



Reimagining the Future of Rare Lung Disease Treatment

Corporate Overview

Nasdaq: AVLN

September 2026

■ TARGETED THERAPIES FOR RARE LUNG DISEASES



Disclaimer

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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 (Nasdaq: AVLN) in April 2026, cash runway projected into 2029

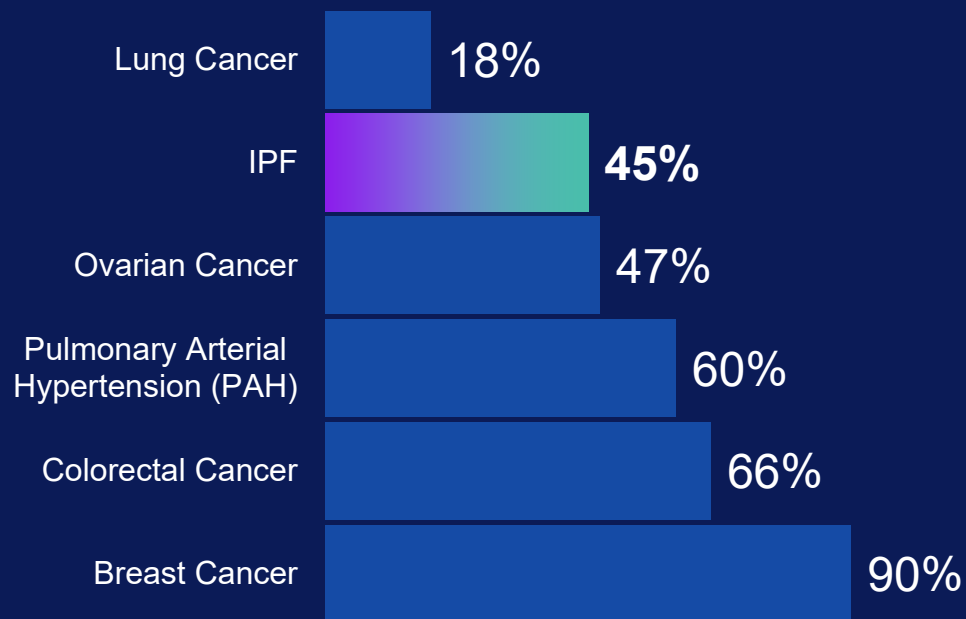


Expert team with deep experience developing & commercializing inhaled therapies

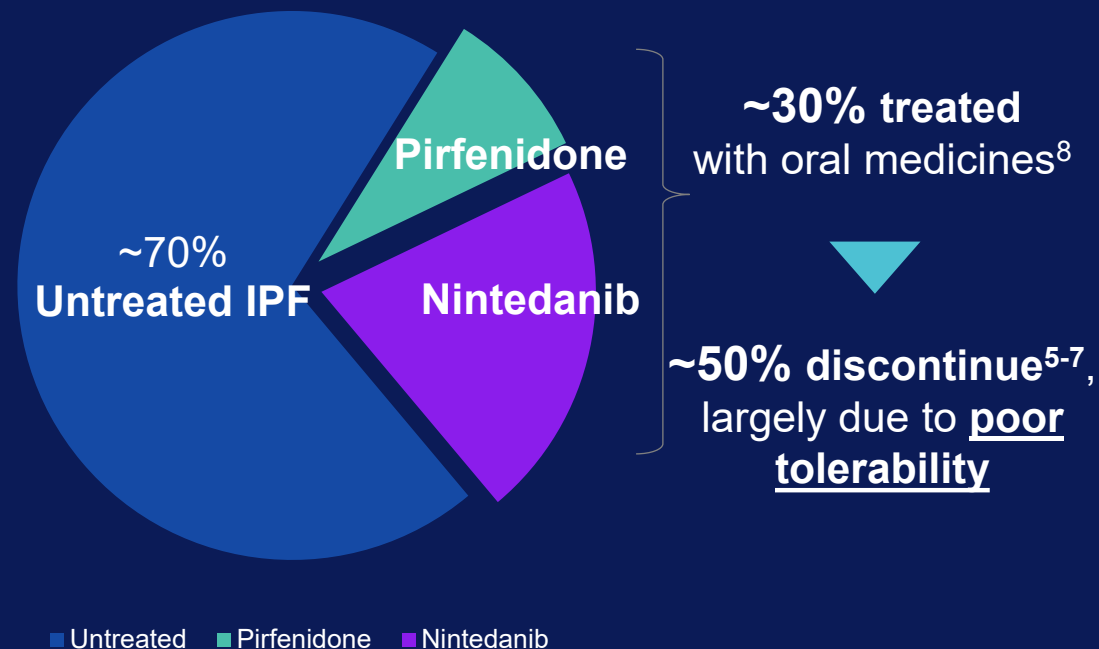


Pulmonary Fibrosis: Deadly Disease with Limited Approved Agents

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 THESIS



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



Decreases systemic exposure



Dramatic improvement to existing product profiles



Clinical Stage Portfolio with Potential to Transform Treatment of Pulmonary Fibrosis

AP01

Inhaled pirfenidone: Enrollment completed in global Phase 2b MIST study in PPF; 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
 - Originally targeting 375 patients, the Phase 2b study enrolled 398 patients due to high level of interest from investigators and patients

AP02

Inhaled nintedanib: Phase 2 global AURA 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: initiating Phase 1 in late 2026; data expected 2H27

- We believe combining mechanisms is only tolerable with inhaled delivery
- Allows for evolution of treatment paradigm in disease towards combos



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

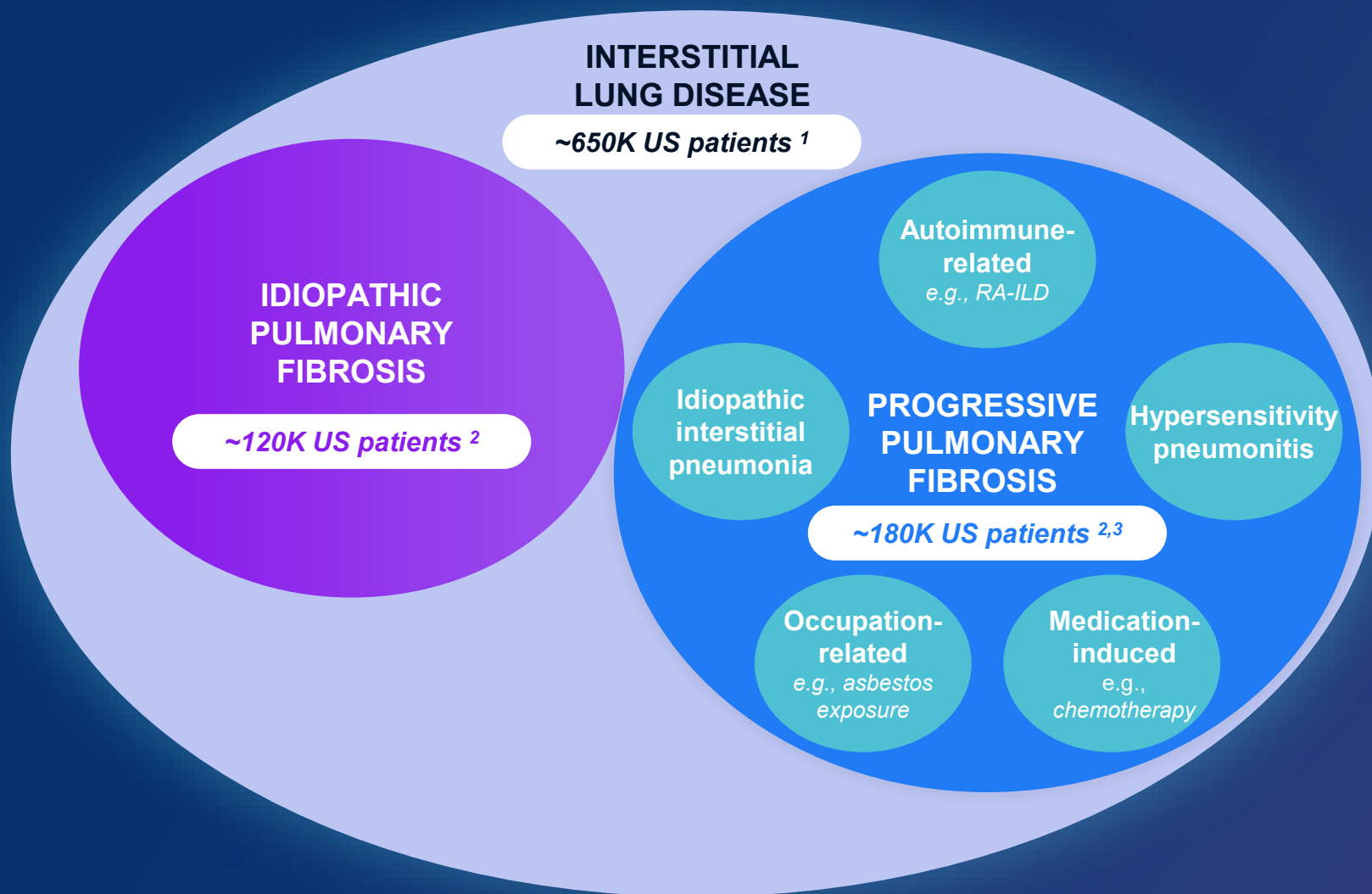
GENERATION 4 → Future

Triple FDCs

avalyn pharma
undisclosed



IPF and PPF Are Two Key Types of Interstitial Lung Disease



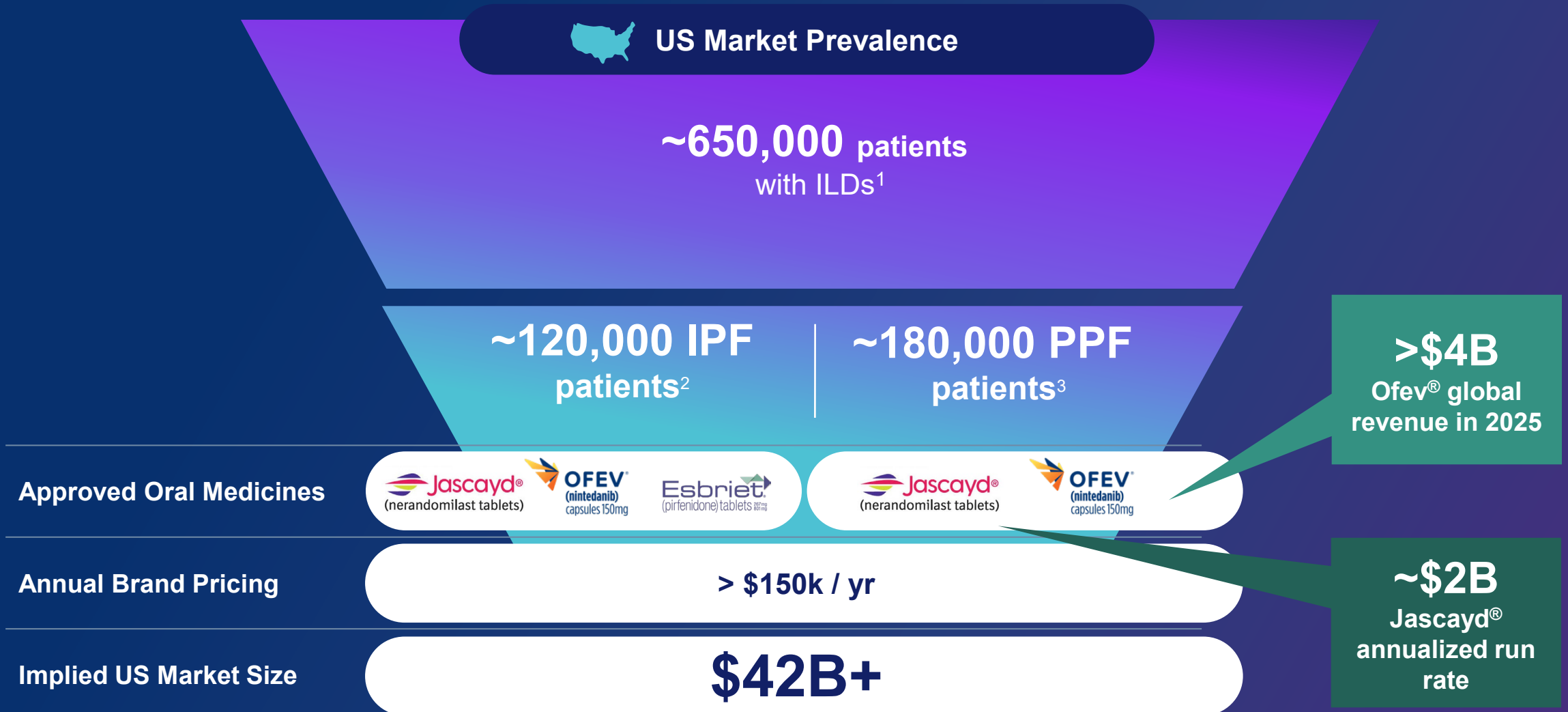
>200 types¹ of interstitial lung diseases (ILDs)

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 Completed		MIST Phase 2b Study Readout	✓ Ph2b trial enrollment completed mid 2026 • Ph2b top line data expected 2H27
AP02 (Inhaled nintedanib)	AURA Phase 2 Initiated			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 Insmed'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

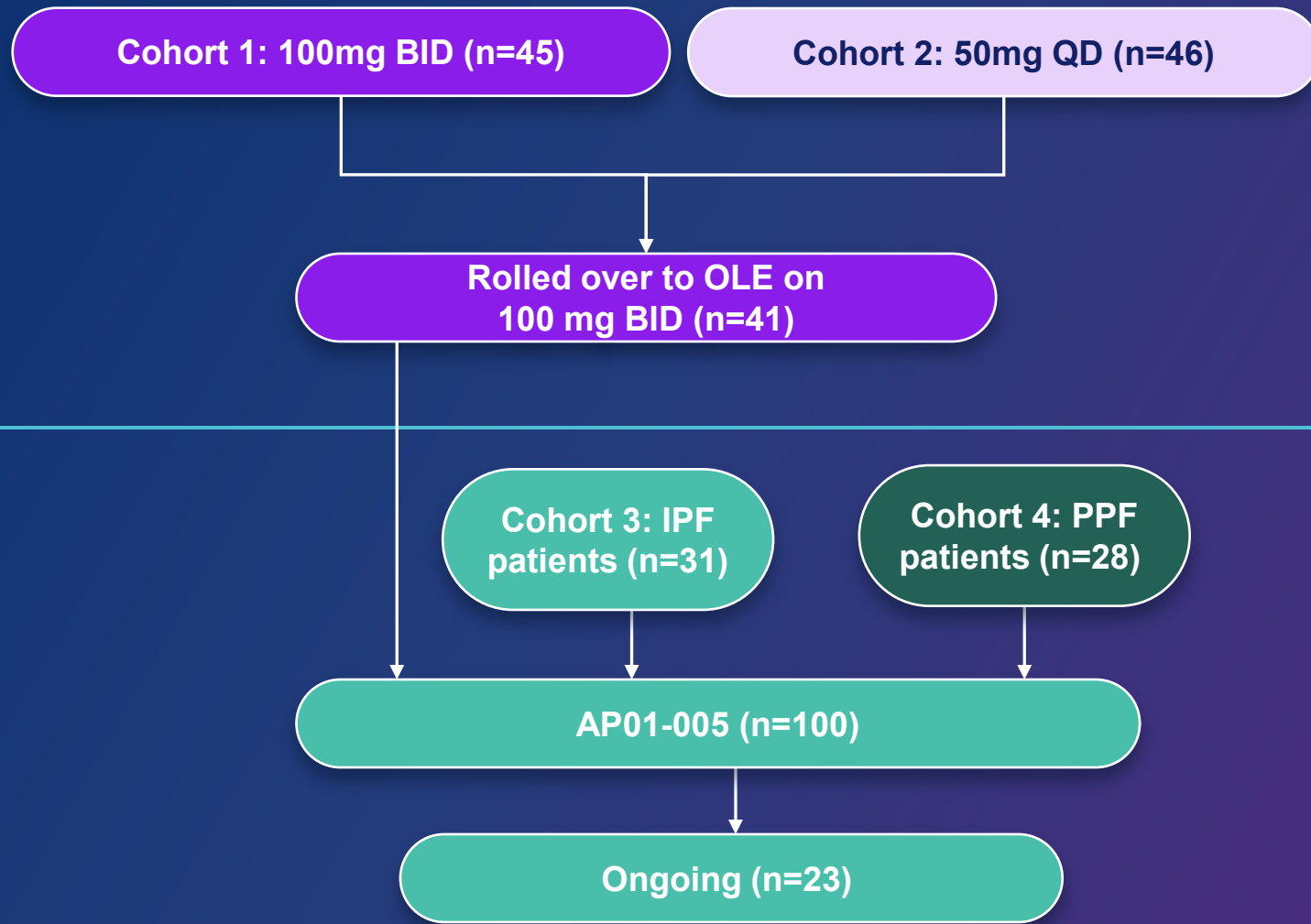
ATLAS Trial in IPF Patients

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

ONGOING

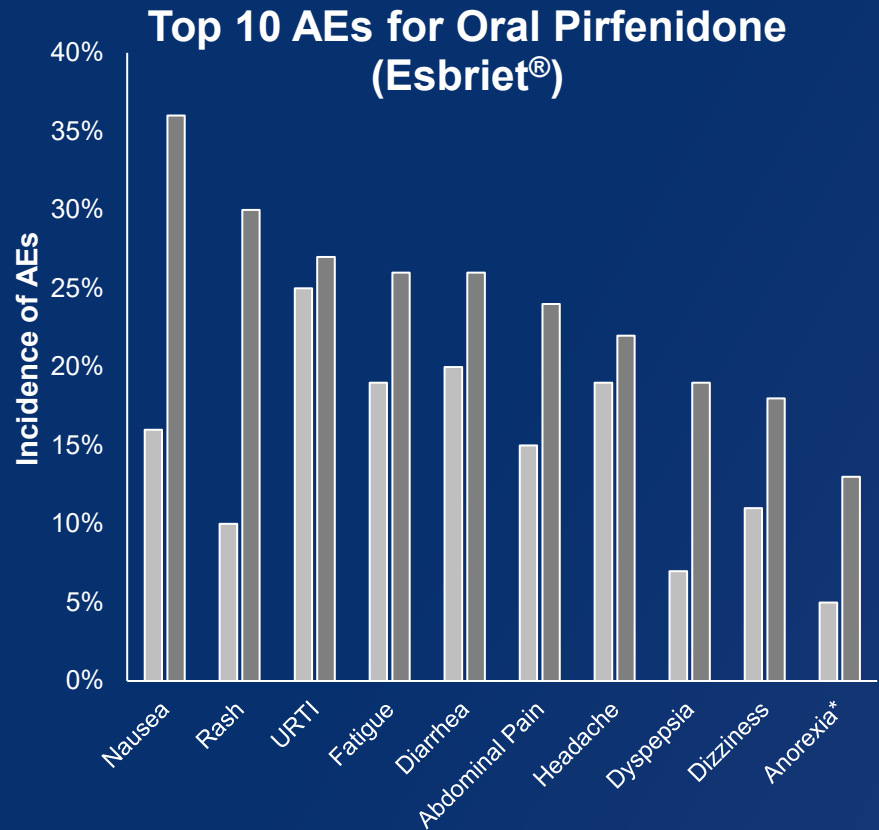
Open-Label Extension (OLE) / Compassionate Use IPF & PPF Trial

- 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

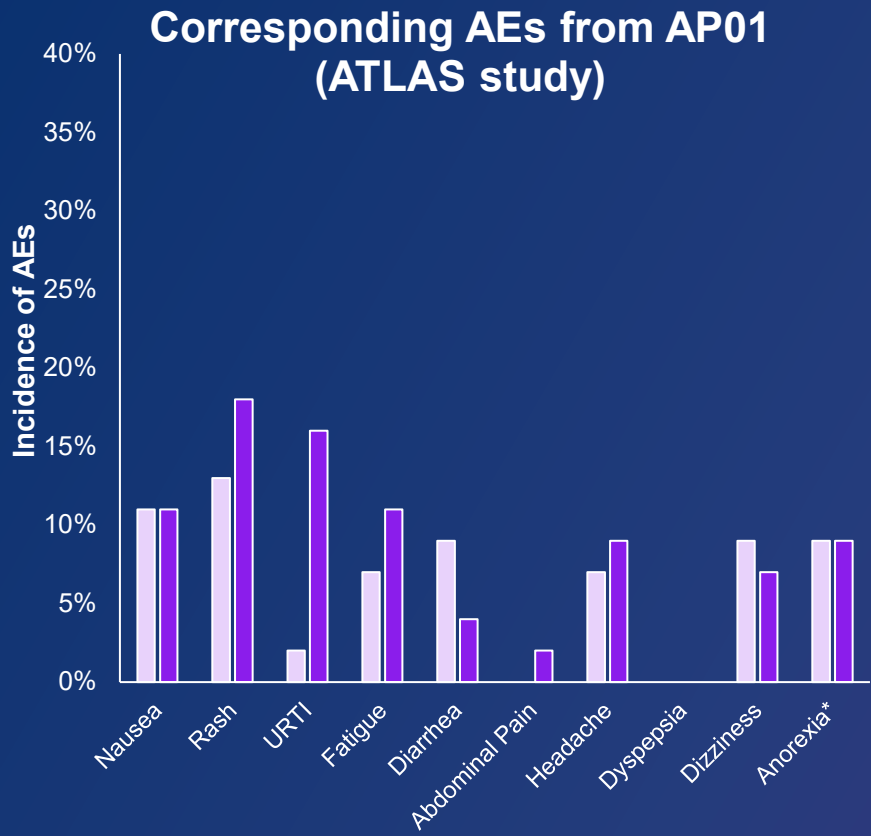




AP01 Showed Improved Tolerability in ATLAS



Pooled Historic Data ¹	
	Oral Placebo (n=624)
	Oral Pirfenidone, 801mg TID (n=623)



AP01-002 ATLAS Trial ²	
	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

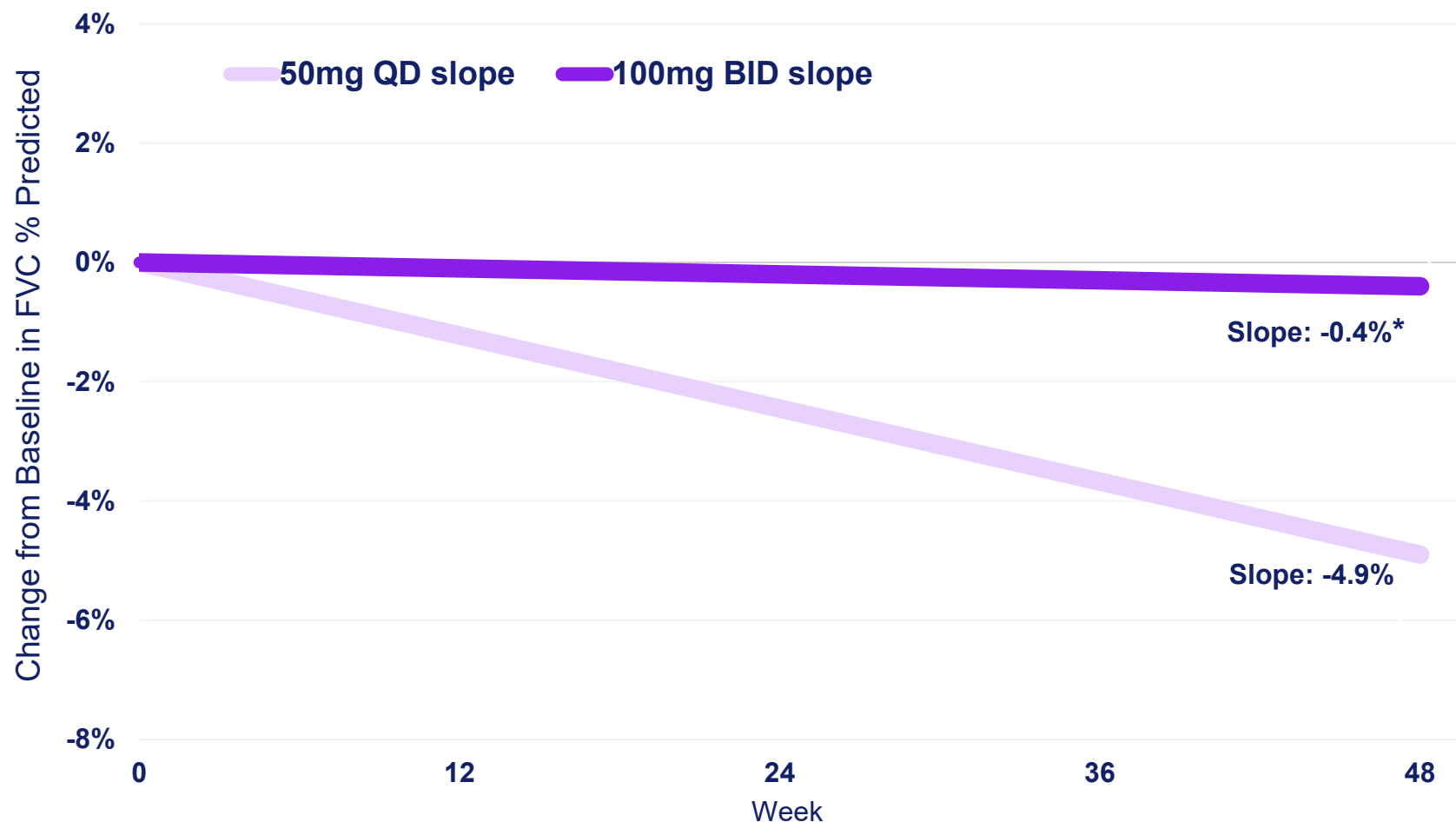
These cross-study comparisons are provided for illustrative purposes only as there are no head-to-head comparison available. Comparing the results from different trials may be unreliable due to factors such as protocol design and trial objectives varying between the trials. Therefore, cross-study comparisons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



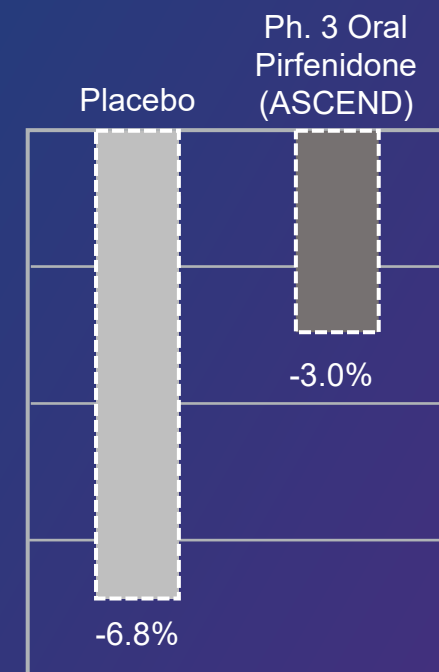


AP01 100mg Achieved Near Stabilization in ATLAS Exhibiting Significant Dose-Dependent Improvement in Lung Function

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



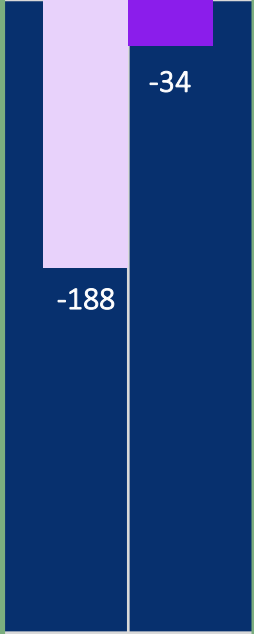
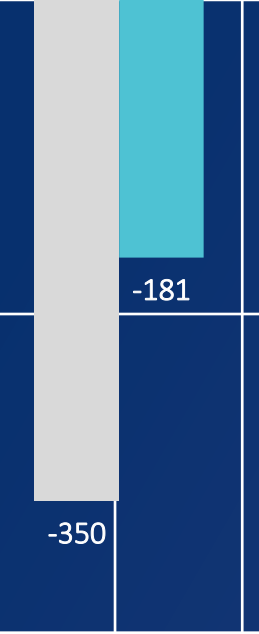
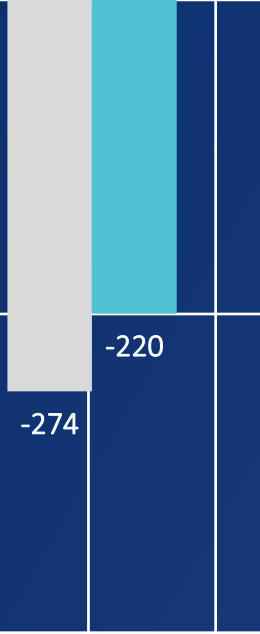
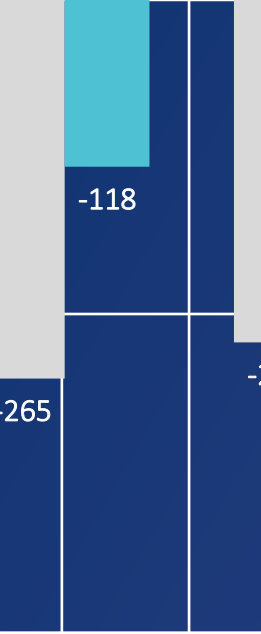
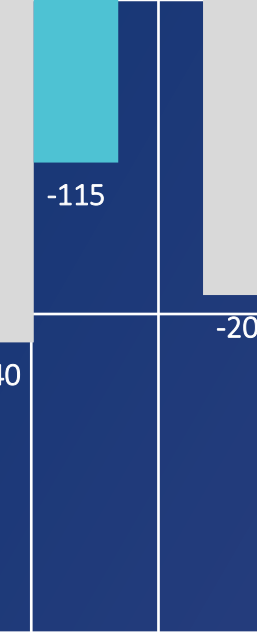
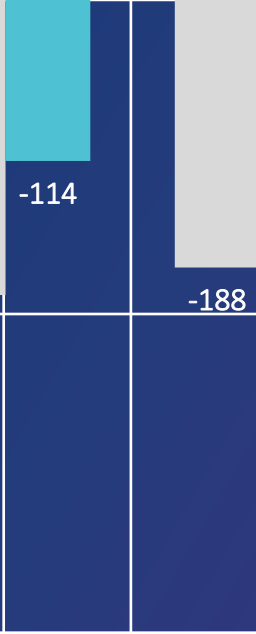
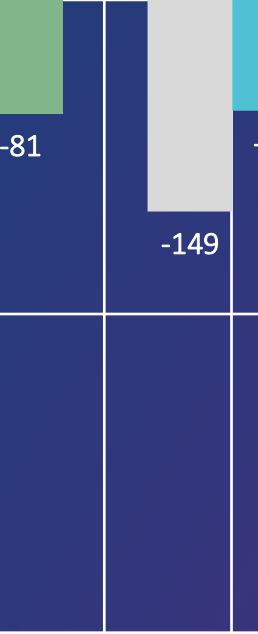
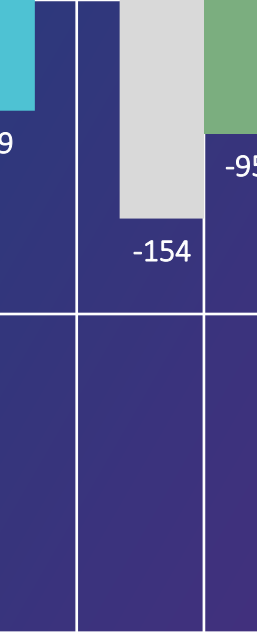
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*Through 48 weeks, 100 mg BID vs. 50 mg QD $p=0.0222$ (24-week $p=0.133$). Historic oral and AP01 data are non-imputed;

¹West et al., *Thorax* 2023 ²King et al., *N Engl J Med* 2014



Oral Data Suggests Avalyn's Inhaled Pirfenidone (AP01) Achieves Favorable FVC Change

Avalyn AP01			Oral pirfenidone (<i>Esbriet</i> ®)						Oral nintedanib (<i>Ofev</i> ®)						Oral nerandomilast (<i>Jascayd</i> ®)			
IPF		Indication	IPF		IPF		IPF		IPF		IPF		PPF		IPF		PPF	
ATLAS ¹		Trial	CAPACITY-1 ²		CAPACITY-2 ²		ASCEND ³		INPULSIS-1 ⁴		INPULSIS-2 ⁴		INBUILD ⁵		FIBRONEER ⁶		FIBRONEER ⁷	
		FVC decline 1 year (mL)																
50 mg QD	100 mg BID		Arm	Placebo	801mg TID	Placebo	801mg TID	Placebo	801mg TID	Placebo	150mg BID	Placebo	150mg BID	Placebo	150mg BID	Placebo	18mg BID	Placebo
46*	42*	# of patients	174	174	173	171	277	278	204	309	219	329	331	332	87	87	222	220

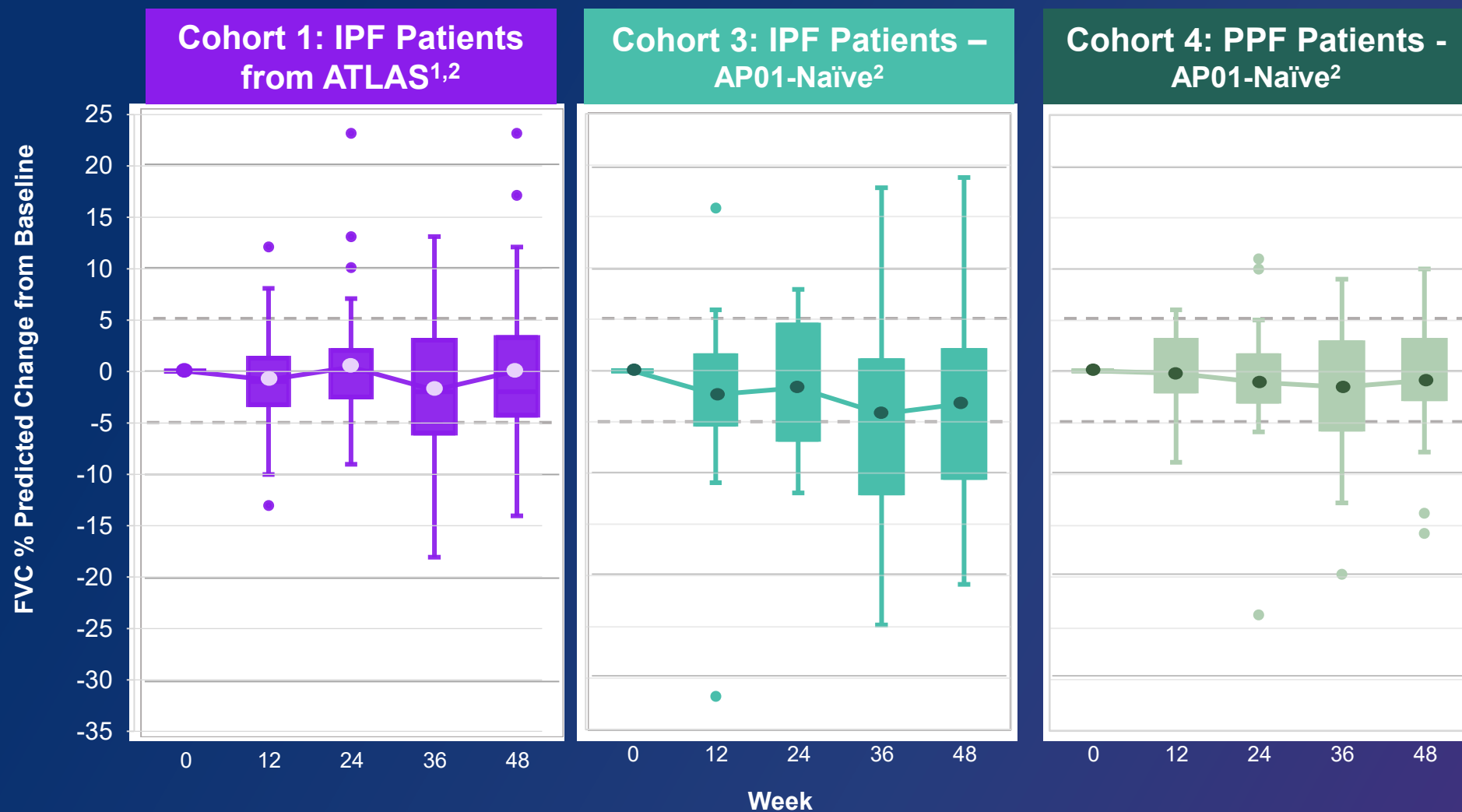
Average rate of decline in lung function due to aging is 20-50mL/year after age 40^{8,9}

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.

¹West et al., 2023; ²Pirfenidone NDA – Medical Reviews; ³Pirfenidone NDA – Statistical Reviews; ⁴Richeldi et al., 2014; ⁵Flaherty et al., 2019; ⁶Richeldi et al., 2025; ⁷Maher et al., 2025. ⁸Torris et al., 2017; ⁹Thomas et al., 2019; *Per protocol set in 48-week trial. ASCEND, INPULSIS, ATLAS, and INBUILD data are non-imputed. CAPACITY and FIBRONEER data are imputed. Note: FIBRONEER data represent patients on no background antifibrotics



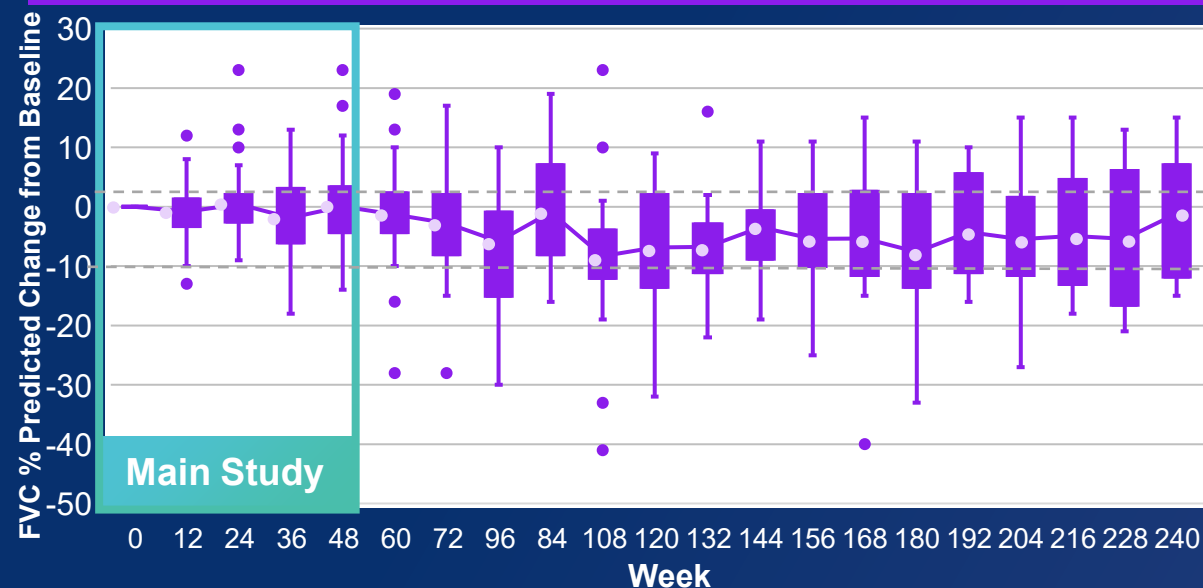
AP01 Activity in AP01-Naïve Use Cohorts Similar to IPF Patients in ATLAS over 48 weeks



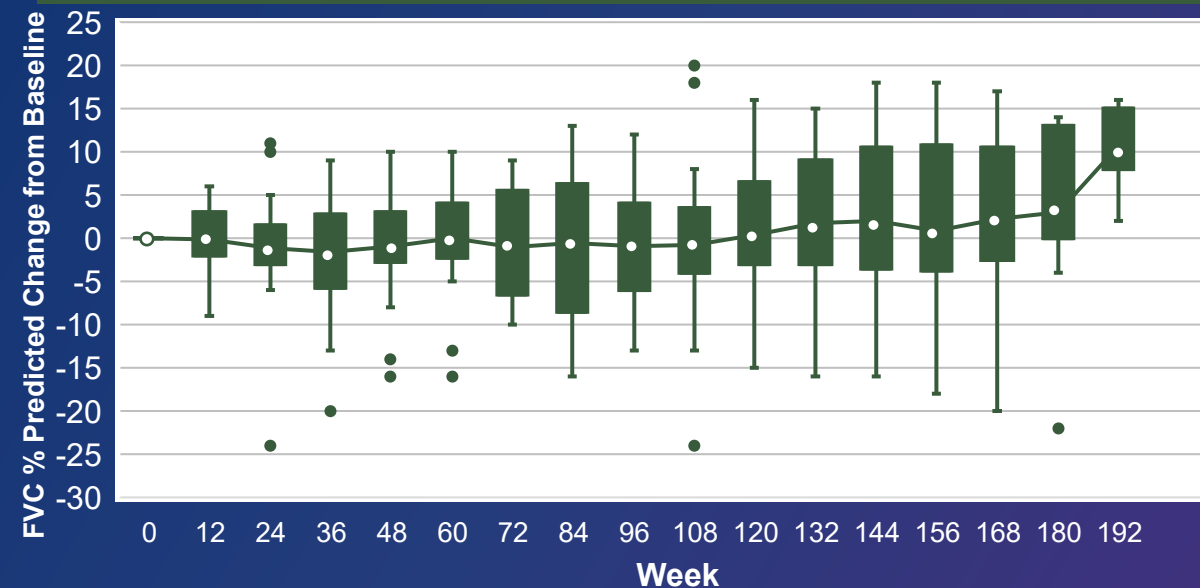


Treatment with 100 mg BID AP01 Showed Favorable Tolerability Profile and Trend Toward Disease Stabilization For Up To Four Years

Cohort 1: ATLAS IPF Patients Rolled Over Into OLE



Cohort 4: AP01-Naïve PPF Patients



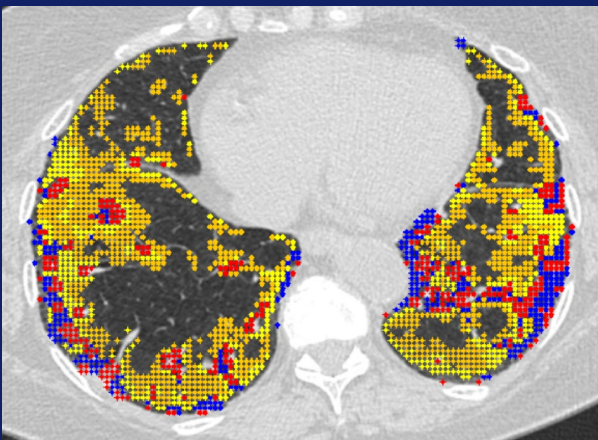
- In AP01-naïve PPF cohort, AP01 was well tolerated with safety profile consistent with IPF cohorts
 - TRAEs were cough (10.5%), decreased appetite (7.1%)
 - Only one TEAE of diarrhea and one rash
- At week 48, the mean change from baseline FVC was -31.7 mL



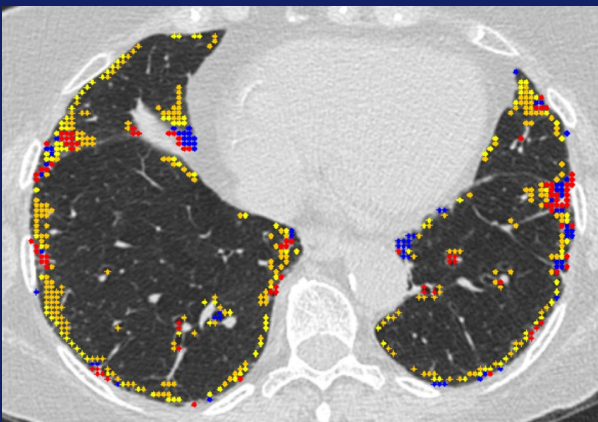
ATLAS Showed Promising Potential for Disease Modification: Imaging Correlated with FVC Data

Axial HRCT Images

BASELINE



24 WEEKS



QLF using HRCT imaging after 6 mo treatment
with AP01

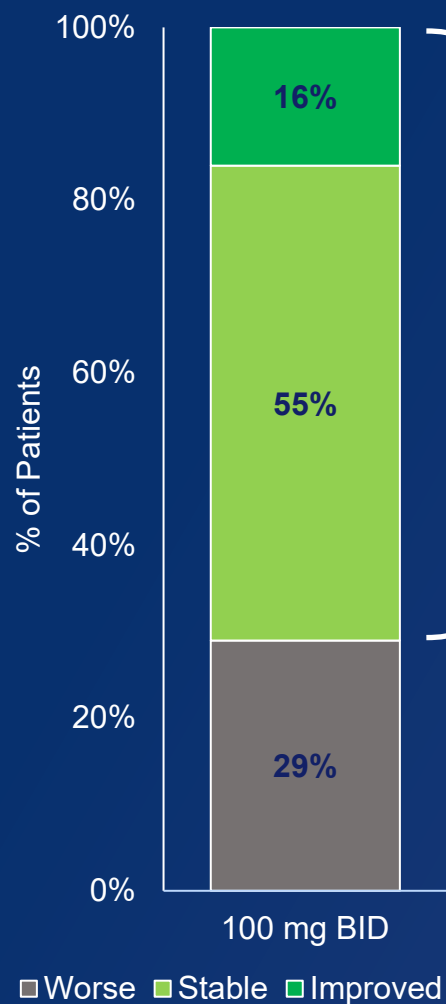
- **>70% of patients in ATLAS showed stabilization or reversal of fibrosis** on 100 mg BID^{1,2}
- Signals of disease course reversal seen, especially with early intervention
- Routine imaging (HRCT) is used to measure and quantify lung fibrosis using AI technology to calculate Quantitative Lung Fibrosis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

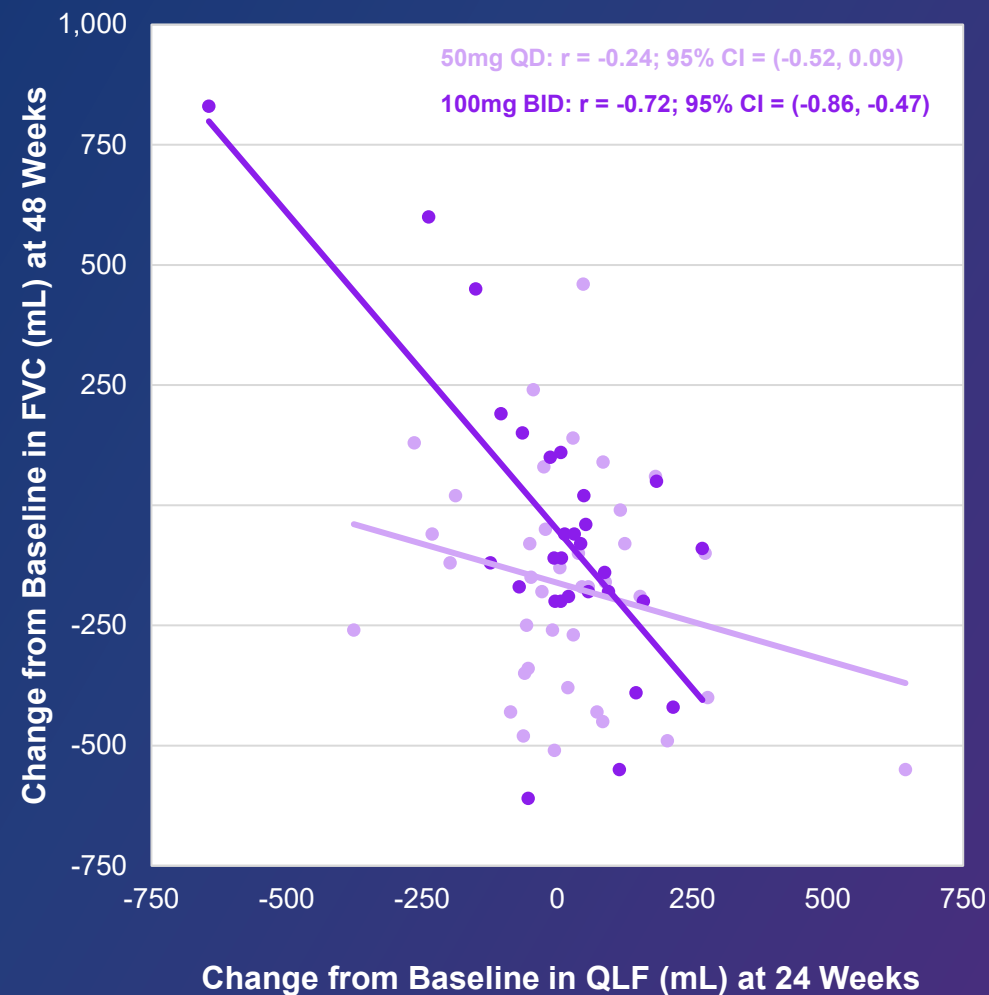


Stabilization or Reversal of Fibrosis Seen in Majority of Patients on 100mg BID Dose, with Correlation between Lung Function, Fibrosis, and QoL



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

Correlation between FVC and QLF³





Modeling of AP01 (nebulized pirfenidone) predicts aerosol distribution throughout the lung

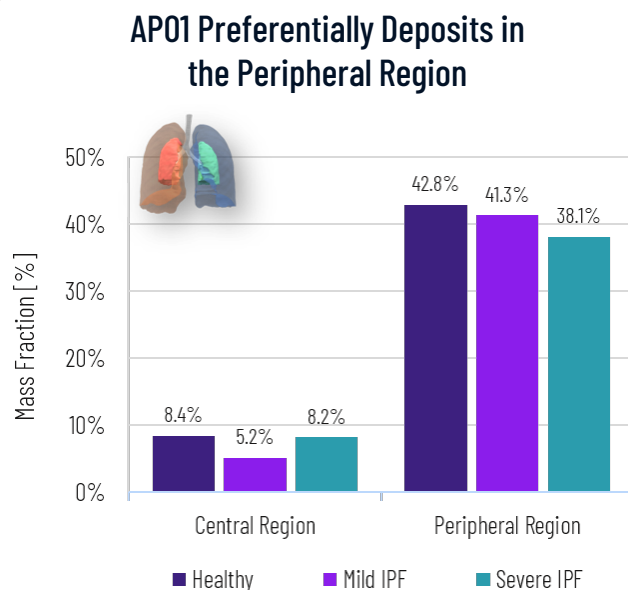


Figure 5. Deposited API mass per central and peripheral region as a fraction of the delivered dose

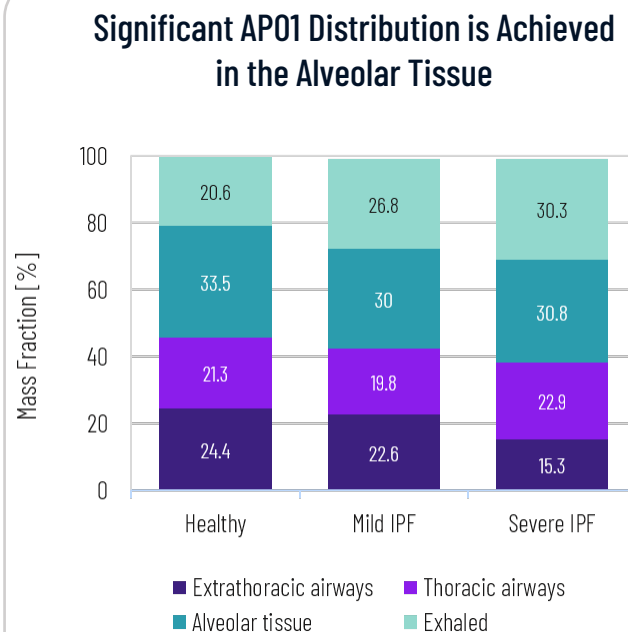


Figure 6. Deposited API mass per functional category as a fraction of the delivered dose.

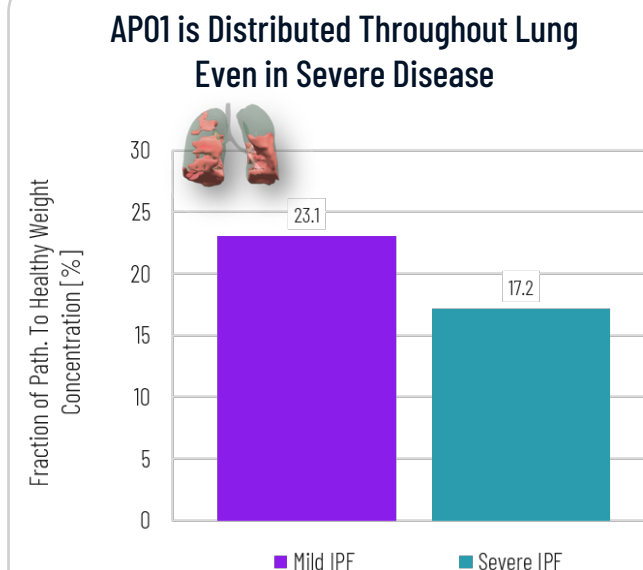


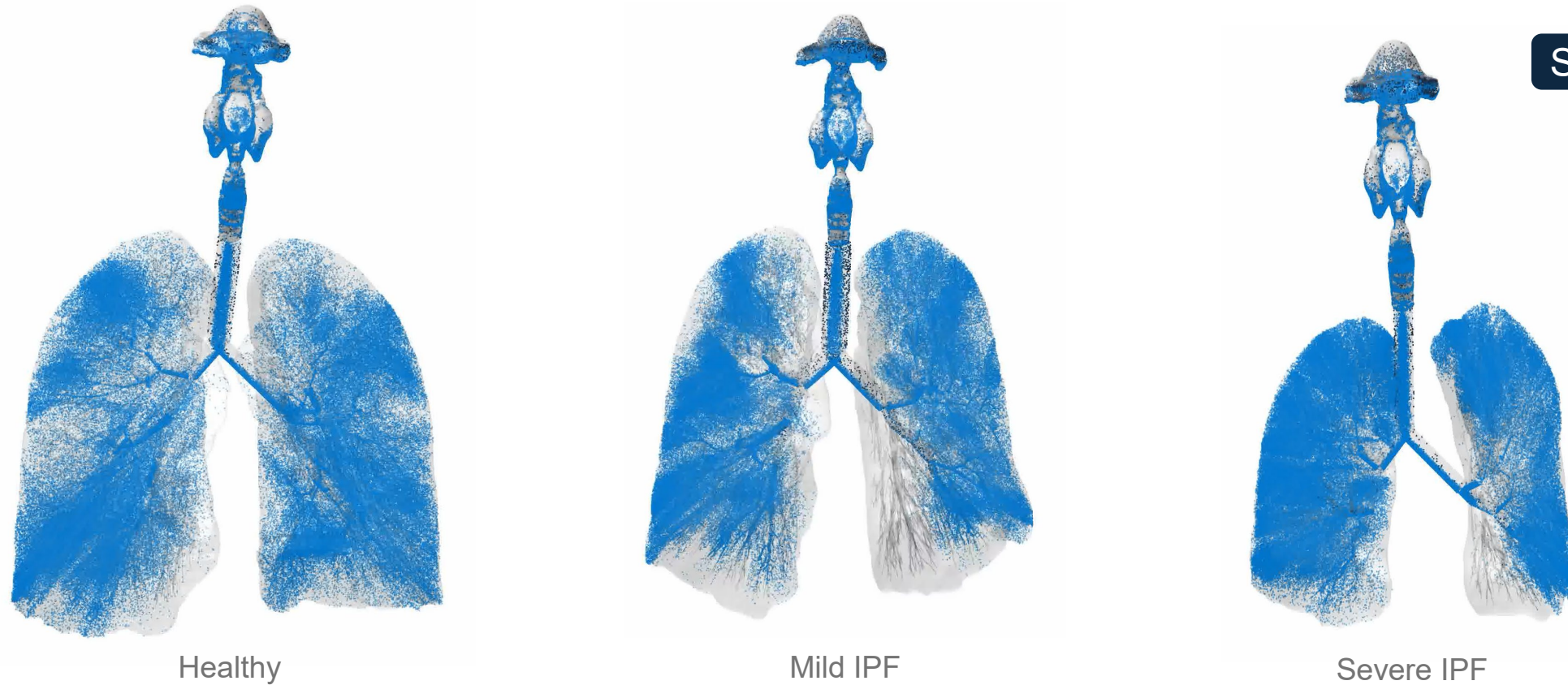
Figure 7. Normalized concentration of deposited aerosol mass per mass for healthy vs. fibrotic regions of the lungs.

- Validated¹ *in silico* model for lung deposition
- AP01 lung deposition was evaluated using HRCT models of healthy lungs and lungs from patients with mild and severe IPF.
- Results predict that AP01 is distributed throughout the lung, even in a severely diseased state.

EBENBUILD



AP01 is predicted to permeate throughout lung tissue in both healthy and diseased tissue



SCAN
ME



Figure 4. Transport and deposition of aerosol mass of three cases, visualized in single breath and in slow motion*

*Variation in lung sizes attributed to differences in age, gender, and anthropometrics of the modeled subjects.

Palacios M, et al. *In silico modeling of a novel nebulized pirfenidone formulation (AP01) predicts aerosol distribution throughout the lung.* Poster #PA4377. Presented at the European Respiratory Society (ERS) Congress 2026, held September 5-9, 2026, in Barcelona, Spain.

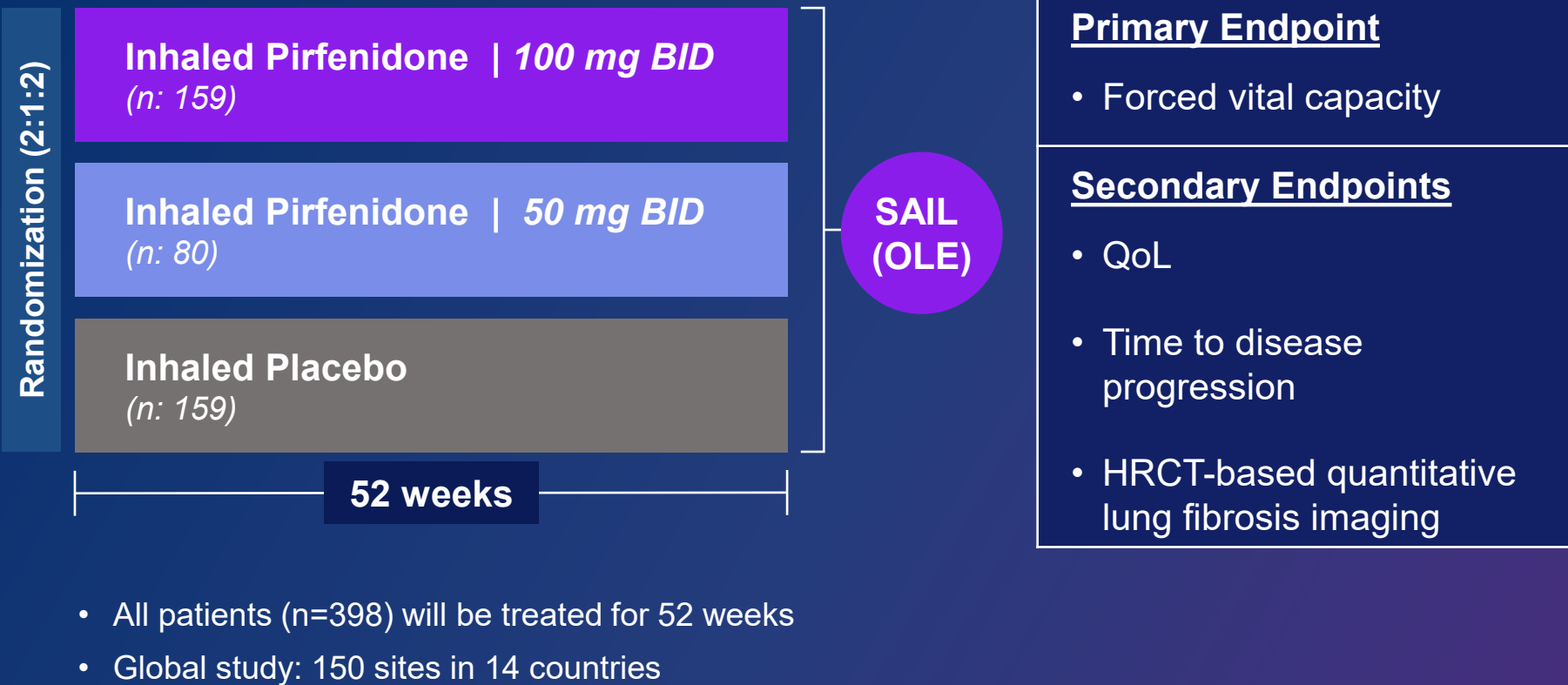


Phase 2b PPF MIST Study is Designed to Support Registration



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%)



Enrollment completed mid-2026; topline data anticipated 2H 2027



AP01 Program Supported By Over 4 Years of Long-Term Data

ATLAS
COMPLETED

ATLAS Phase 1b
50 mg QD or 100mg BID (n=91)
IPF patients

OLE
COMPLETED

ATLAS Rollover to OLE
100mg AP01 BID
IPF patients (n=41)

AP01-naïve* cohorts
100mg AP01 BID
IPF patients (n=31)
PPF patients (n=28)

**ATLAS Open Label
Extension Study Complete**

- Over 4 years of open label extension data
- Some patients from ATLAS on AP01 for 5+ years

MIST
ONGOING

MIST Phase 2b
Placebo, 50mg AP01 or 100mg BID AP01
PPF patients (n=398)

Option to rollover to new OLE

*Option to
rollover to
OLE*

SAIL OLE
ONGOING

SAIL: Ongoing OLE
100mg AP01 BID, IPF & PPF patients

* Patients with IPF (cohort 3) or PPF (cohort 4) who had no other treatment options.

Last updated August 2026. West, A. et al, (2023) *Thorax*; Poster Presentation at ATS 2025. Poster Presentation at EULAR 2026

OLE; open label extension. MIST NCT06329401; SAIL NCT06951217

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:

- 92 healthy volunteers and 6 patients with IPF have participated in Phase 1 studies to date
- 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 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 N=24 6 active, 2 PBO per cohort	NHVs N=8 4 per cohort	IPF N=6
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)

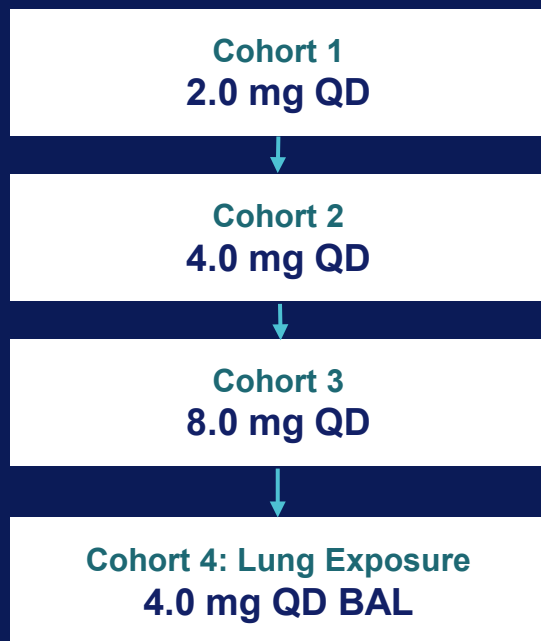
Safety & Tolerability

- ✓ **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**



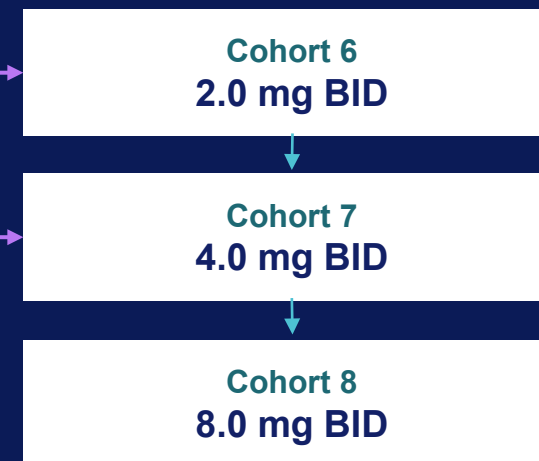
Second AP02 Phase 1 SAD / MAD Study Design Included Epithelial Lining Fluid Samples

Phase 1 Part A: Healthy Volunteer SAD



- Single inhalation dose in Healthy Volunteers
- Cohorts 1-3: N=24 (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)



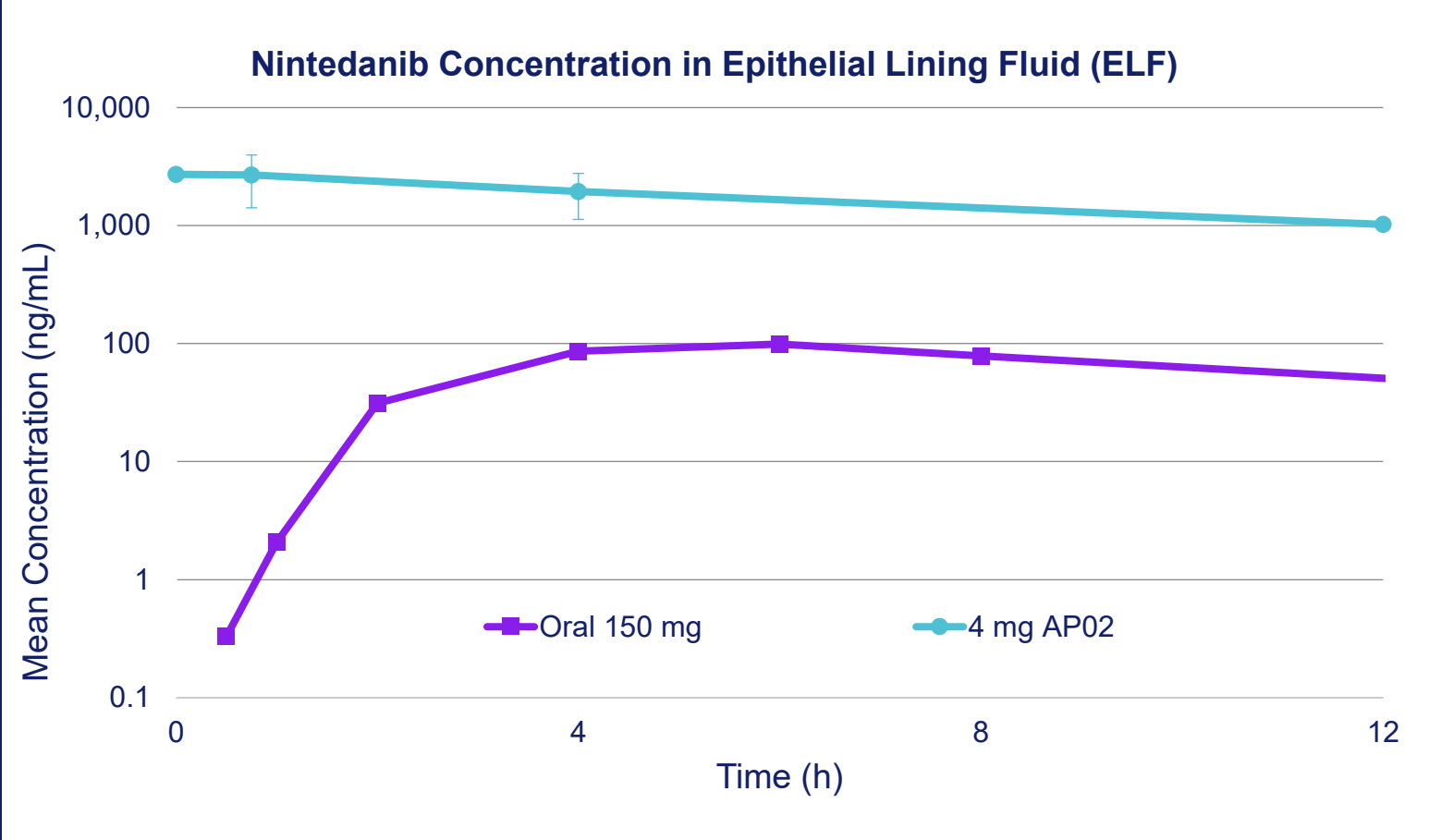
- Multiple inhalation doses in Healthy Volunteers
- N=24 (6 active vs 2 placebo per cohort)
- Endpoints: Safety, PK

→ Safety Review Committee (SRC) Review

→ May be conducted following completion of specified Cohort



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

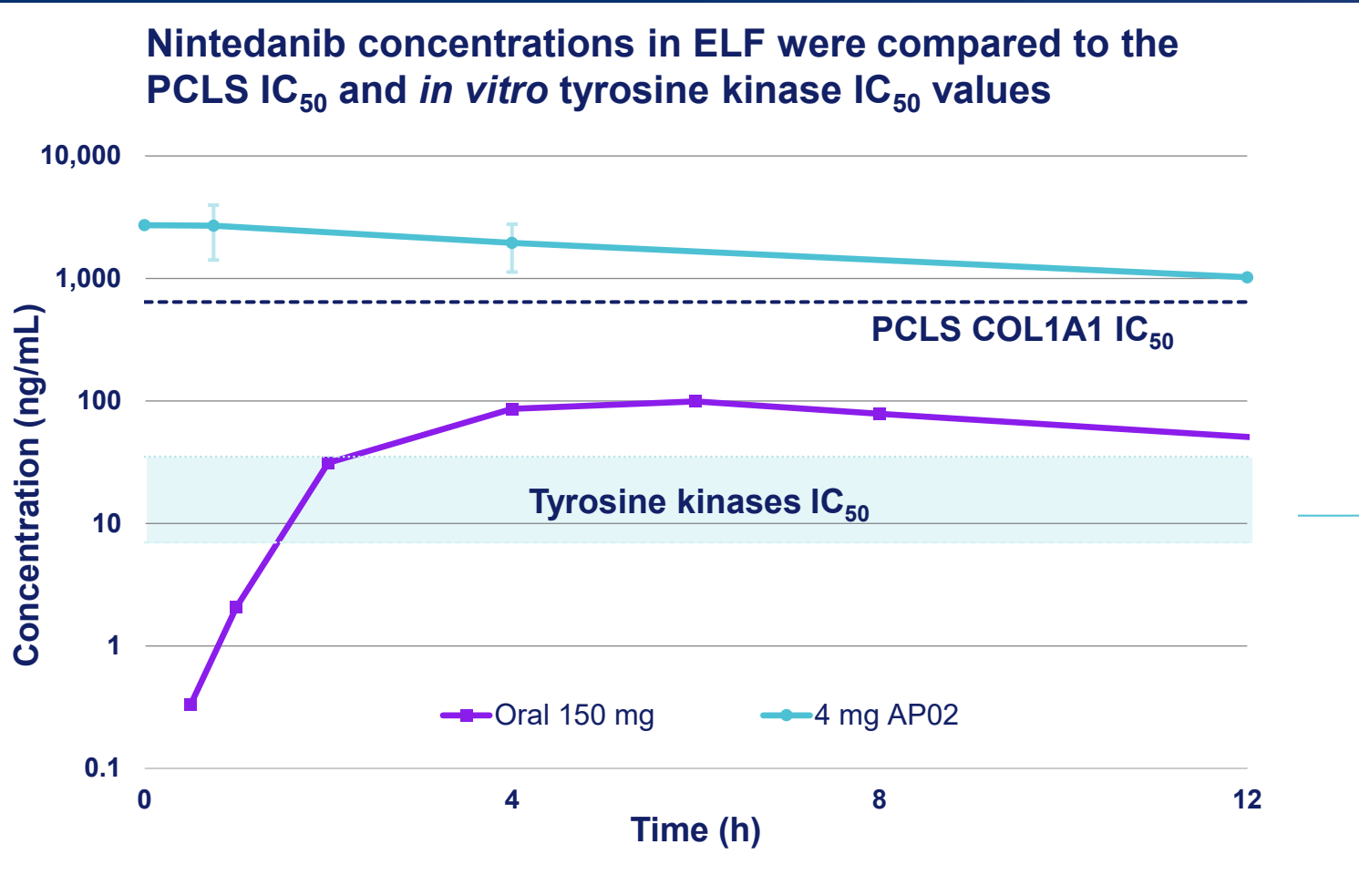
No drug-related AEs at 4 mg BID

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, pirfenidone, or nerandomilast previously but were intolerant to orals



- All patients (n=160) will be treated for 12 weeks
- Subjects will have 1 week of open-label nebulized saline to establish a baseline for cough

Primary Endpoint

- Change from baseline FVC over 12 weeks

Secondary Endpoints

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

Enrollment initiated 1Q 2026; topline data anticipated late 2027

AP03: Fixed Dose Combination



AP03 Fixed Dose Combination: Advancing Toward Phase 1 Readiness

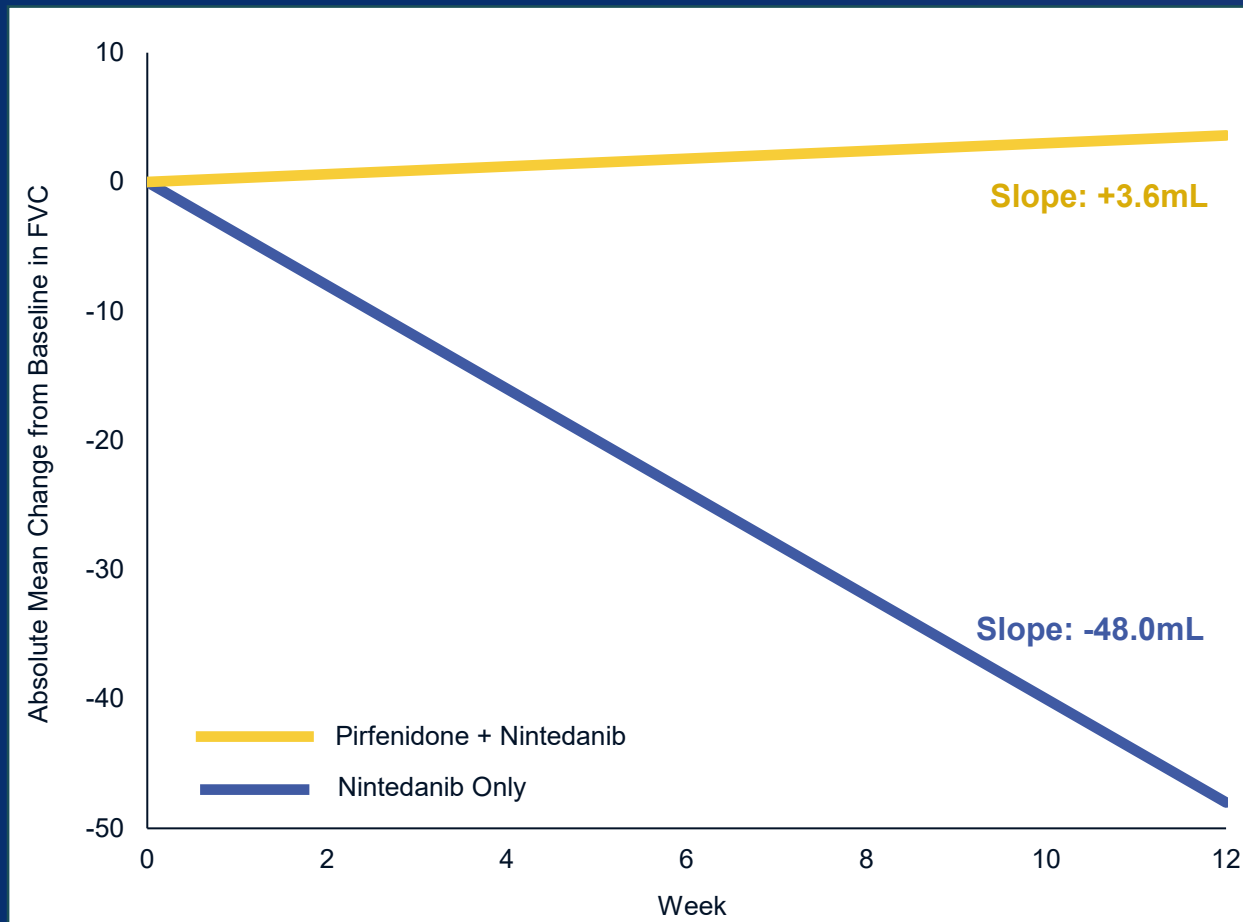
- ✓ CMC fixed dose formulation identified that supports full dose range potential
- ✓ CMC engineering batches manufactured
- ✓ Completed IPF patient-derived Precision Cut Lung Slice (PCLS) pharmacology studies to help guide AP03 Phase 1 dose selection
- ✓ Clinical supply manufacturing completed 1H 2026

Initiation of Phase 1 study anticipated in late 2026

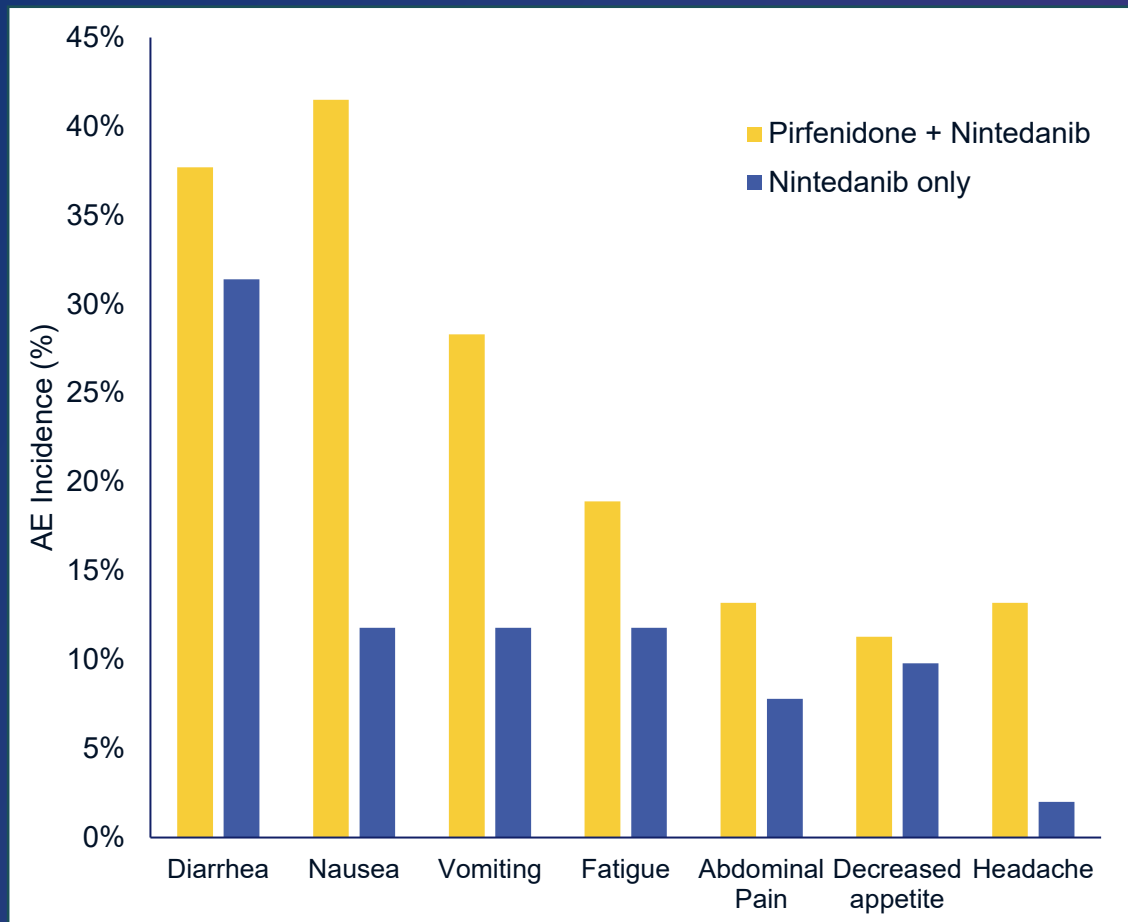


AP03 Informed by Third Party INJOURNEY Trial That Showed Improved Efficacy in Combination with Significant Tolerability Challenges

Increased Efficacy Benefit with Combination at 12Wks



Worse Tolerability with Combination of Oral Agents

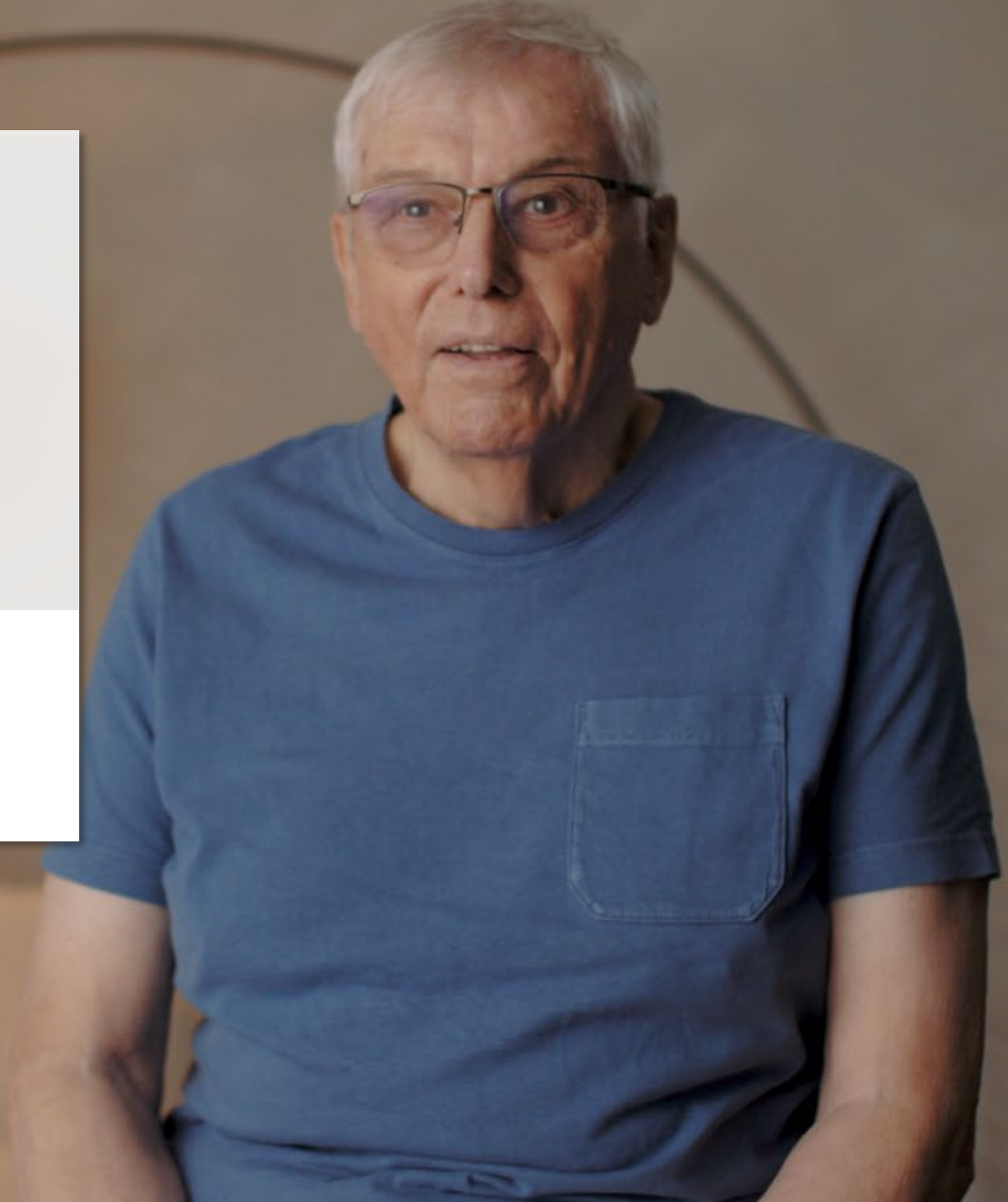


For patients like Peter...

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 patients.*





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



Large patient base
with **high unmet
need**



New formulation of
approved **medicines**
with derisked
mechanism of action



Device selection
that offers medical
and commercial
advantages

Multiple near-term clinical catalysts anticipated in 2H 2027