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Synairgen joins the 2020 coronavirus winners club



[Jacob Plieth](#)



A small trial of inhaled interferon marks a 30-fold increase in Synairgen stock since January, but the endpoints warrant scrutiny.

With investors and governments itching to analyse the first clinical data from Astrazeneca/Oxford University's Covid-19 vaccine today, it was in fact a different UK company – the tiny biotech Synairgen – that seized most of the morning's attention.

Synairgen is a group focused on respiratory disease, whose key technological advance has been an inhaled form of interferon beta-1a. But its masterstroke was to [begin a study of this in Covid-19](#), and the results of this small trial, toplined today, have sent its stock up 400%, notwithstanding questions over what the company has actually demonstrated.

Even more remarkably, Synairgen now stands over 30 times higher than it did at the start of 2020, putting it in line to be one of this year's best-performing biotechs. But even after the share price surge its market cap is still just £250m (\$315m).

The study of Synairgen's inhaled interferon beta-1a, a project coded SNG001, has two parts, made up of 101 hospitalised patients and 120 in the home setting. It was the former that generated what the markets today deemed a clinical win.

Endpoints?

Still, Synairgen has disclosed very little about its study's primary endpoint of absolute 28-day improvement versus placebo on an eight-point ordinal scale on which 0 represents "well" and 8 is "death".

Instead, [it press-released three apparently secondary efficacy measures](#): developing severe disease, recovery as defined by no limitation of activities or no evidence of infection, and improvement in breathlessness, all by day 16. All were backed by p values that were below 0.05, but at no point did Synairgen's press release claim that any was statistically significant.

On a media call the group accepted that the p values had not been adjusted for multiplicity – 10 or 15 analyses had been done, it revealed – leaving open the possibility that they lacked statistical significance. Moreover, it cited an extremely wide confidence interval range, suggesting a high likelihood of chance.

The group was also evasive as regards the primary endpoint of absolute improvement at 28 days, its chief

executive, Richard Marsden, saying he did not have these results at hand.

Professor Tom Wilkinson, the study's lead investigator, argued that this involved a complicated statistical analysis. "We have performed that analysis [and it] demonstrates that there was a clear treatment effect. It was statistically significant," he stated.

Management argued that the primary outcome was captured in the measures of improvement it cited for day 16, but the absence of a primary efficacy analysis – a study's most important metric – is puzzling.

UK biotech win

All that said, perhaps given Synairgen's market cap a borderline numerical benefit in what is ultimately a small trial can be called a win. After all, every other company working on Covid-19 that has revealed clinical data – most with multi billion-dollar valuations – has raised some red flags.

It is also clear that Synairgen needs more trials of SNG001 and more money to run these, but today's announcement certainly raises the group's profile. Interestingly, its study's at-home part has proved difficult to enrol, and "completion will depend on there being a second wave [of Covid-19 in the UK], which we believe will happen", said Mr Marsden.

Synairgen, a University of Southampton spin-out, had earlier focused SNG001 at asthma and COPD, and its greatest success until now was [a \\$7m tie-up with Astrazeneca](#). Perhaps the Covid-19 data will attract further funding, though this will likely come from investors; the UK government has so far focused its spending efforts largely on securing vaccine supply.

Today, the UK government announced that it had secured 30 million doses of Biontech/Pfizer's BNT162, for delivery in 2020/21, and 60-100 million doses of Valneva's VLA2001. An agreement to supply the UK with 100 million doses of the Astrazeneca/Oxford University vaccine AZD1222 [was also reportedly struck in May](#).

Whatever doubts might remain about Synairgen's statistical rigor, the company's co-founder Stephen Holgate insisted: "We do feel confident that there's a real biological and clinical signal here within the data."