

Weekly thoughts on the healthcare sector from finnCap's life sciences analysts: Mark Brewer and Arshad Ahad

COVID-19 News Alert

Implications of Moderna's Early Vaccine Data

Moderna announced the first interim analysis from the Phase III study of its COVID-19 vaccine candidate, which was found to be c.95% effective in preventing symptomatic COVID-19 disease. This follows a similar announcement from Pfizer/BioNTech last week, and the caveats we mentioned at that time remain the same. AstraZeneca-Oxford University are also due to announce initial results this month. While these results are highly encouraging, we reiterate that they do not diminish the urgent need for COVID-19 treatments and testing, which will still be required for years to come, and we outline why. We consider Synairgen, Avacta, genedrive, Omega Diagnostics and Open Orphan to offer good buying opportunities.

- ▶ **News** Moderna announced the first interim analysis from its Phase III COVID-19 mRNA-based, two-dose vaccine candidate, mRNA-1273, which was found to be c.95% effective in preventing symptomatic COVID-19 disease. The 1:1 placebo-controlled study included 30,000 participants in the US, aged 18 and older. The interim analysis was based on 95 confirmed cases of COVID-19, of which 90 were within the placebo group, versus 5 cases in the vaccine group, resulting in the estimated vaccine efficacy of 94.5%. No serious safety concerns have been observed thus far. The vaccine is generally safe and well-tolerated, with the most frequent side effect being fatigue and muscle pain after the second dose (experienced by 9.7% and 9% of the trial participants, respectively). Moderna hopes to submit to the FDA and other regulatory agencies for emergency approval in the coming weeks. It expects final analysis to be based on 151 confirmed cases of COVID-19 and a median follow up of more than 2 months. The company expects to manufacture 500m to 1bn doses globally in 2021.
- ▶ **Comparisons to Pfizer.** Both vaccine candidates are based on mRNA technology that encodes for a form of the SARS-CoV-2 spike protein. Pfizer had announced efficacy of >90%, compared to Moderna's 95%. While Pfizer's BNT162b2 candidate requires ultra-cold storage at c.-70°C, Moderna's candidate remains stable at -20°C for up to 6 months, which is equal to most home or medical freezer temperatures. It also remains stable in refrigerated conditions for up to 30 days and at room temperature for up to 12 hours. Moderna has released more detailed breakdowns than Pfizer. Moderna stated that there were 11 severe cases of COVID-19 in the placebo group but none in the vaccine group. 15 of the 95 cases were in people aged over 65, and overall 7,000 of the total 30,000 participants are over 65, and medically high risk groups represent 42% of the total participants. While the UK Government has secured 40m doses of Pfizer's vaccine, it has only secured 5m doses of Moderna's vaccine. These doses would become available in spring 2021 in the UK, at the earliest. Moderna's vaccine is predicted to cost £38-£45 for a course of two shots, in comparison to Pfizer's predicted price of £30 for two shots.
- ▶ **Unknowns** Full results have not been released or peer-reviewed. Multiple unknowns remain. While it is promising that there were no severe cases in the vaccine group, the trial is not designed to show whether the vaccine prevents severe cases – it is designed to show whether the vaccine prevents any symptom of the disease, which may be as minor as cough or sore throat. Similarly, while the released data shows promising signs that the vaccine may be effective in older age groups, we do not yet have enough data to reach that conclusion. While the vaccine may prevent illness in response to SARS-CoV-2, it is unknown whether it will prevent asymptomatic infection – whether it will prevent virus shedding, and therefore have an effect on community transmission. Duration of protection is also unknown, as are long term safety implications.

- ▶ **Challenges** Vaccine manufacturing is complex, and every batch has to be quality assured before release. This vaccine requires two doses, 28 days apart before it can be effective. A roll-out campaign is likely to be slow, and will require many months to cover a significant proportion of the population. Anti-vaccination movements, and general public concerns over the rapid speed of COVID-19 vaccine development also pose challenges for vaccine uptake.
- ▶ **Not a silver bullet.** Herd immunity would require 60-70% of the global population to be immune (billions of people). Even if a vaccine is perfectly effective, this will take years. Until then, the vast majority of the population will need to rely on treatments and testing for COVID-19. A vaccine is a major tool in the fight against this disease, but it cannot be the only one. Demand for effective treatments and convenient testing outstrips supply and should continue to do so into 2021 and beyond. Overall: a vaccine roll-out will take many months, while cases, hospitalisations and deaths continue to surge and, as such, little has changed with regards to the COVID-19 opportunity, despite this very positive news.
- ▶ **Stock implications.** We believe COVID-19 stocks, including Synairgen, Avacta, Genedrive, Omega Diagnostics and Open Orphan remain good buying opportunities. Synairgen (TP 420p): countries will still want to stockpile SNG001 as there is currently no broad spectrum antiviral and there isn't enough data on how effective this vaccine is on elderly or sick people. Avacta (TP 310p) and genedrive (TP U/R): there is a continued need for rapid and convenient tests. Omega Diagnostics (TP U/R): antibody tests could be used to confirm immunity. Open Orphan (TP 28p): challenge studies could be used to perform head-to-head clinical trials between different first generation vaccines, and the eventual second generation COVID-19 vaccines.

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