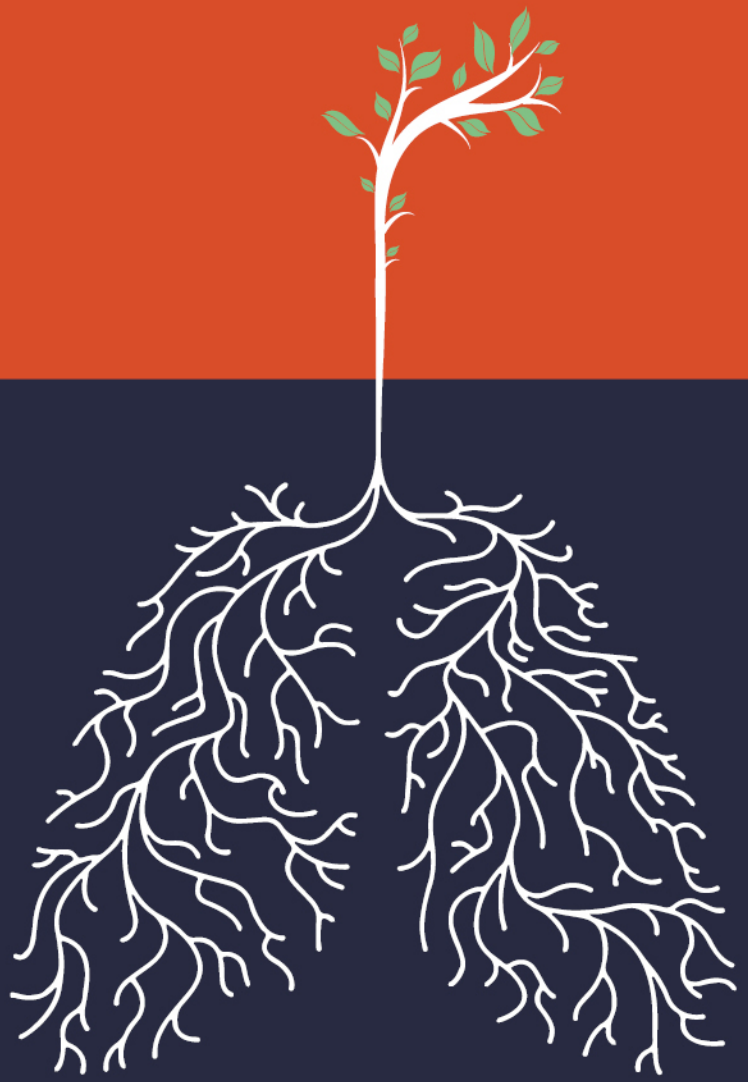
# VICORE PHARMA AB

C21 in COVID 19, December 2020



# Forward looking statement

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Vicore Pharma's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement.

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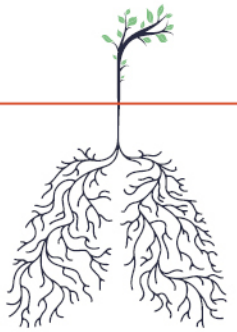
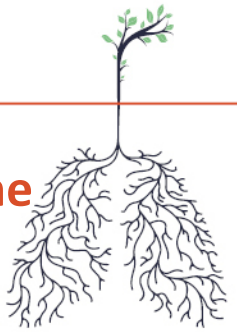
No assurance can be given that such expectations will prove to have been correct. Vicore Pharma disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

# C21 COVID-19 STUDY



## Top line data

# STUDY DESIGN



**A randomized, double-blind, placebo-controlled trial investigating the safety and efficacy of C21 in COVID-19**

| Screening | Randomization | C21 100 mg BID + SoC for 7 days<br>n=51 | Follow-up<br>7-10 days |
|---|---|---|---|
| | | Placebo BID + SoC for 7 days<br>n=55 | |

- Key inclusion criteria were hospitalization and severe inflammation as measured by C-reactive protein
- The study measured disease progression by the means of C-reactive protein, disease severity, as well as clinical outcome
- Secondary endpoints also include safety and biomarkers

**The study included 106 COVID-19 patients with efficacy read-out**

# TOP LINE DATA - I

## Demographics

- The treatment groups were well balanced regarding age and sex
- The treatment groups were well balanced regarding oxygen treatment at baseline
- The vast majority of patients (>100/106) patients received corticosteroid treatment

**The demographics suggest balanced study groups**

# TOP LINE DATA - II

## Reduced need of oxygen at the end of the treatment period

- In the C21 group, 14/51 patients received oxygen therapy at the end of the treatment period compared to 25/55 in the placebo group
  - This corresponds to a reduced risk of needing oxygen by 40%, which is statistically significant at the 10% level as predefined in the SAP- Statistical Analysis Plan (P=0.057)
  - The odds ratio for not needing oxygen was 2.20 (90% CI 1.11-4.35) in favor of C21

## Fewer patients progressed to mechanical ventilation

- There were 5 patients who progressed to mechanical ventilation, 4 in the placebo group and 1 in the C21 group

## Fewer deaths

- There were 4 deaths in the study, 3 in the placebo group and 1 in the C21 group

**The study showed a significant clinical benefit on top of steroids**

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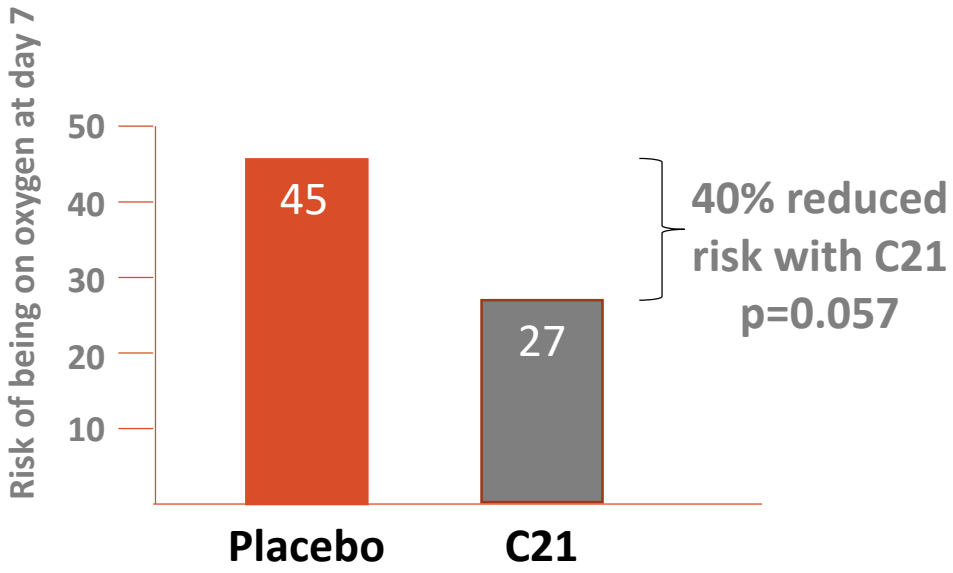
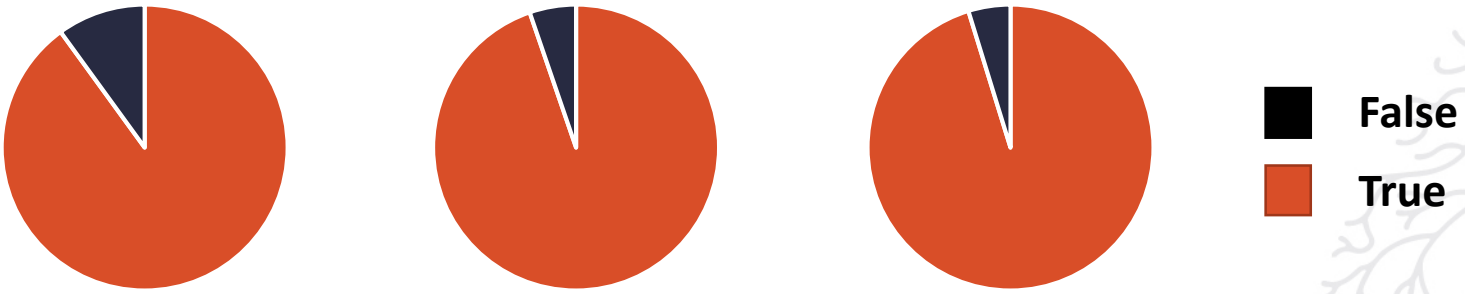
# REDUCED NEED OF OXYGEN




**The risk of needing oxygen at the end of treatment is reduced by 40%**

# STATISTICS

**In a phase II proof of concept study with 80% power the definition of statistical significance is a p-value < 0.1**




p=0.1 ATTRACT p=0.05

The data in favor of C21 is **statistically significant**, well within the 10%-level as predefined in the Statistical Analysis Plan

**The reduced need for oxygen therapy is statistically significant**

# TOP LINE DATA - III

**CRP, TNFα, IL-6 were similar in both groups, which is expected due to the corticosteroid use**

- Corticosteroids became standard of care in July, just when we started to enroll patients
- Corticosteroids are well known to reduce CRP, TNF and IL-6 induced by infection

**C21 was well tolerated in this population of severely sick patients**

**There were no safety concerns related to C21 in the study**

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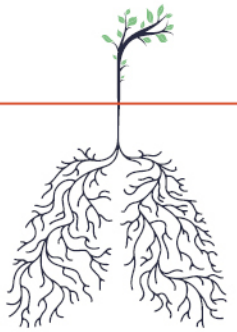
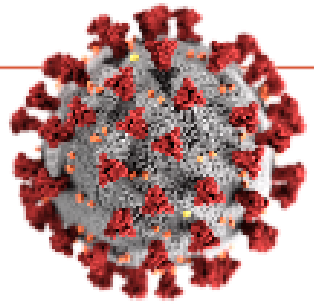
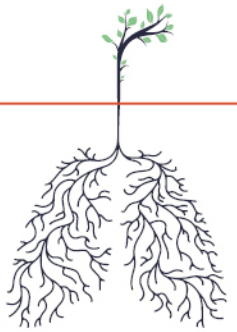


## A pandemic with a different profile

# COVID-19



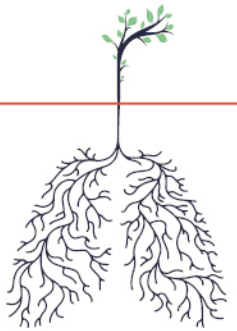


## COVID-19 is a SARS-CoV-2 respiratory infection

- It primarily affects the upper airways
  - Dry cough and fever are the main initial symptoms
- After a few days, some patients deteriorate rapidly – the tipping point
  - The disease changes from an upper respiratory tract infection to involve the lungs as well
  - Infection of alveolar cells leads to acute respiratory distress with low oxygenation followed by systemic inflammation with multiorgan failure (ARDS)
- More contagious than common flu or SARS with 65 million cases to date
- Mortality is estimated to 1 % with 1.5 million reported deaths

**COVID-19 is a pandemic with high morbidity and mortality**

# COVID-19 - THE DISEASE



**URTI**

Upper airways
Common cold

**Alveolar infection**

**Tipping point**

Alveolar type II cells
Large surface area
Impaired oxygenation

**ARDS**

Systemic disease
Intravascular coagulopathy
Multiorgan failure

**SARS-COV-2 in the alveoli results in the impairment in oxygen saturation**

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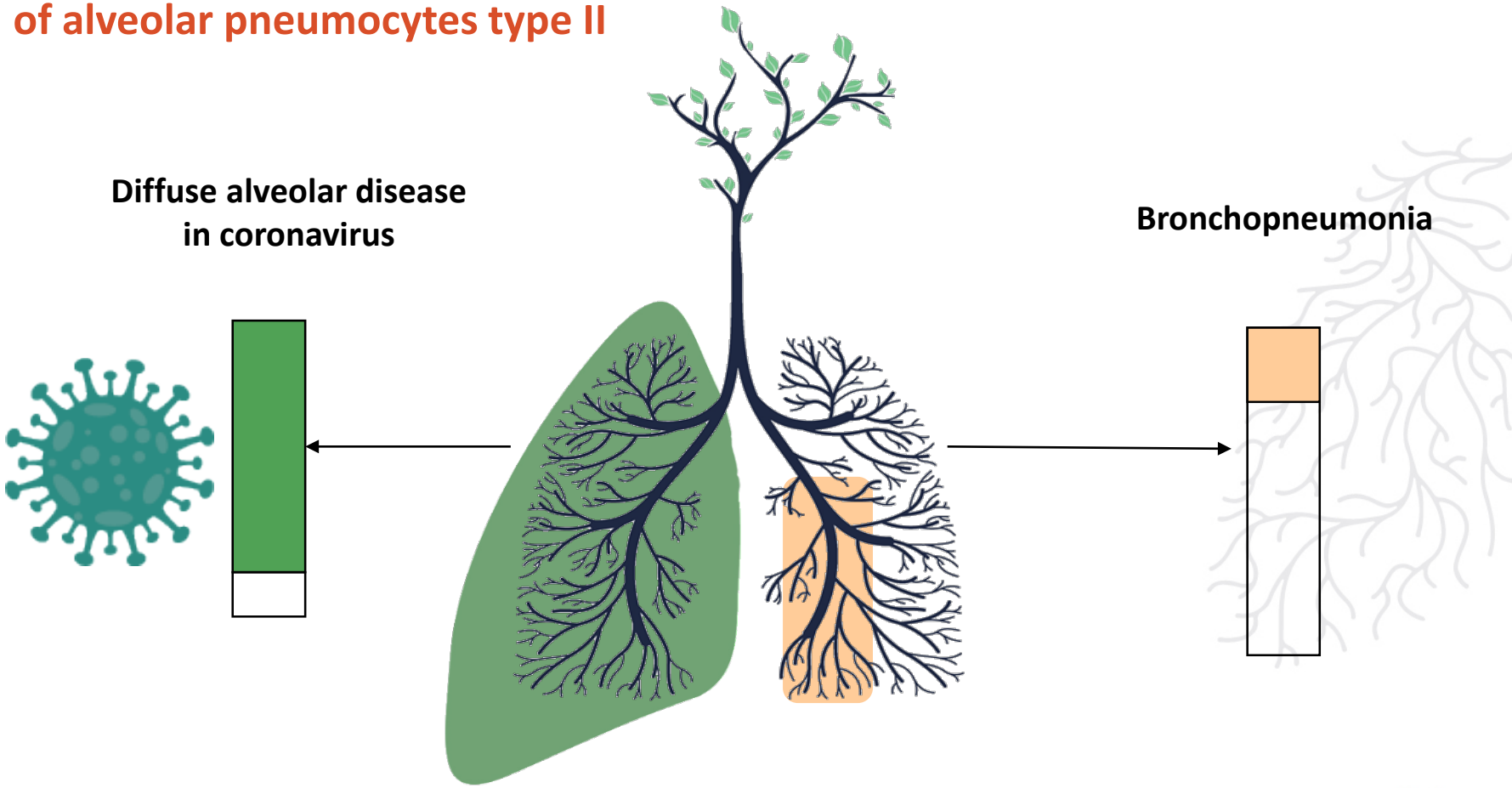
# SARS-CoV-2 PNEUMONIA

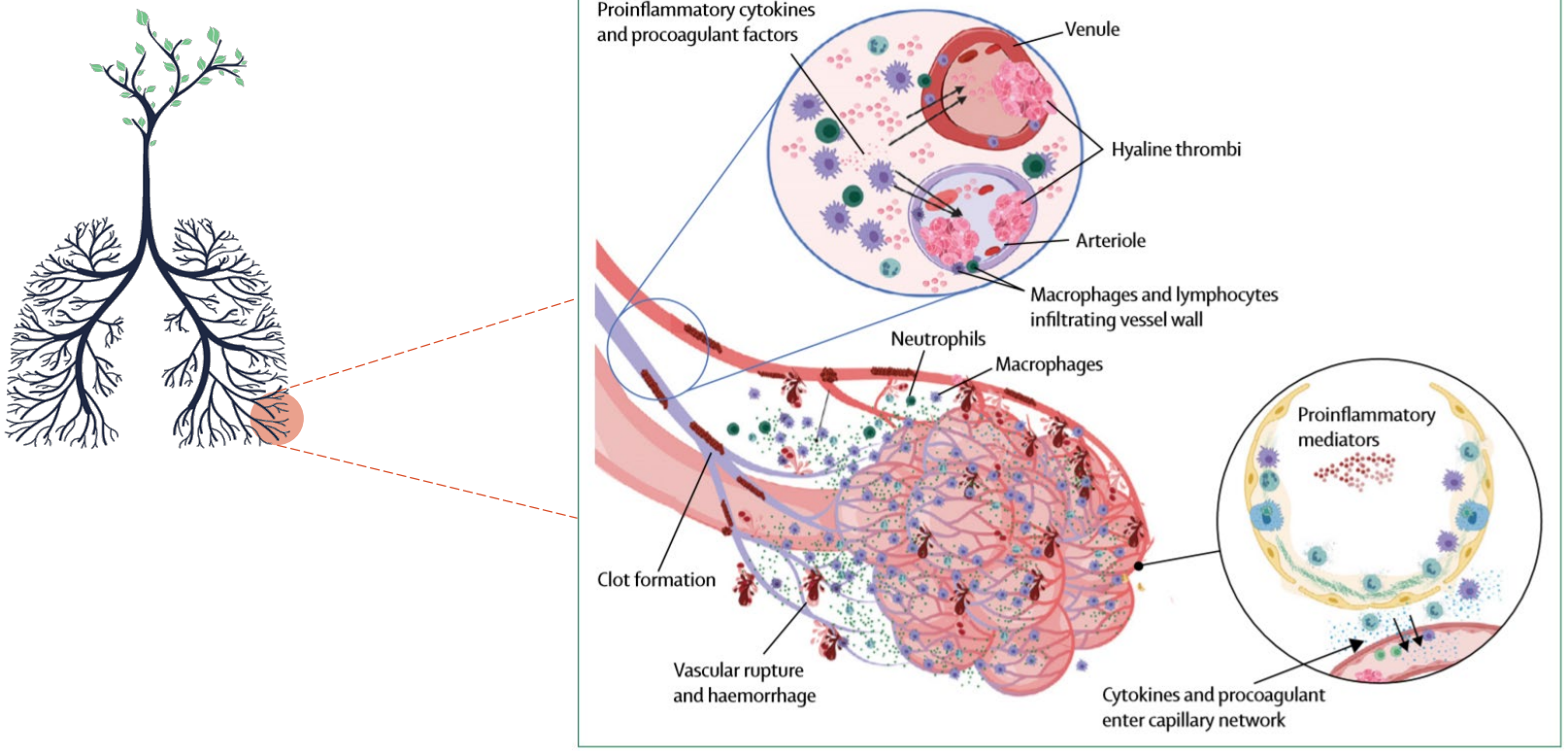
**The larger surface area involved in the SARS-CoV-2 infection compared to broncho-pneumonia (bacterial or influenza) is due to the specific engagement of alveolar pneumocytes type II**




**The large surface area explains the rapid clinical course**

# PULMONARY INTRAVASCULAR COAGULOPATHY

**Scheme showing extensive COVID-19 lung involvement with large anatomical interface between infected type II pneumocytes, leading to extrinsic inflammation with immunothrombosis**




**The diffuse alveolar infection triggers the intravascular coagulopathy**

# SUMMARY

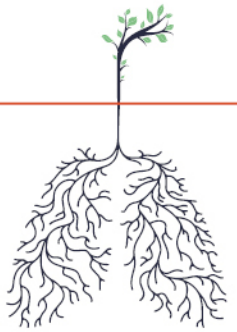
**The infection of alveolar pneumocytes type II is what makes COVID-19 a fatal disease and differentiates it from an ordinary coronavirus infection**

**The diffuse alveolar infection results in impaired gas exchange**

**A sudden engagement of a large surface area is the background for the clinical “tipping point” when patients rapidly deteriorate**

**The deterioration is followed by systemic cytokine release and intravascular coagulopathy leading to multiorgan failure**

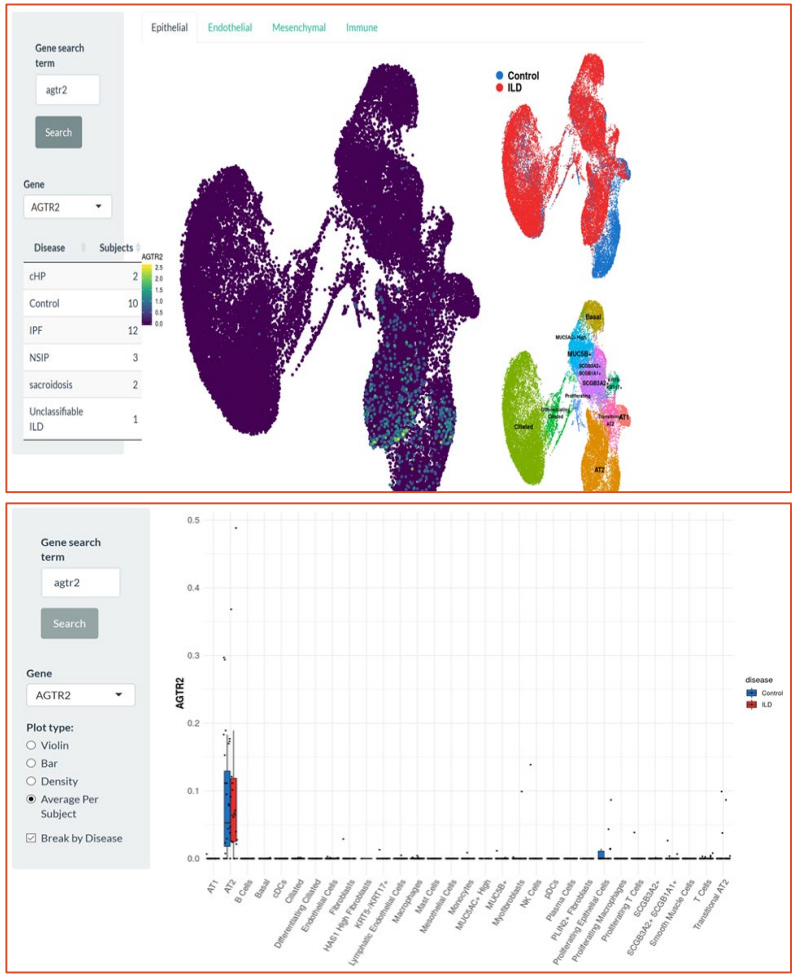
# RAS IN COVID-19



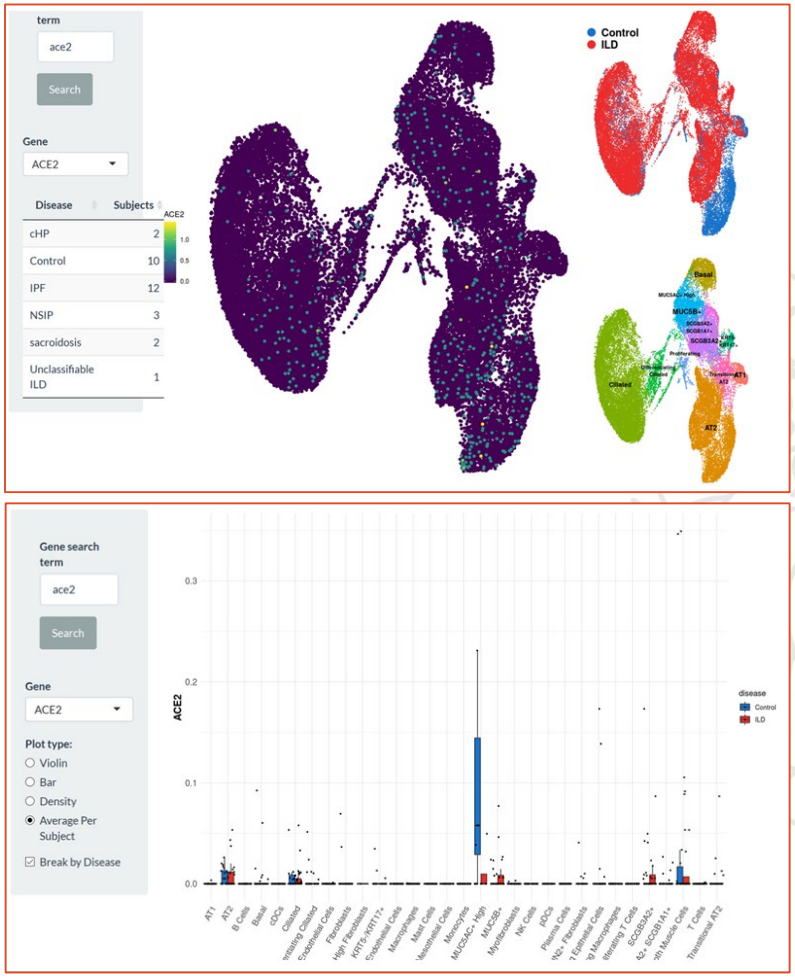
## AT2R in COVID-19

# AT2R & ACE2 CELLULAR EXPRESSION IN HUMAN LUNG

## AT2R

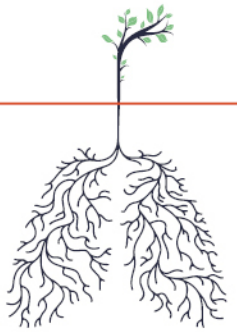



## ACE2



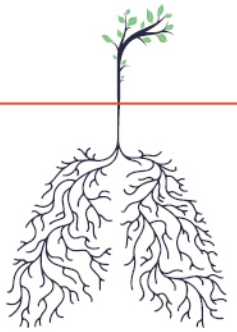

**AT2R, but not ACE2, is specifically expressed in type II pneumocytes**

# CLINICAL DEVELOPMENT



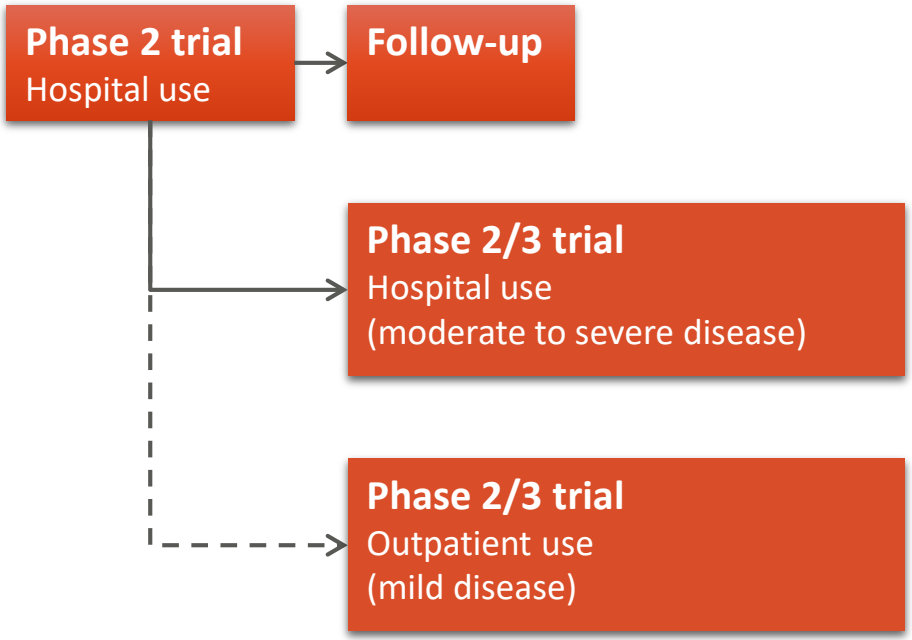
## Progress to pivotal phase 2/3 trial

# CLINICAL DEVELOPMENT PLAN IN COVID-19

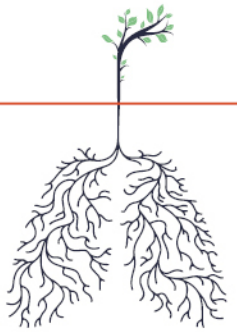


**Proof-of-Concept in patients hospitalized due to COVID-19 gives possibility to:**

- **Progress to pivotal study in moderate to severe disease**
- **Study C21 in outpatient use**
- **Follow-up of patients participating in phase 2 trial to explore effects on lung fibrosis**



# COVID-19 PHASE 2 FOLLOW-UP

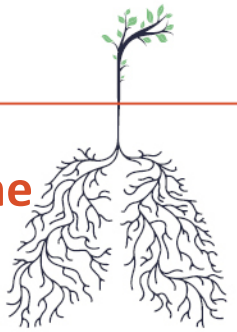


## Non-interventional, retrospective study evaluating the effect of C21 on lung fibrosis in subjects enrolled in the VP-C21-006 trial

| COVID-19 Phase 2 trial | Extended follow-up 24 weeks |
|---|---|

- Lung pathology will be assessed by high-resolution computed tomography (HRCT) which was performed as part of normal clinical practice
- Any available in-patient HRCT recorded before IMP administration (baseline) and up to 24 weeks after completion of VP-C21-006 trial will be collected
- The HRCT will be evaluated by a blinded, central reader

# COVID-19 PHASE 2/3 STUDY DESIGN



**A randomized, double-blind, placebo-controlled trial investigating the safety and efficacy of C21 in COVID-19**

| Screening | Randomization | C21 100 mg BID + SoC for 14 days<br>n=350-500 | Follow-up<br>14 days |
|---|---|---|---|
| | | Placebo BID + SoC for 14 days<br>n=350-500 | |

- Key inclusion criteria: hospitalization, confirmed SARS-CoV-2 infection and signs of acute respiratory infection
- The study will investigate improvement in clinical status up to Day 29 using the 8-point Ordinal Scale
- Secondary endpoints also include duration of hospitalization, mortality, safety and biomarkers

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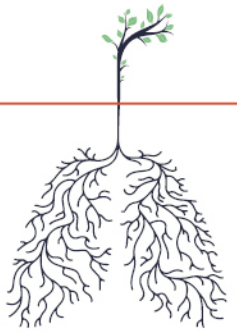
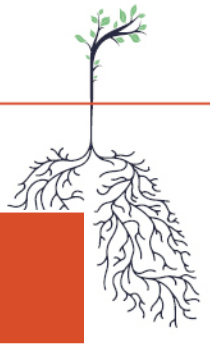
# COMPETITORS



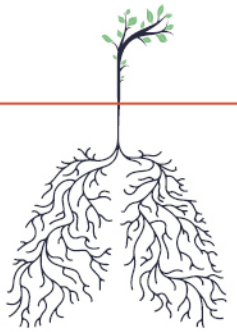
## Competitors and data

# COMPETITORS



| | MoA | Route of administration | Results | Comments |
|---|---|---|---|---|
| LY-CoV555 Lilly | Neutralizing antibody | i.v. infusion | Trend for slightly lower severity. Trend for reduced viral load. | FED buys for $812M ($1250-3120 per dose) |
| SNG001 Synairgen | IFN1β | Nebulized daily inhalation | Increased recovery. | |
| Saccovid Oncoimmune | CD24Fc | i.v. infusion | 60% increased chance to achieve recovery. | Acquired by Merck $425M |
| Remdesivir | Antiviral | Tablet or i.v. | Limited efficacy. | WHO has recommended against use |
| Regen-COV2 Regeneron | 2 neutralizing antibodies | i.v. | Reduced viral load. Tendency to reduced symptoms. | |

# MARKET



## Place in therapy

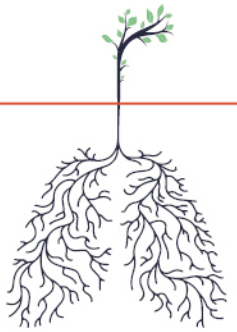
# POSITIONING

**“Outpatient treatments for COVID-19, coupled with an effective vaccine, would have significant implications for the ability to end this pandemic.”**

Kim, Read, Fauci, JAMA, December 1, 2020

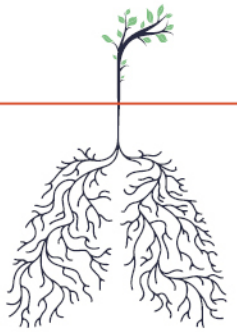
C21 is an oral treatment which is well tolerated and with a favorable safety profile, that in an outpatient setting could reduce need for oxygen support, hospitalization and hence development of severe disease and long term sequele

# SUMMARY



## C21 and AT2R in disease

# SUMMARY



**C21 demonstrates significant clinical efficacy without safety concerns in a phase II pilot study in COVID-19**

- The result merits further development with a pivotal trial

**This is the first time an AT2R agonist shows benefit in human disease**

- Strengthening the rationale for C21 in IPF

**Vicore Pharma has increased the efforts to develop new series of compounds with different profiles to meet the needs in other therapeutic areas**

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