Evaluate Vantage

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Moderna takes its Covid-19 vaccine to the FDA

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mRNA-1273 shows 94.1% efficacy at its final analysis, in line with Pfizer/Biontech's 95%.

The full results are in, and Moderna's Covid-19 vaccine candidate, mRNA-1273, is on its way to regulators after showing efficacy of 94.1% in its pivotal trial. The final data from the Cove study are in line with the 94.5% shown at the interim analysis, and the 95% reported for Pfizer/Biotech's rival, BNT162b2.

Still, investors are bound to look for differences between the projects, and one thing Moderna bulls can latch on to is severe Covid-19 infection – or the lack of it. There have still been no severe cases of Covid-19 in subjects receiving mRNA-1273, while there was one in the active cohort of BNT162b2's pivotal trial.

Moderna's stock was up as much as 16% this morning, taking its market cap to nearly $59bn. But this is a win-win situation, with Biontech and Pfizer up 5% and 2% respectively.

Of course, the complete, peer-reviewed datasets on both vaccines still need to be scrutinised. Of particular interest will be how efficacy breaks down across different age groups and ethnicities. Moderna has only said that the efficacy of mRNA-1273 was consistent across these demographics. Pfizer, meanwhile, reported that its vaccine was over 94% effective in people aged over 65.

Safety will also be closely watched when the full results are available. All Moderna is saying for now is that there have been no new serious safety concerns, and that the most common adverse events included injection site pain, fatigue and headache.

Two approvals by year end?

The focus now turns to how quickly the vaccines can get approved; BNT162b2 is set to go before an FDA panel on December 10, while mRNA-1273's adcom will likely be on December 17, Moderna confirmed today. Rolling reviews for mRNA-1273 have already begun in the EU, Canada, Switzerland, the UK, Israel and Singapore.

Swift approvals would be good news for investors and governments alike, but perhaps not so much for another Covid-19 vaccine developer, Novavax, which has again delayed the start of its US pivotal trial of NVX-CoV2373. This was once pegged to start in October, was then delayed until the end of November, and is now slated to begin in "the coming weeks".

Recruiting participants could be tough if there are already vaccines on the market; Novavax shares slumped 2% this morning. Astrazeneca might also face a similar problem: the UK group is reportedly planning a new global study, to test a half-dose/full-dose regimen of its candidate, AZD1222.

Company	Biontech/Pfizer	Moderna
Project	BNT162b2	mRNA-1273
Pivotal study	NCT04368728	Cove
Dosing	Day 0 & day 21	Day 0 & day 28
Readout timing	Day 28	Day 42
Enrolment	43,538	30,000
Cases in active cohort	8 (1 severe)	11 (0 severe)
Cases in placebo cohort	162 (9 severe)	185 (30 severe)
Efficacy	95%	94%
Manufacturing capacity 2020	50m doses (global)	20m doses (US only)
Global manufacturing capacity 2021	1.3bn doses	500m to 1bn doses
Source: Company announcements and Evercore ISI.		