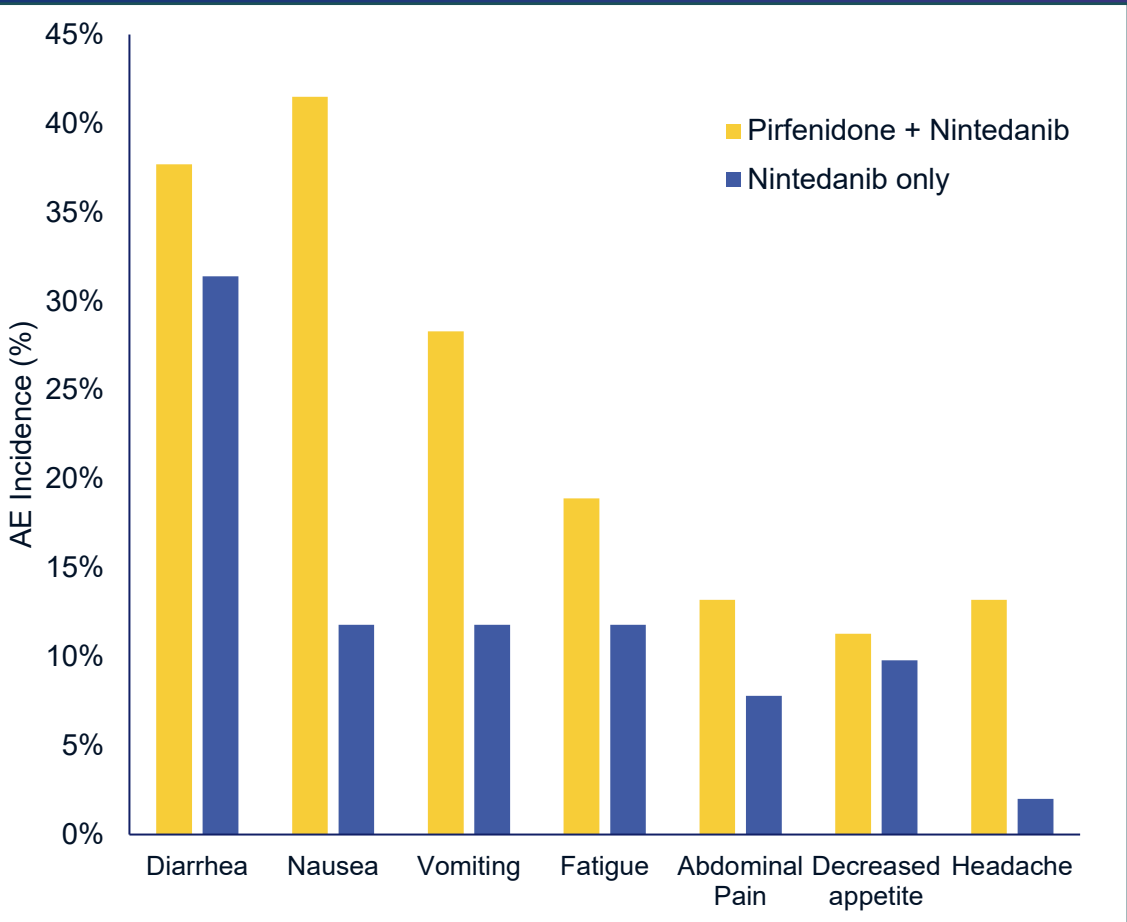


AP03 Informed by Third Party INJOURNEY Trial That Showed Improved Efficacy in Combination with Significant Tolerability Challenges

Increased Efficacy Benefit with Combination at 12Wks



Worse Tolerability with Combination of Oral Agents

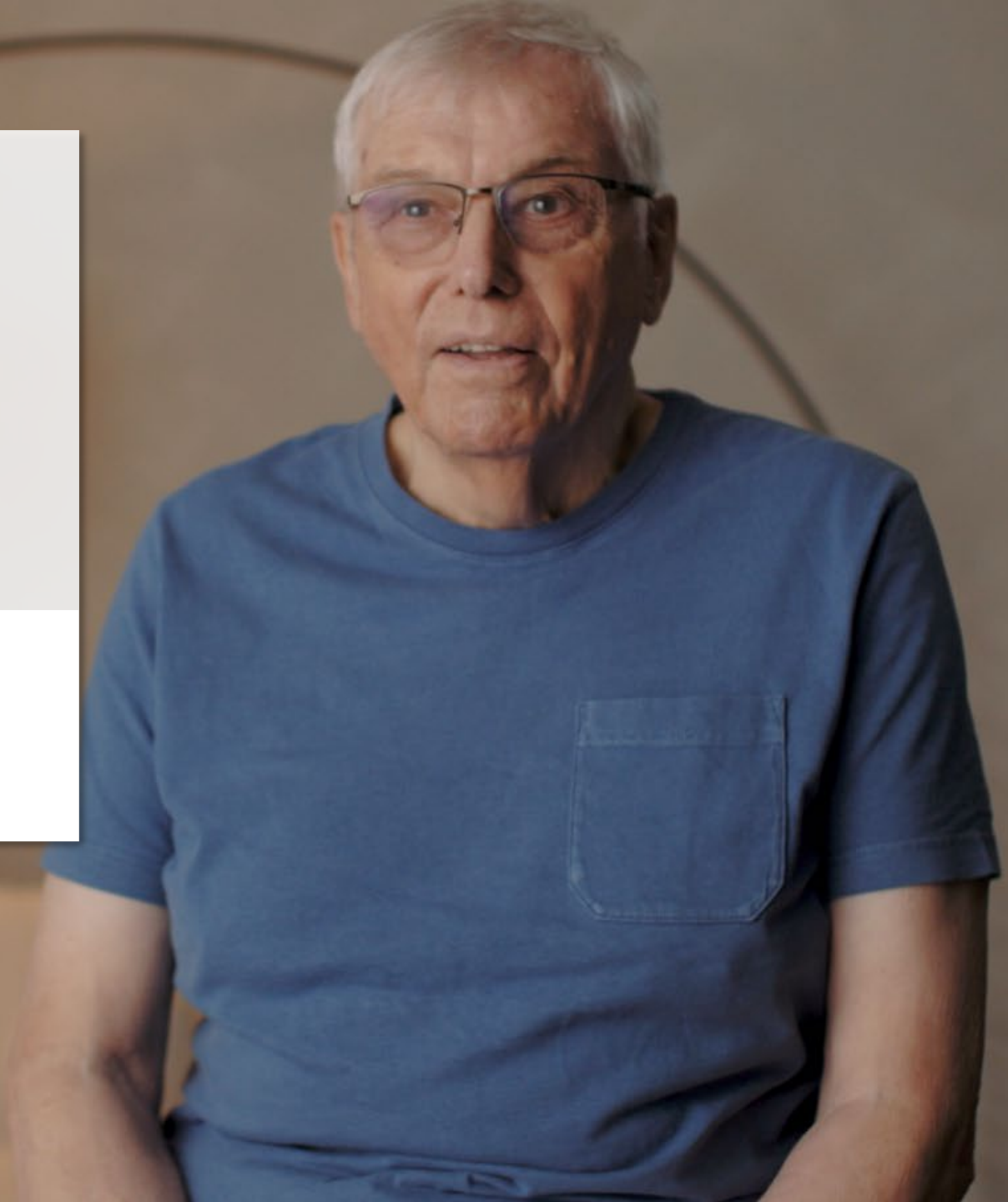


For patients like Peter...

He was first treated in our ATLAS study in 2020 and remains on treatment in our open-label extension today, over five years later.



We wake up every day to improve the lives of IPF & PPF patients.





Innovation With The Goal Of Improving Patient Outcomes In Rare Lung Diseases



Large patient base with
high unmet need



Approved **medicines**
with high probability of
success



Device selection that
offers medical and
commercial advantages

Multiple near-term clinical catalysts anticipated by 2H 2027