Evaluate Vantage

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Pfizer and Biontech snatch first Covid vaccine victory

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With more than 90% efficacy it seems clear that the partners' Covid-19 vaccine works, but this is only the first hurdle.

News that Pfizer and Biontech's Covid-19 vaccine candidate sailed through its first pivotal trial interim efficacy analysis sent shares soaring today – and not only in those two companies. Confirmation that protection against the pandemic could start rolling out before the end of the year sent global stock markets higher, lifting sectors from airlines to retailers.

With efficacy coming in at greater than 90% it seems pretty certain that BNT162b2 offers protection against the coronavirus that causes Covid-19. But it should be remembered that this is only a brief glimpse of the results. A more detailed breakdown of the data, and later cuts, remain crucial, while safety too has yet to be confirmed.

But, for the first late-stage readout from the clutch of Covid-19 vaccines in development, the news could not have been much more positive. Expectations among the financial community had sat at around 70% efficacy, while the FDA had set a 50% threshold for any project to qualify for consideration of early approval.

Shares in Pfizer were 6% higher in early trade, while Biontech, which contributed the mRNA technology on which the vaccine is based, jumped 12%.

Other leading vaccine developers also reacted: Astrazeneca, which is expecting its first pivotal readout in December, dropped 3%, while Novavax climbed 6%. Up 7% was Moderna, the other developer with a late-stage mRNA-based project, mRNA-1273; some might be betting that BNT162b2's success raises chances here.

Important differences between all of these assets make that very hard to assume, however. With Moderna promising a first readout in the coming weeks, comparisons will soon become easier to make.

First peek

The 90% efficacy figure was derived from 94 cases, which implies 86 infections in the placebo cohort and 8 in those who received the vaccine. This was measured at seven days after the second dose, pointing to protection 28 days after the first shot, the companies said.

The statement also contained news that, in agreement with the FDA, the groups decided against conducting the first planned interim analysis, which was supposed to happen after the first 32 infections according to the

initial protocol. It is not clear why this decision was taken, though many will note that it pushed the first readout beyond the US Presidential election.

Politics aside, at least this explains the apparent delay to the first interim analysis, which caused some concern two weeks ago. Efficacy thresholds of 77% and 68% had been set for these first two analyses, which have easily been beaten.

The next hurdle will be a safety analysis to satisfy the terms of any US emergency use authorisation; these data remain on track for the third week of November. After filing the FDA will convene an advisory committee, likely in December, with approval expected before the end of the year. In Europe, a rolling review has already commenced, pointing to a similar timeframe for regulatory action.

Final cut

The final analysis will happen once 164 Covid-19 infections have been confirmed among the 40,000-plus participants in the trial. There is a good chance that these will have occurred by the time the FDA gets hold of the data, and the regulator and its assembled experts will be very keen to review a full package.

This should include the extent to which the vaccine prevented severe infections – nothing was said on this in today's release. The protection afforded to more vulnerable populations is another important measure; if infections are still being seen in the elderly, for example, the product's utility could be questioned.

Safety, of course, remains crucial. No serious safety concerns have been reported, the companies said today, but a more detailed look at adverse events is needed.

Still, it seems likely that BNT162b2 will be the first Covid-19 vaccine to reach the market in the West. Its commercial potential remains hard to know until the durability of protection is confirmed – another big unknown here – and before rival projects report.

However huge numbers are already being mooted. Mizuho analysts said today they expect more than $8.5bn in revenues in 2020-21.

The final barrier that Pfizer must overcome is distribution, given that BNT162b2 must be transported and stored at -70C. That is a problem for tomorrow, however, and for now the world is celebrating very impressive results achieved at breakneck speed.