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C21 IPF AIR Study – Interim Analysis

February 2022

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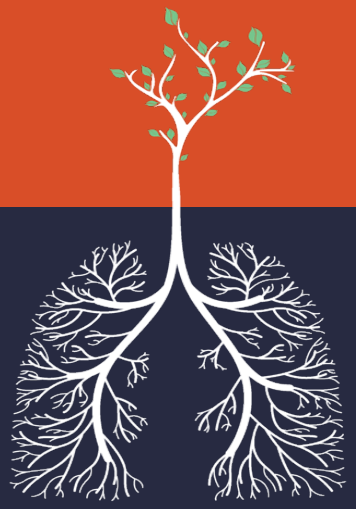
C21 IPF AIR Study – Interim Analysis

Study Design



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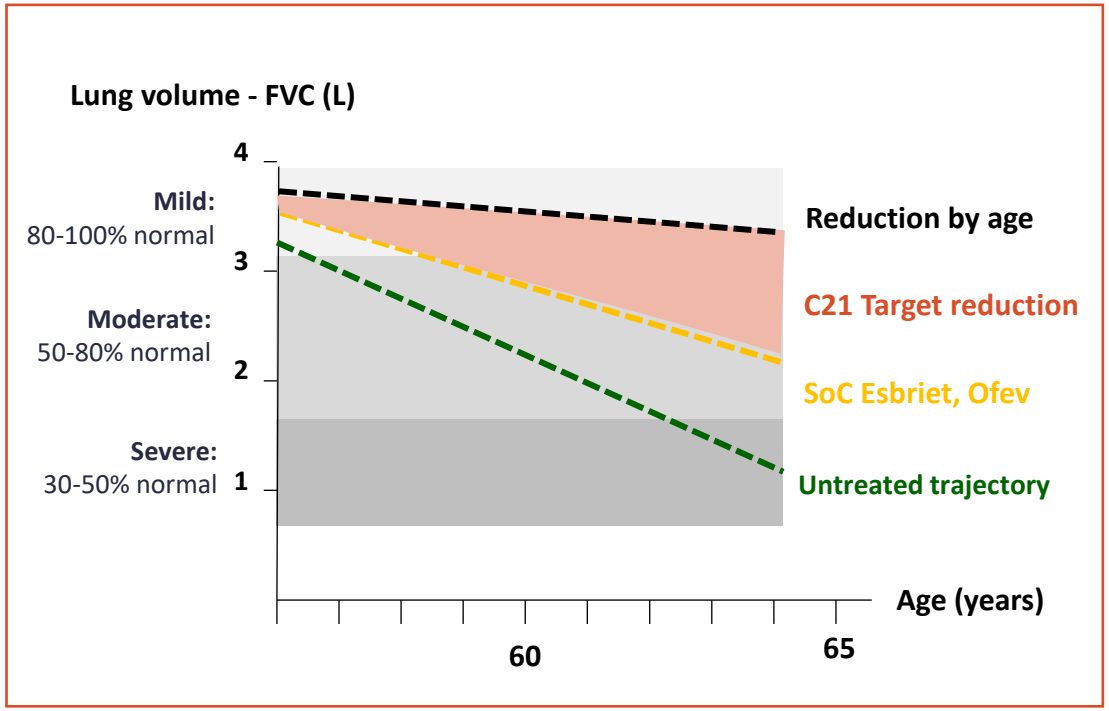
C21 – Phase II AIR trial in IPF

- Multicenter, open-label, single-arm trial
- 60 subjects with IPF
  - Central reader of HRCT to secure IPF diagnosis
  - Gold standard FVC measurement
- Primary endpoint - safety
- Primary efficacy endpoint - change in FVC at week 24 from baseline
- Treatment naïve patients, without SoC
- Untreated patients decline 120 ml/24 weeks



Baseline data from Kolb, 2017

Recruitment status and analysis

- Enrolled: 25
- Evaluable at time of analysis: 21
  - 36-week data: 7
  - 24-week data: 9
  - 12-week data: 13
  - 4-week data: 18
  - 2-week data: 21
- Slope analysis based on observed values
- Statistical analysis is based on estimated 24-week slopes
- For missing values, data was imputed (i.e., missing data is replaced with substituted values)
  - Conservative approach for imputation. Historical control data for untreated IPF patients was used, meaning an FVC decline with -240ml/y (-60 ml/12 weeks).

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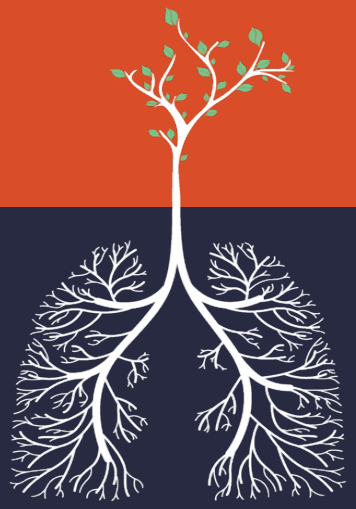
Interim Analysis After 21 Evaluable Patients



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C21 is safe and well tolerated

- No related serious adverse events
- No acute exacerbations
- No gastrointestinal signals

- The safety profile is supported by previous and other ongoing trials:
  - 3 phase 1 studies
  - Phase 2 mechanistic study in SSc
  - Phase 2 COVID-19
  - Phase 3 COVID-19 (ongoing)

So far, an excellent safety profile at 36 weeks

Placebo response in IPF studies

Reference	Title	Mean change in FVC from baseline at 24 weeks (ml)	No. of patients in placebo group	Treatment period (weeks)
King et al. N Engl J Med 2014; 370:2083-2092	A Phase 3 Trial of Pirfenidone in Patients with Idiopathic Pulmonary Fibrosis	-129	277	52
Richeldi et al. Lancet Respir Med. 2020 Jan;8(1):25-33	Pamrevlumab, an anti-connective tissue growth factor therapy, for idiopathic pulmonary fibrosis (PRAISE): a phase 2, randomised, double-blind, placebo-controlled trial	-150	53	48
Brown et al. Respir. Med. 2019; 146: 42-48	Lung function outcomes in the INPULSIS® trials of nintedanib in idiopathic pulmonary fibrosis	-103	423	52
Maher et al. Lancet Respir Med. 2019 Sep;7(9):771-779	Biomarkers of extracellular matrix turnover in patients with idiopathic pulmonary fibrosis given nintedanib (INMARK study): a randomised, placebo-controlled study	-140	231	12
		Average: -131 ml		

There is a consistent decline in FVC of 100-150ml/24 weeks on placebo

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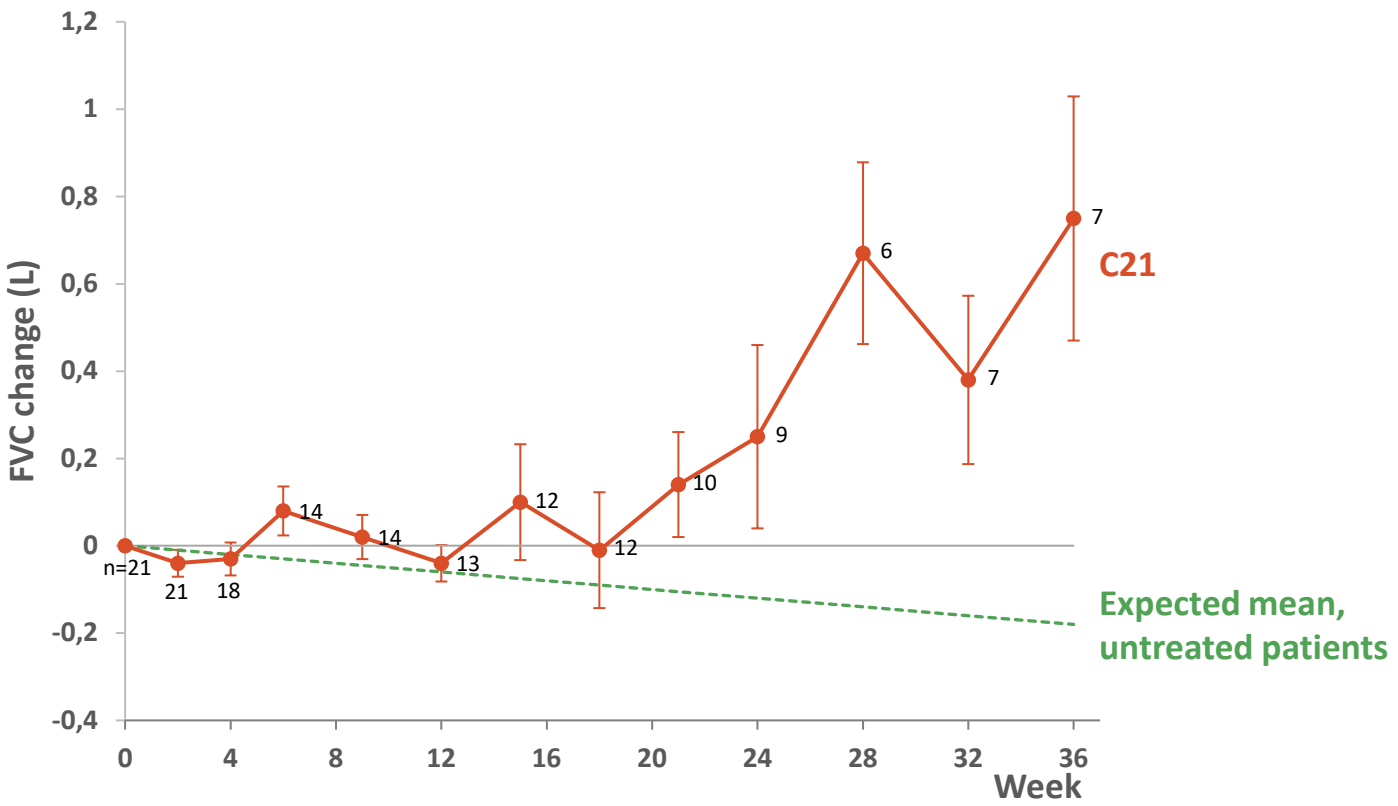
C21 stabilizes IPF and increase lung volume – Observed values

Mean change (SEM) from baseline in FVC over time, observed values

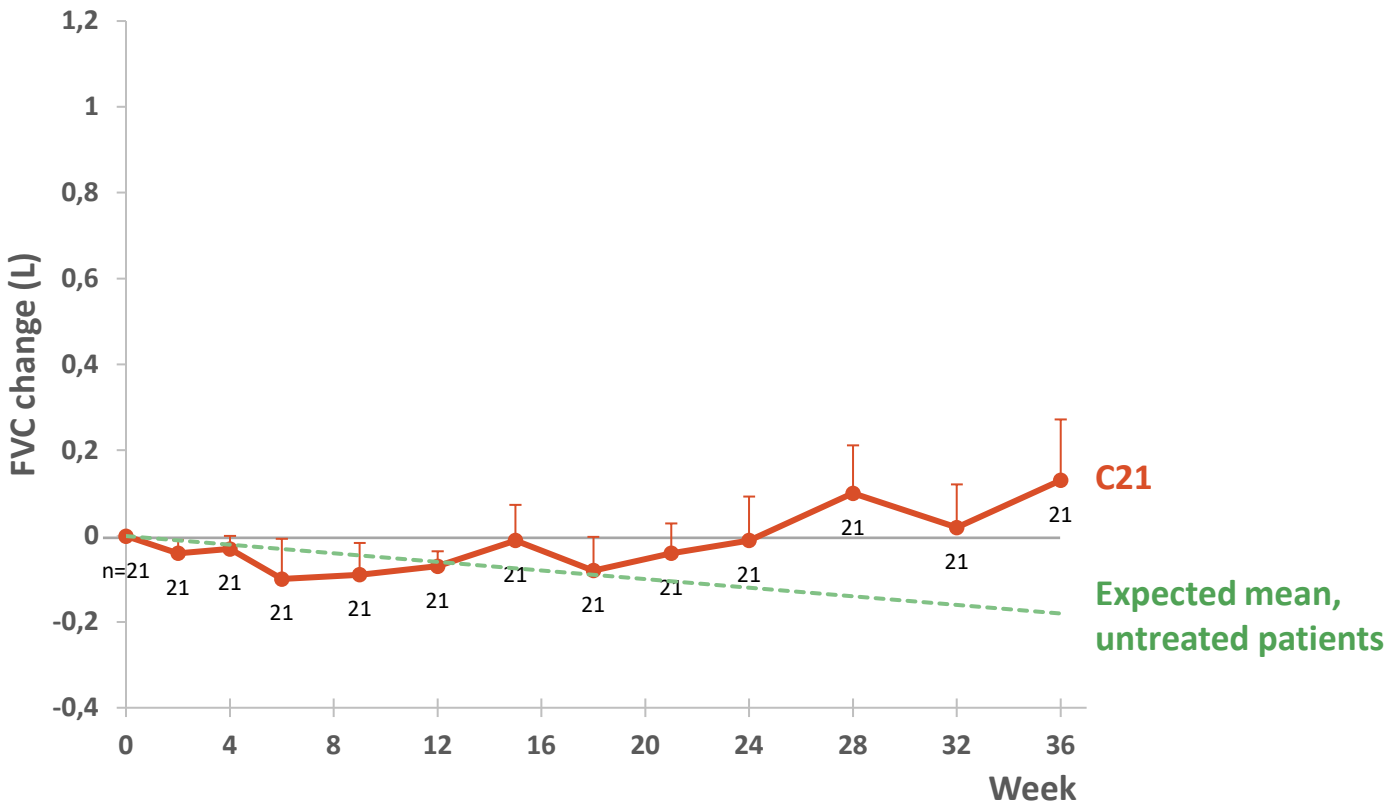


- After an initial stabilization there is an increase in FVC.
- At 24w, FVC increase is +251 ml vs. an expected change of -120 ml in untreated patients. At 36 weeks the FVC increase is +750 ml.
- Slope values at 28w, 32w and 36w are statistically significant (p=0.016 at 36w) vs. the expected mean for untreated patients.

With C21 the slope is positive compared to negative for untreated and SoC

C21 stabilizes IPF and increase lung volume – Observed and imputed values

Mean change (SEM) from baseline in FVC over time with observed and imputed values



- Imputed values used are based on historical decline in untreated patients (-120ml/24w).
- Even with this conservative approach, the slope is still positive.

Despite a very conservative imputation of missing observations, the slope is still positive

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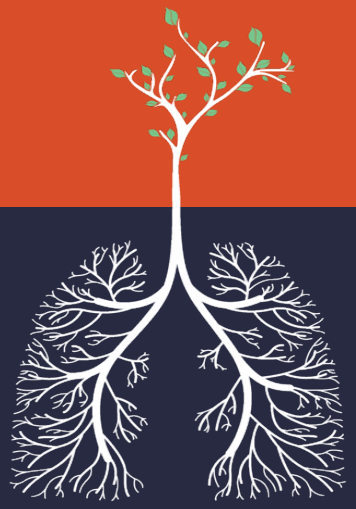
C21 - Mode of Action



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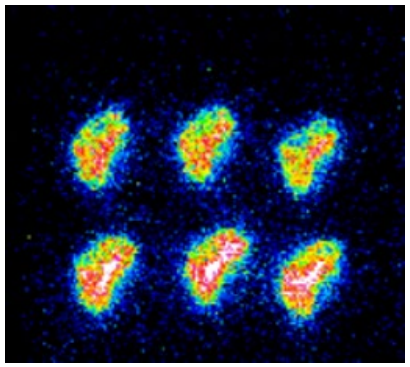
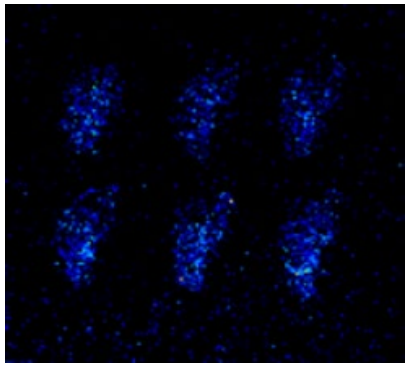
Receptor autoradiography and target validation in human lung

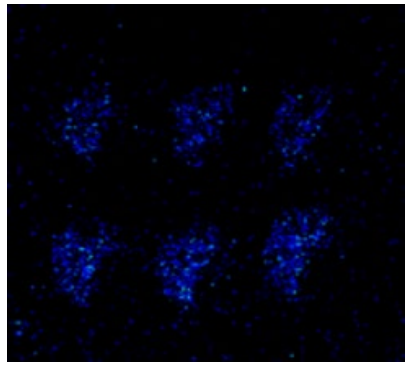
Abundant AT2R in human lung



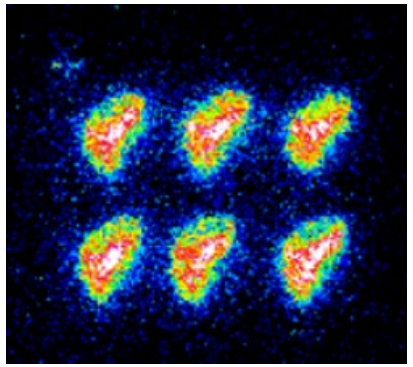
[^{125}I]Ang II 0.15 nM
(Ki AT2R 0.1 nM)



[^{125}I]Ang II 0.15 nM
+
Ang II 1 µM



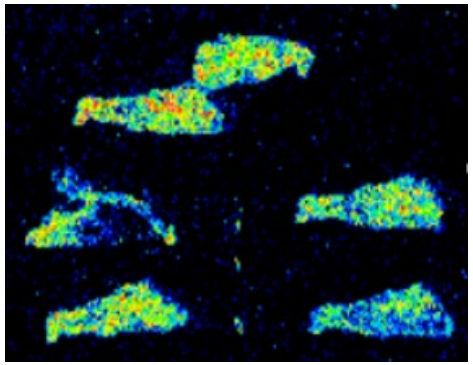
[^{125}I]Ang II 0.15 nM
+
C21 0.75 µM
(Ki AT2R 1-2 nM)



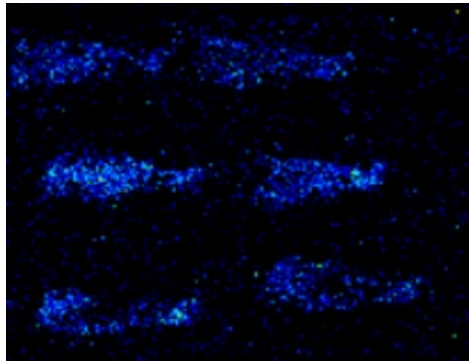
[^{125}I]Ang II 0.15 nM
+
Valsartan 1 µM
(Ki AT1R 2-3 nM)

- Receptor autoradiography performed with human lung tissue. slices shows abundant AT2 receptor expression
- No or little AT1R

C21 binds specifically to AT2R in the lung



[^{3}H]C21 1 nM
(Ki AT2R 1-2 nM)



[^{3}H]C21 1 nM
+
C21 0.75 µM

- Receptor autoradiography performed with human lung tissue
- Significant and specific C21 receptor binding at 1 nM.

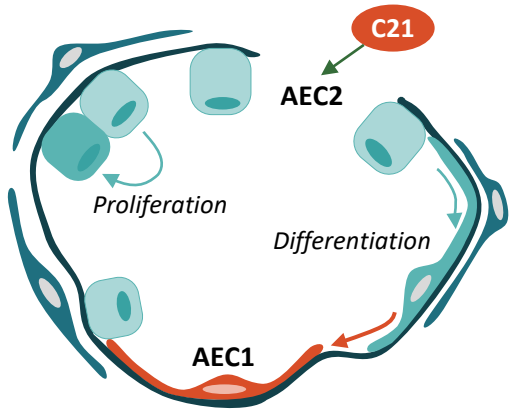
Abundant AT2R in human lung enable multiple points of attack for C21

Source: Vicore data on file.

Multiple mechanisms mediating AT2R agonist effects

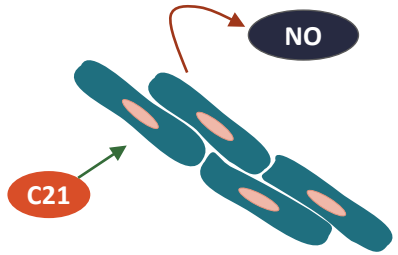
Alveolar integrity

1 Epithelial function



Vascular remodeling and vasodilation

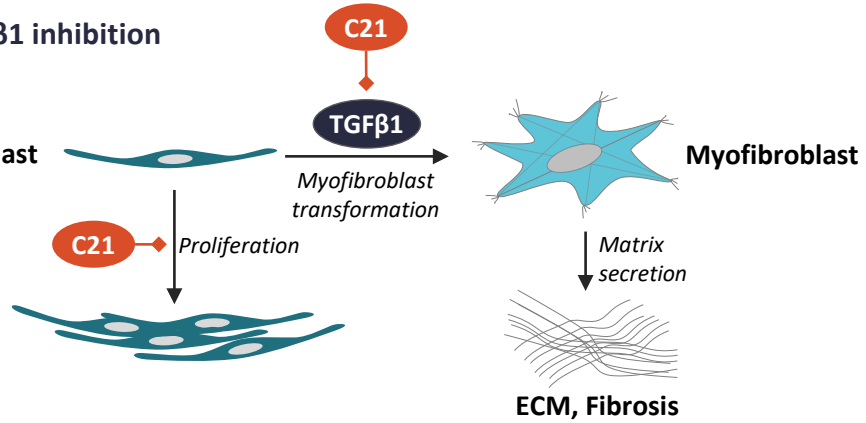
2 NO release



Endothelial cells

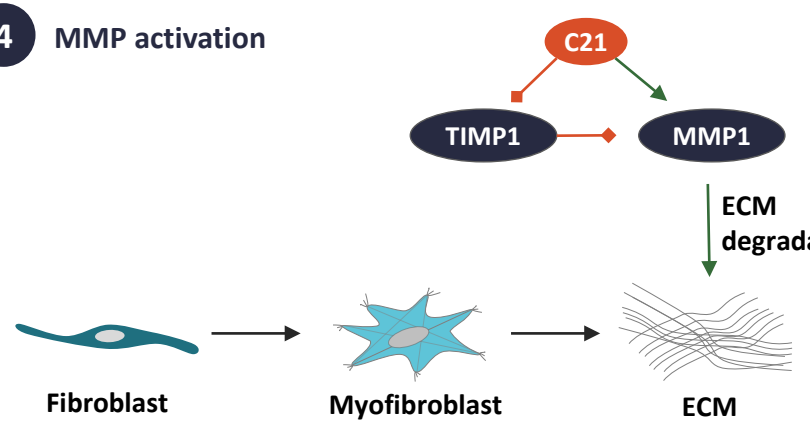
Antifibrosis

3 TGFβ1 inhibition



Fibrolysis

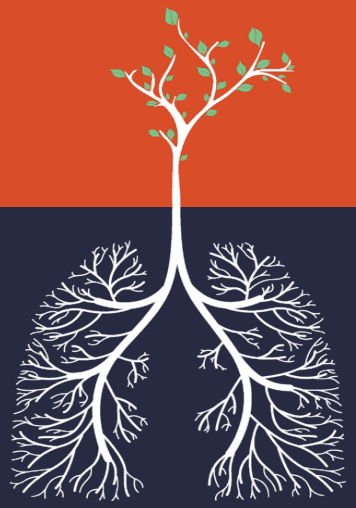
4 MMP activation



Multiple mechanisms can possibly contribute to the observed effect in IPF

C21 IPF AIR Study – Interim Analysis

Idiopatic Pulmonary Fibrosis (IPF)



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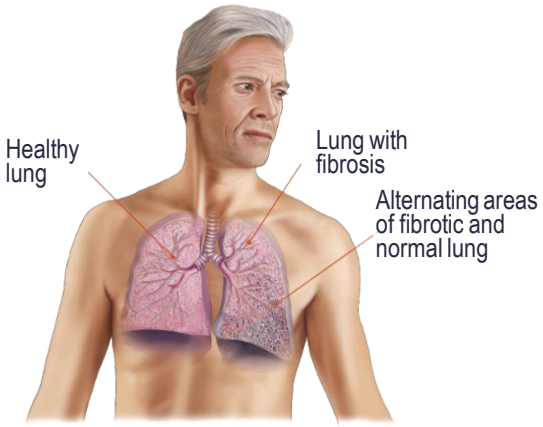
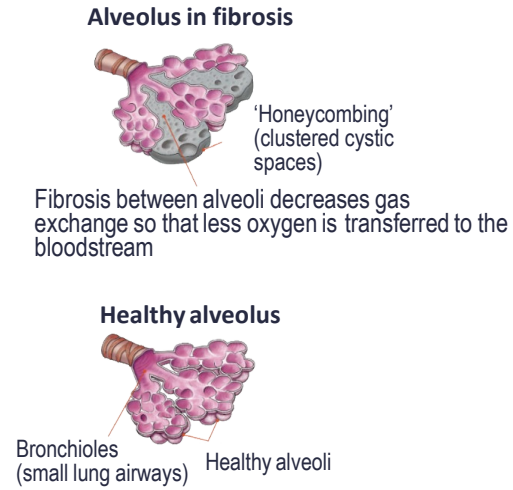
A devastating disease with significant unmet need

A rare interstitial pulmonary disease with unknown etiology

- Life expectancy 3-5 years. Progressive loss of lung function, pulmonary hypertension, cardiac failure
- Fibrosis and vasculopathy are hallmarks of the disease
- Rapid decline, therapies rarely improve disease or quality of life
- No approved drugs for ILD/IPF cough or for IPF/PF anxiety
- Orphan disease: ~250 000 patients in the US and Europe





Opportunity for market leadership

Market expected to grow to $5.2 Bn in 2027

- Esbriet approved since 2011/2014 and Ofev since 2014/2015 in Europe and the US
- $4.0 billion combined global sales 2021 (estimated); 70% in US (1)
- $5.2 billion - Market projection IPF 2027(2)

Significant unmet need

- Approved IPF drugs highly unsatisfactory due to limited efficacy together with GI and other side-effects
  - 40% of US IPF patients not on approved drugs; 11% discontinue (3)
  - Market potential much larger than existing market due to large share of untreated patients

➢ C21 aiming at going head-to-head with current SoC to establish new first-line SoC

Source: (1) Company Quarterly Reports (2) iHealthcareAnalyst (3) Pulmonary Fibrosis Foundation, Respiratory Research 21, Article number: 48 (2020)

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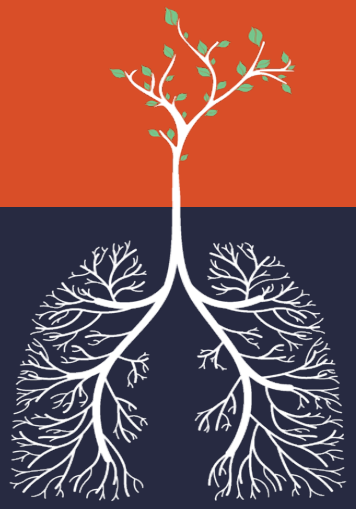
Conclusions



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Conclusions

AIR interim data	• Treatment was safe and well tolerated with no exacerbations • C21 stabilizes IPF disease without further decrease in lung function • From week 18 to 24 there is an increase in lung function (n=9) • At 24 weeks the slope is +251 ml • Between week 24 and 36, five patients continue to improve and two remain stable (n=7)
MoA	• There is an abundance of AT2R on different cell types in the human lung • C21 receptor binding in the human lung show multiple points of attack • There are multiple mechanisms that possibly can contribute to the observed effect in IPF
Next steps	• Accelerate planning of a double-blind placebo-controlled dose finding study for start Q4 2022


Vicore is well positioned
to develop novel therapies
for fibrotic lung disease