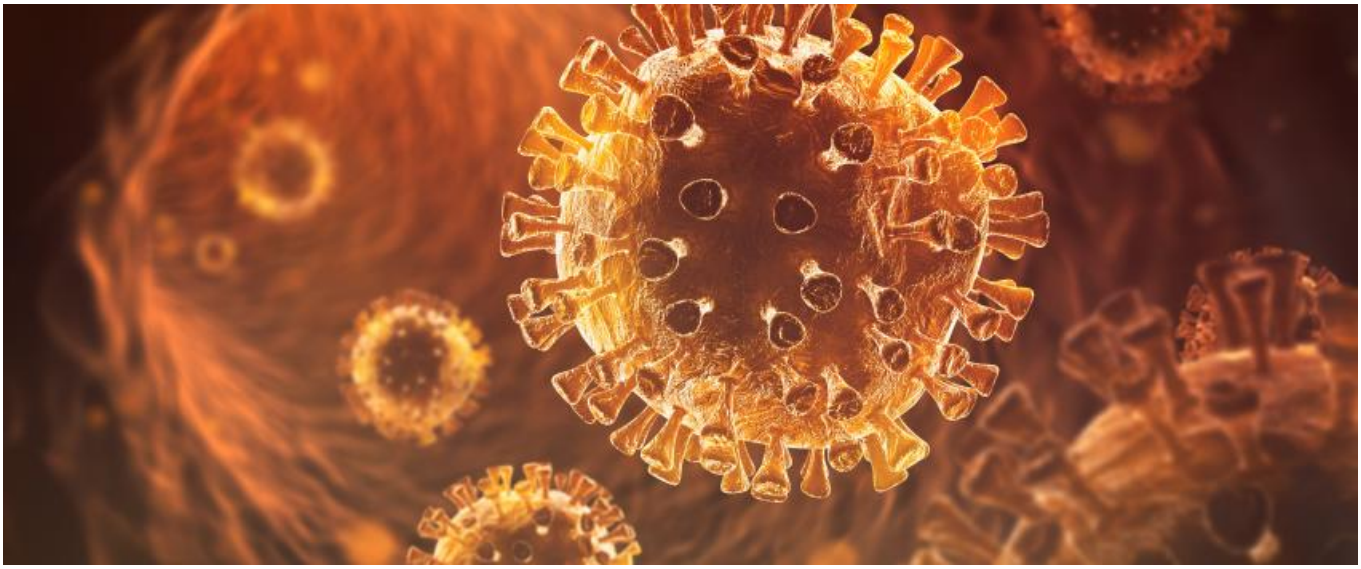
Evaluate Vantage

October 28, 2020

Pfizer keeps the world waiting

Amy Brown



Pfizer confirms that the pivotal trial of its Covid-19 vaccine has yet to undergo an interim analysis.

For a company committed to transparency of disclosure, Pfizer's plans for disseminating its Covid-19 vaccine updates have been pretty opaque. Sellside analysts spent 1.5 hours dragging information out of chief executive Albert Bourla today when a clear statement of intent would have made the situation a lot simpler.

This intense scrutiny is entirely of Pfizer's making, of course; the company had long talked up an October interim readout, and when an update failed to materialise alongside third-quarter results today Mr Bourla was forced to explain when news might come. The answer was November. Probably.

Much of the uncertainty centres on exactly what Pfizer will disclose from the first interim analysis. This will be triggered by the first 32 Covid-19 infections among participants, as per the protocols of the study (*US panel puts the spotlight on pivotal Covid vaccine readouts, October 23, 2020*).

Those 32 events have yet to happen, Mr Bourla confirmed today, and the independent data-monitoring board remains blinded. This at least rules out a scenario mooted by some: that the first pass of the data had already occurred and it was decided that the trial should continue, but that Pfizer and its partner, Biontech, had chosen not to disclose that this had happened.

Mr Bourla today seemed to confirm that nothing would be announced should this outcome materialise. "We do not expect to speak publicly about the interim analysis until we have a conclusive result from the data monitoring committee," he said, going on to define conclusive as "futility or demonstrated efficacy readout on the primary endpoint".

Dates for the diary

Whether the outcome is disclosed or not, this first pass seems likely to happen very soon, going by Mr Bourla's comments. The company did at least commit to disclosing any "conclusive" findings within five to seven days of getting the news in house.

This means no news until the second week of November at the earliest; notably, this is after the US Presidential election.

Mr Bourla also confirmed that the company would have sufficient safety data to fulfil the requirements of a US emergency use application, in the third week of November. As such, if the primary endpoint is hit early, Pfizer could submit BNT162b2 for emergency use in the closing days of November.

Of course a separate question here is what the apparent delay to the interim analysis means, particularly as Pfizer said infection rates were tracking at around the rate expected. Fewer confirmed cases could be good news, if it means that the vaccine is actually working.

On the other hand, in the biopharma world delays to event-driven trial readouts are rarely considered encouraging. It has to be hoped that the October timeline was always a very best-case scenario, and that under normal conditions Mr Bourla would have been less inclined to make such optimistic predictions.