

# SNG001

A clinical stage  
inhaled broad-spectrum antiviral  
therapeutic for patients with  
severe respiratory viral  
infections



# Synairgen and SNG001: The Context

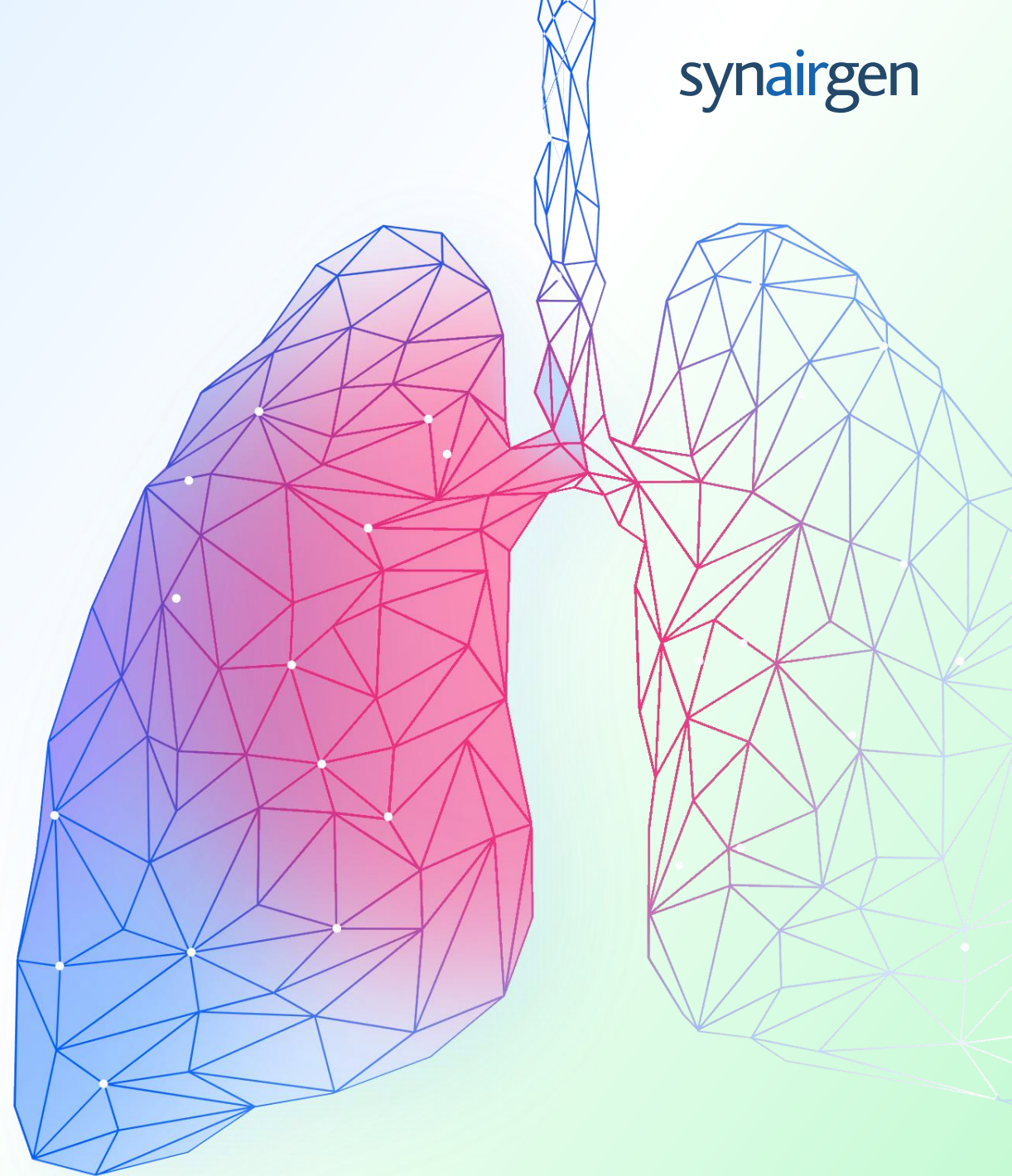
- Phase 2 study initiated in 2025 impacted by low viral season and patient recruitment challenges in the intensive care setting
- Challenging financing environment and majority shareholder “direction of travel”
- Strategic Board review concluded in a decision to wind-down the business
- A significant outreach to third parties with interest in the field and in a promising phase 2 stage asset

## A high value opportunity: Key headlines

### **SNG001** **“At a glance”**

- Groundbreaking novel therapeutic
- Inhaled antiviral for severe viral lung infections
- Substantial supporting non-clinical and clinical data
- Significant peak sales potential (>\$2bn)
- Phase 2 clinical stage asset
- In-market protection from patents, market and data exclusivity, and exclusive device agreement

# Clinical need



A wide range of respiratory viruses cause >2million hospitalisations each year in the US.



**Proportion of patients hospitalised with individual viruses pre-COVID**

● Rhinovirus	37%
● Non-COVID Coronavirus	14%
● Influenza	20%
● HMPV	8%
● Parainfluenza	8%
● RSV	10%
● Adenovirus	2%

>2m  
patients hospitalised  
per year in the US

▼  
~15%

progress to ICU

▼  
~300,000 patients  
ventilated with viral  
ARDS

per year in the US

Only approved antiviral  
for hospitalised adults in the US  
is remdesivir for COVID-19 only

Note: percentages do not sum to 100% due to rounding of data points

Sources: \* 1 US CDC COVID-NET [2. HCUP Data Tool] 3. CDC Influenza Data] 3. Sieling WD et al., Influenza Other Respi Viruses. 2021;15:670-67

1. Piroth L, Cottenet J, Mariet AS, Bonniaud P, Blot M, Tubert-Bitter P, Quantin C. Comparison of the characteristics, morbidity, and mortality of COVID-19 and seasonal influenza: a nationwide, population-based retrospective cohort study. Lancet Respir Med. 2021 Mar;9(3):251-259.

2. Louie JK, Acosta M, Winter K, Jean C, Gavali S, Schechter R, Vugia D, Harriman K, Matyas B, Glaser CA, Samuel MC, Rosenberg J, Talarico J, Hatch D; California Pandemic (H1N1) Working Group. Factors associated with death or hospitalization due to pandemic 2009 influenza A(H1N1) infection in California. JAMA. 2009 Nov 4;302(17):1896-902.

3. [www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs](http://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs)

4. Shrestha SS, Kompaniyets L, Grosse SD, Harris AM, Baggs J, Sircar K, Gundlapalli AV. Estimation of Coronavirus Disease 2019 Hospitalization Costs From a Large Electronic Administrative Discharge Database, March 2020-July 2021. Open Forum Infect Dis. 2021 Dec 20;8(12):ofab561. doi: 10.1093/ofid/ofab561. PMID: 34938822; PMCID: PMC8686820.

# High unmet clinical need and significant financial burden: *Translates into large commercial opportunity*

## Significant unmet clinical need

Patients with respiratory virus infections on mechanical ventilation have  
**high mortality**

**25-45%**

## Significant healthcare cost burden

Average cost in US  
of a hospitalisation caused by SARS-CoV-2  
requiring invasive mechanical ventilation was

**~\$60k**

## Commercial opportunity

A drug that reduces mortality, reduces the risk of progressing from NIV to IMV, or time on a ventilator:

**Peak sales projection > \$2bn**

# Compelling Product Profile & Clinical Evidence Base



# SNG001 a unique late-stage clinical asset

## 1 Strong scientific rationale

- First-in-class immuno-modulator
- Naturally-occurring protein driving the body's antiviral defences
- Demonstrated potent and broad-spectrum anti-viral activity
- Targeted directly to the lung



## 2 Significant clinical evidence base

- Leveraging robust clinical efficacy and safety data from >750 patients
- Global clinical studies conducted by Synairgen and its historic pharma partner (AZ) and US National Institute of Health (NIH)
- Studies in asthma, COPD and COVID



## 3 Attractive potential responder populations

- Highly encouraging efficacy signal (45-80% reduction in disease progression and in mortality) in high-risk COVID patients
- Range of potential clinical indications and target patient populations, particularly those with high morbidity and mortality



## 4 Value-generating clinical study

- Phase 2 clinical trial design options based on selected target indications
- Exemplified by indicative 150-ICU patient study, providing rare access to respiratory samples to characterise innate immune responses to virus, and to investigate the effects of SNG001 on the immune response.

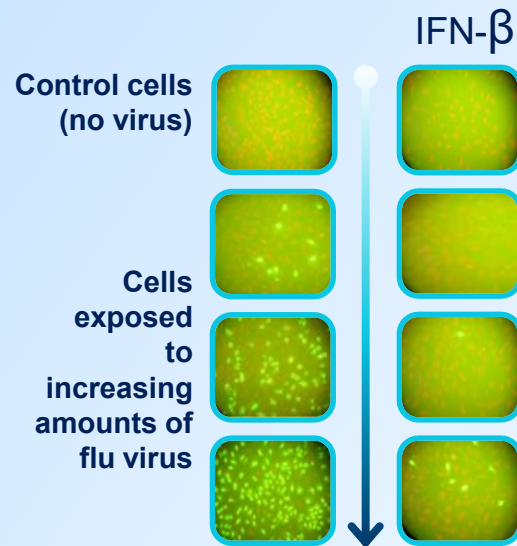


\* Includes patients with Flu A, Flu B, RSV, RV, adenovirus, parainfluenza, HMPV, or coronaviruses (including SARS-COV-2 and seasonal coronaviruses)

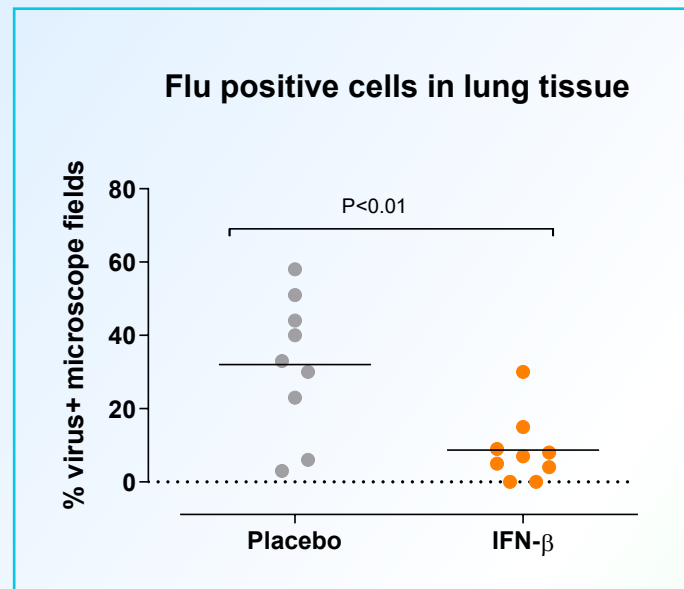
# Broad spectrum antiviral activity demonstrated against key respiratory viruses

## Antiviral activity shown in vitro and confirmed in vivo

### In vitro assay



### Viral pneumonia model



## Broad-spectrum activity against respiratory viruses

Rhinovirus	Influenza
RSV	Coronaviruses including SARS CoV-2

# Phase 2 and 3 studies

## Support SNG001 positioning in severe respiratory infections

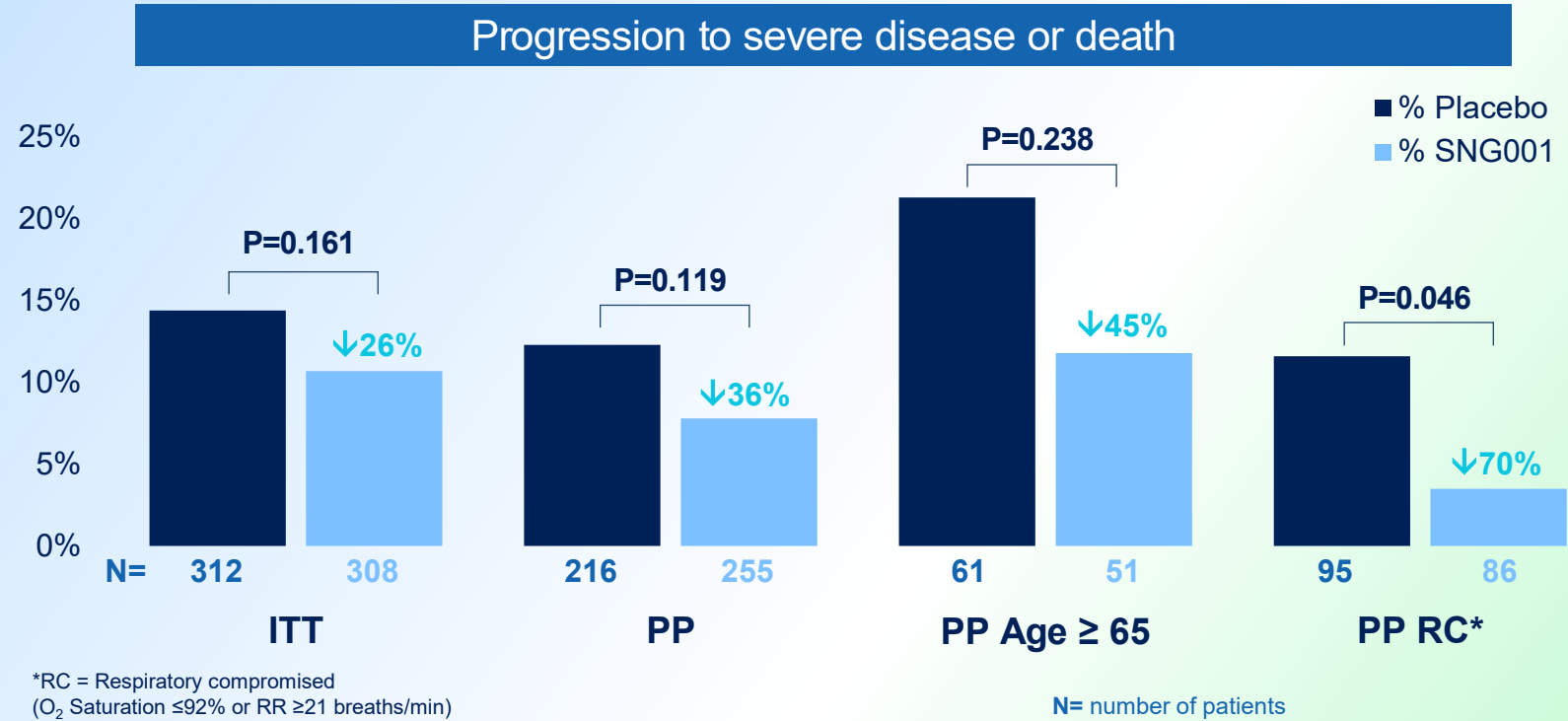
### SNG001:

Accelerates lung viral clearance

Good tolerability in >750 patients

Potential to reduce poor outcomes, particularly in high-risk patients

### Phase 3 SPRINTER trial<sup>1</sup> data (hospitalised COVID-19 patients)



Pre-defined analyses

Post-hoc subgroup analyses

Source: 1. Monk et al. Nebulised interferon-β1a (SNG001) in hospitalised COVID-19: SPRINTER phase III study. ERJ Open Res. 2023 Mar 27;9(2):00605-2022. ITT – Intention to Treat; PP – Per Protocol; RR – Respiratory Rate; RC – Respiratory Compromised

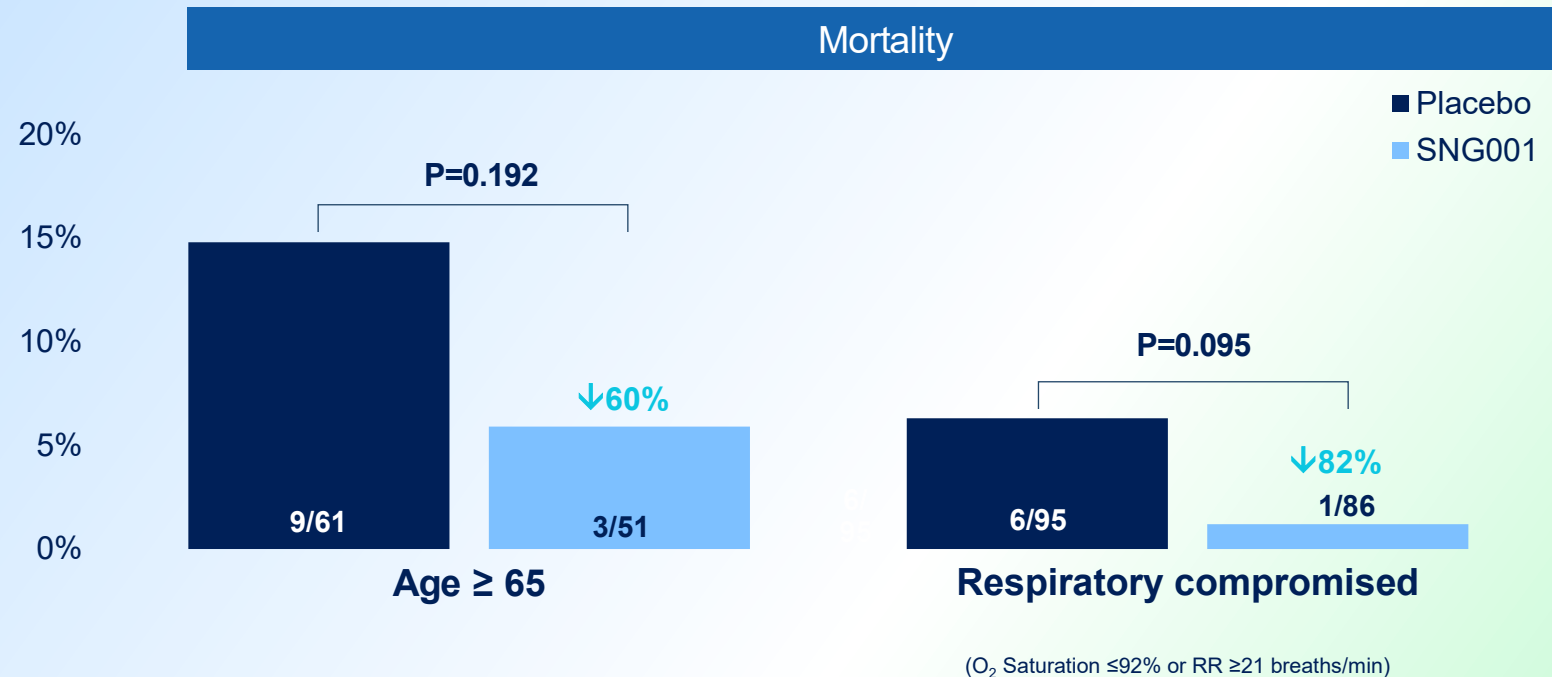
# Mortality reduction in high-risk patients

## Post hoc analysis

High-risk patients (>65 years, and respiratory compromised)

Mortality reduction provides rationale for proposed asset positioning

## Phase 3 SPRINTER trial<sup>1</sup> data



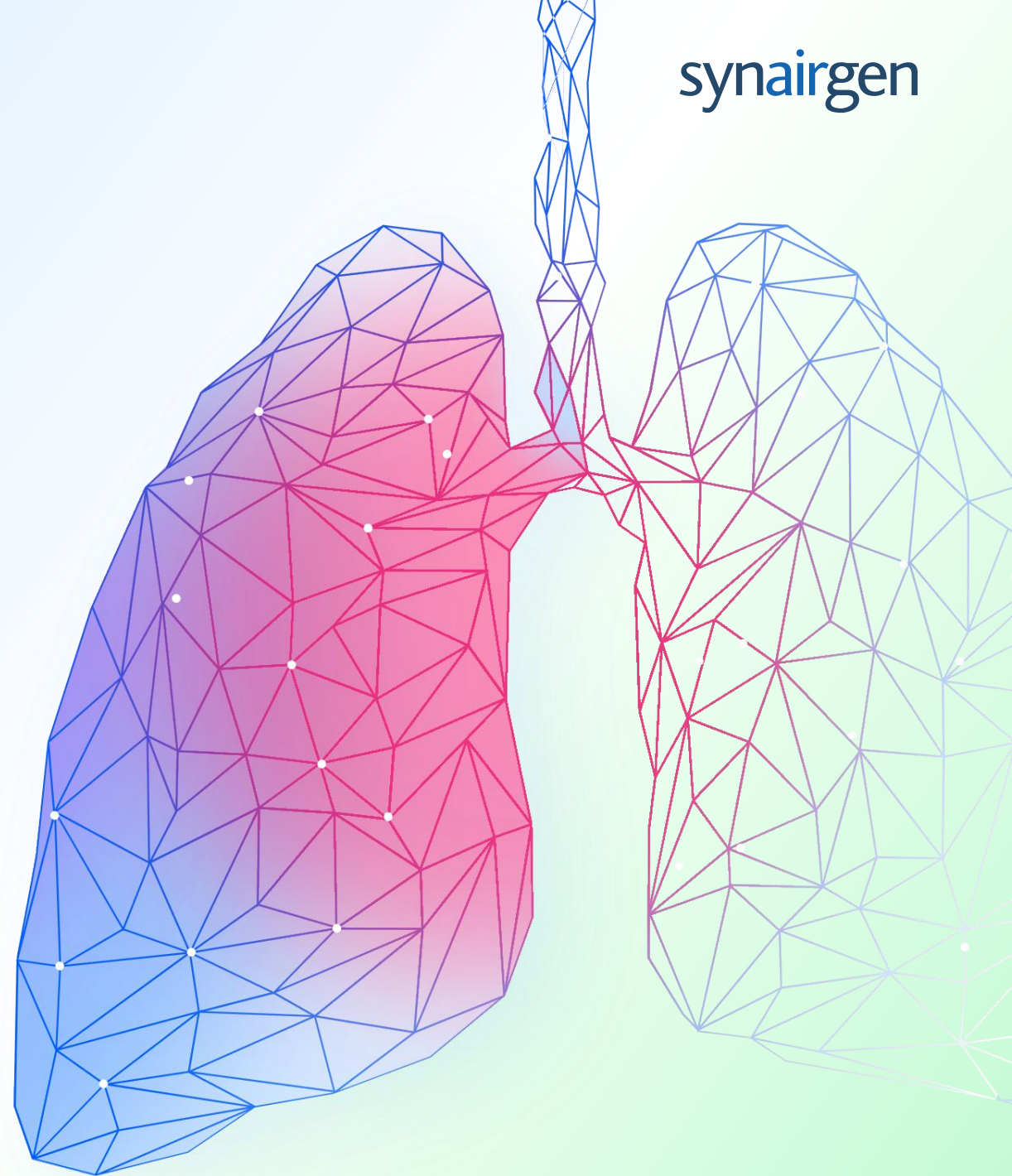
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# Appendix



# SNG001: Substantial Clinical Database Showing Favourable Local and Systemic Tolerability



Substantial clinical safety data base from **7** clinical trials (predominantly randomised, double-blind, placebo-controlled) in range of populations including non-hospitalised and hospitalised patients



Total of **750** patients treated with SNG001, majority of which had confirmed or suspected respiratory viral infections (*rhinovirus (RV)*, *influenza*, *coronavirus*, *SARS-CoV-2*, etc.)



**515** patients had COVID-19

**67** had COPD

**168** patients had Asthma



Favourable, apparently benign, safety profile; generally fewer patients on SNG001 reporting any adverse event or any serious adverse event versus patients on placebo.

No specific safety signals seen.



Well tolerated locally (*lung*); lack of significant systemic tolerability concerns consistent with local delivery and negligible systemic exposure (or anti-drug antibodies) to SNG001 after inhalation

# Phase 2 in ventilated patients in ICU

*POTENTIAL trial design to leverage  
value from patient population with  
high unmet medical need  
Whilst recognising the potential clinical  
and commercial value in other clinical  
settings*



# Exploratory Phase 2 trial in ventilated patients

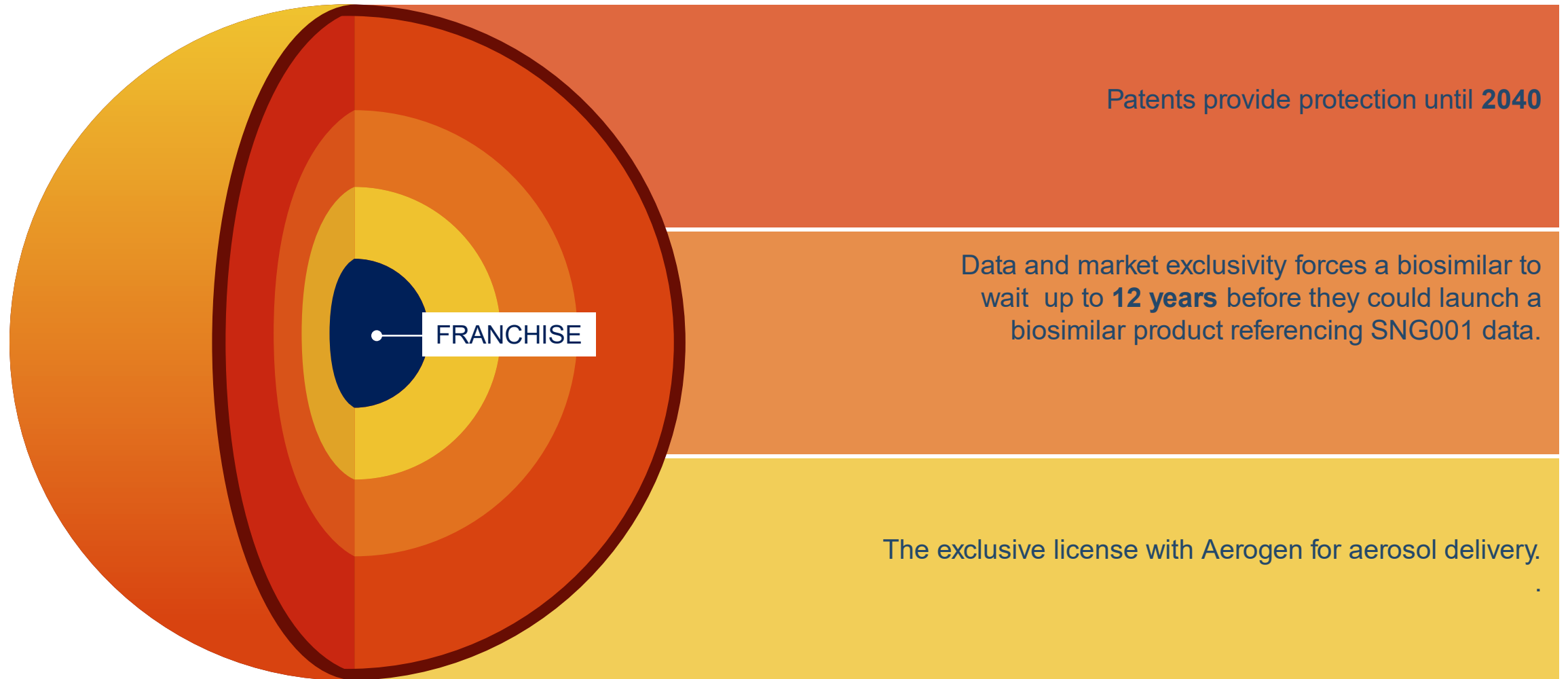
Placebo controlled trial in ventilated (NIV + IMV) patients in ICU

Broad consideration of all endpoints / product profile

- Prevention of disease progression/death
- Ventilator free days
- Mortality
- Virological and innate immune responses to severe viral lung infections
- Safety

Approx 150 patients

# Enduring layers of in-market protection



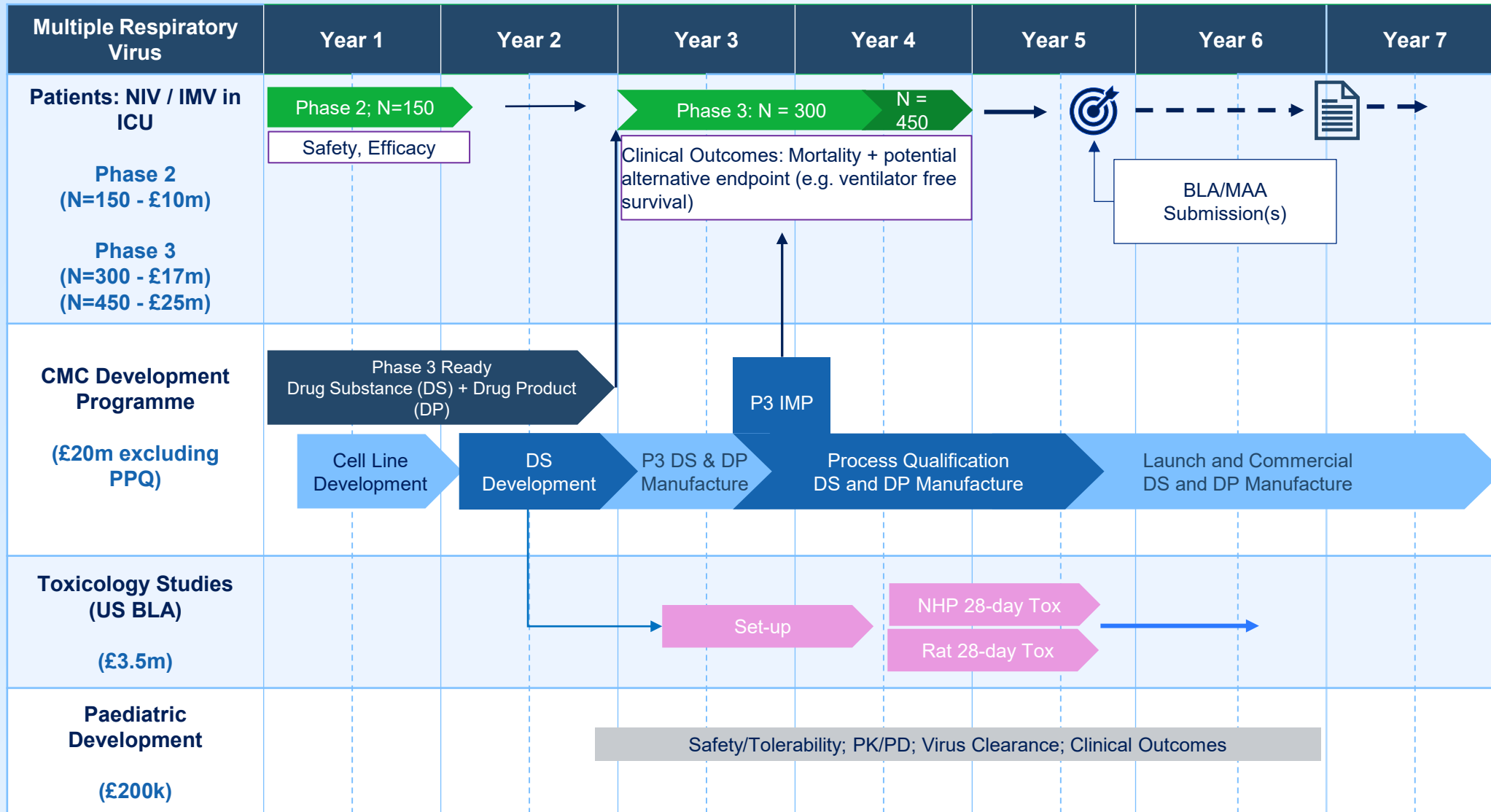
synairgen

# SNG001: Development plan and budget estimate



# Overview of Development Plan

## Summary of Development Activities, Regulatory Pathway and Budgets\*



\* All timelines and budgets are high-level estimates