HSBC Global Research

15 October 2020

COVID-19 vaccine Q&A

Phase III data close by, but widespread use much further away

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- Some late-stage COVID-19 vaccine data could be available by end-2020 and lead to emergency approvals
- That could lead to positive headlines, but public confidence in vaccines that have not been extensively tested might be low
- The logistics of shipping billions of doses of vaccines suggest no widespread use of a vaccine until well into 2021 or beyond

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COVID-19 vaccine prospects. As COVID-19 cases continue to rise – we estimate there will be 40m infections globally by the end of October and if the current trajectory continues, around 60m infections by Christmas and close to 1.5m deaths (based on a third order polynomial fit projection of 38m cases so far, with an R-squared value of 0.998). So, it is timely to look again at the progress on vaccines and ask when a vaccine might be available widely. We try to answer 10 key questions.

Some phase III data by end-2020 and potential emergency approvals… Preliminary phase III data from the Pfizer/BioNTech, Moderna, AstraZeneca and Johnson & Johnson vaccines could be available before the end of 2020 and could lead to emergency approvals by end-2020/early 2021. While approvals based on preliminary efficacy and safety data may be viewed as necessary by regulators, healthcare policy makers (and politicians), **the risk is that such preliminary approvals could undermine confidence in those vaccines and deter their widespread uptake.**

Logistics are a major barrier to widespread vaccine distribution. Logistics firm DHL has estimated that to distribute 10bn doses of vaccine over a two-year period would require 15,000 flights, full cold-chain distribution and the distribution of vaccines in 15m cold boxes (some vaccines will need cold-chain distribution from the point of manufacturing to their administration to each patient, which is not available in every country). International Air Transport Association (IATA) estimates that to ship a single dose of COVID-19 vaccine to every patient globally (7.8bn) would fill 8,000 Boeing 747s, and that in normal times (versus in a pandemic), around 25% of vaccines shipped are degraded before they reach their destination. **As such, even with safe and effective vaccines approved by end-2020/early 2021, distribution of those vaccines widely is likely to take well into 2021 at the earliest and possibly well beyond then.**

Risk of "vaccine nationalism". Much of the R&D and manufacturing for COVID-19 vaccines has been funded by governments or government agencies in different countries. A major unknown, then, is whether COVID-19 vaccines would be initially distributed on medical criteria (to those most at risk) or on national criteria (to those countries that paid for the vaccine development or paid for the doses first).

This is a redacted version of the report published on 15-Oct-20. Please contact your HSBC representative or email AskResearch@hsbc.com for information.

Issuer of report: HSBC Bank plc

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Logistics are also a hurdle

- Even if some COVID-19 vaccines produce positive phase III data by end-2020 and are approved, logistics are a hurdle to widespread use
- The ability to distribute potentially billions of doses of vaccine, much of which could require cold-chain distribution, is limited globally
- The widespread adoption of COVID-19 vaccines, even when approved early, could take well into 2021 and potentially beyond

1. Which COVID-19 vaccines are in phase III (late-stage) development?

In this report, we focus on the late-stage (phase III) COVID-19 vaccines in development. That does not imply any negative view on vaccines at earlier stages of development (we have noted previously that the first approved vaccine might not be the best, and other vaccines may be needed); we simply want to focus on nearer-term timelines for clinical data and potential approvals. This report also does not cover potential antibody treatments for COVID-19.

COVID-19 vaccines in phase III development

Company	Vaccine	Type	Doses	Timing	Patients	Final completion
Pfizer/BioNTech/Fosun	BNT162b2	mRNA	2	0, 28 days	44,000	Dec-22
Moderna	mRNA-1273	mRNA	2	0, 28 days	30,000	Oct-22
AstraZeneca	AZD1222	Chimpanzee adenovirus	1 or 2	0, 28 days	30,000	Dec-22
Sinovac	CoronaVac	Inactivated	2	0, 14 days	8,870	Oct-21
CanSino	-	Adenovirus 5 vector	1	Day 0	40,000	Jan-22
Sinopharm	-	Inactivated	2	0, 21 days	18,000	Dec-21
Johnson & Johnson	Ad26.COV2.S	Adenovirus 26 vector	2	0, 21 days	60,000	Mar-23
NovaVax	SARS-COV-2 rS	Recombinant, adjuvanted	2	0, 21 days	11,900	Jan-22
GlaxoSmithKline/Sanofi	-	Recombinant, adjuvanted	ND	ND	ND	ND

Source: Company reports, ClinicalTrials.gov, GlobalData. ND = not disclosed.

2. When will the first phase III data be available?

Based on what companies have said publically (rather than the protocol-defined end of each trial), phase III data can be expected for the following vaccines:

- BNT162b2 (Pfizer/BioNTech) – by end-October 2020
- mRNA-1273 (Moderna) – by end-2020
- AZD1222 (AstraZeneca) – planned by end-2020
- Ad26-COV2.s (Johnson & Johnson) – planned by end-2020
- GSK/Sanofi COVID-19 vaccine – data likely in H1 2021

3. When could the first vaccine(s) be approved?

Earliest approval will be late 2020 on an emergency use basis

The earliest that any vaccine could be approved (aside from Sputnik V in Russia) in the US or Europe on an emergency approval basis is end-2020. However, the risks in preliminary vaccine approvals without long-term safety and efficacy data are that it could undermine confidence in the vaccine and limit its widespread use.

US FDA guidelines for efficacy are not a really high hurdle; question is whether that is robust enough

The approval of any vaccine will depend on the details and timing of the data from the ongoing phase III clinical studies, with positive data and an adequate safety profile. Most regulatory agencies have indicated that they are willing to provide preliminary emergency use authorisations for COVID-19 vaccines. Full regulatory approvals will depend on more extensive follow-up data in due course. The US FDA has provided guidance for companies that are looking for rapid vaccine approvals. The guidelines include an efficacy hurdle of at least 50% (50% of patients reaching the FDA's pre-specified hurdles for efficacy) with at least two months of safety follow-up for half the participants in each study.

The first COVID-19 vaccine has been approved in Russia – Sputnik V. Sputnik V is derived from two attenuated adenoviral vectors: adenoviruses 5 and 26. The vaccine was approved in Russia based on phase I/II data and before the planned 40,000 patient phase III trial has completed. Some of the data that have been published (76 patients, publication in The Lancet) showed an antibody response at day 21 and a T-cell response at day 28, but there is some scepticism that the approval is premature, and the inability to scrutinise the development programme in detail has not diminished that scepticism.

4. Will vaccines from AstraZeneca and Johnson & Johnson be delayed?

AstraZeneca's COVID-19 vaccine development programme, AZD1222, was paused due to an unexplained side effect seen in the phase III study. The clinical trial has resumed at most locations except in the US. The delay in re-starting the full study in the US could delay approval of the vaccine, but there could be sufficient data from the ex-US locations conducting the study to support an approval on the same timeline that had previously been indicated. AstraZeneca indicated in September that it expected clinical trial results before end-2020. That suggests an approval – assuming positive efficacy and safety in H1 2021 – if eligible, for emergency use authorisation in the US, and we would expect a similar timeline in Europe and elsewhere.

Johnson & Johnson has also paused its phase III clinical study with its type 26 adenovirus vaccine candidate due to an unexplained illness in a patient. Again, depending on when the study re-starts, JNJ may have enough to announce data before end-2020 as previously planned, and gain an emergency use authorisation in 2021.

5. Are COVID-19 vaccines a one-shot dose, or is a booster dose needed later?

Considering logistics, administration and compliance, single-dose vaccine is more suitable than two doses, all things equal

Much of the pre-clinical and limited clinical data suggest that two doses of most vaccines provide a more rigorous immune response than a single dose of the same vaccine, with the caveat that we still do not know what the human correlates of protection against COVID-19 actually are. For the time being, it is not apparent whether a two-dose vaccine will be any more effective than a single-dose vaccine. However, logistically (in terms of transport of the vaccine, see below), as well as from an administration (two visits versus one to the medical centre) and compliance points of view, a single-dose vaccine would be preferable to a two-dose vaccine,

assuming efficacy and safety were comparable. **As can be seen from the table on page 2, most of the vaccines in development are two-dose vaccines.**

6. If approved, who will get the vaccine(s) first?

From a medical perspective, those most at risk of contracting COVID-19, as well as the most vulnerable in society with underlying health conditions, should get access to an effective COVID-19 vaccine first. In theory, this would include front line healthcare workers, the elderly – especially those in crowded nursing homes – and those with underlying health conditions (with immune-compromising conditions, respiratory illnesses, diabetes) that places them in a higher risk category.

There is a risk of vaccine nationalism – whoever paid already gets the vaccine first

However, the reality may be somewhat different. The US government via the Biomedical Advanced Research and Development Authority (BARDA) is funding a large amount of research, development and manufacturing build-out related to COVID-19 vaccines. Some of those agreements – for example, in its collaboration with Moderna for its mRNA-1273 vaccine – are **explicitly for the benefit of US patients**. Furthermore, when companies have received funding from both BARDA in the US and either national governments or, say, the EU, who gets first call on the vaccines produced? **While we would expect from a humanitarian point of view that there would be a fair distribution of vaccines on a timely basis, we do not have access to the specifics of those government contracts with each company, and vaccine nationalism (which country paid first or which country paid more) may take priority.**

7. How long will it take for vaccines to become widely available?

As we outline below, the logistics of not only manufacturing, but distributing, a large amount of vaccine suggests that, at best, even if vaccines are approved under emergency use authorisations before end-2020, it would be well into 2021 at the earliest – and possibly much later – before they would become more widely available.

Logistic requirements are staggering for the widespread distribution of COVID-19 vaccines

Manufacturing. Many of the companies that have signed clinical trial and supply agreements with government organisations will have their manufacturing costs covered by the financial terms in those agreements. As such, where manufacturing capacity was not already available, that capacity is will be satisfied via collaborations with third parties or, in some cases, by expanding or building new facilities with costs covered. So, while the manufacturing for traditional vaccines can take months to years, a lot of effort has gone into setting up manufacturing despite not knowing whether any of the vaccines will actually be effective. However, it is not clear that even with this monumental effort to ramp up manufacturing capacity, the needed safety and efficacy will be achieved.

The Pfizer/BioNTech and Moderna vaccines are mRNA-based drugs, more akin to small molecules, and so production should be significantly more rapid than for a traditional vaccine. **However, these mRNA-based vaccines need to be stored at low temperatures from the point of release from the vaccine manufacturing facility to the administration to the patient.**

Potential logistical complications include:

Temperature. As some of the vaccines in development need to be stored at below zero degrees Centigrade (and for the Pfizer vaccine, well below that), cold-chain distribution will be needed. Not every country has a reliable or viable cold-chain distribution network.

Administration of the vaccine. If a vaccine is one shot, that would make a vaccination programme easier to administer; it would also provide more rapid protection while minimising risks to healthcare providers. Further, it would reduce transport logistics (see below).

Volume. In a paper published in September 2020, logistics company DHL estimated that to deliver 10bn doses of vaccine globally would require:

- 15,000 flights
- 200,000 shipments by pallet shippers
- 15m deliveries in cooling boxes, likely filled with dry ice

The IATA noted that just providing a single dose of vaccine to 7.8bn people world-wide would fill 8,000 Boeing 747 aircraft. IATA also noted in 2015 that one-quarter of all vaccines reach their destination degraded due to improper shipping – **and that was in normal, not exceptional, times, and for relatively frequently utilised supply chains**.

8. Will annual vaccinations against COVID-19 be needed (like flu vaccines)?

It is not clear if one vaccination will be sufficient

At the moment, it is not clear how long protection against COVID-19 will last after vaccination. Unlike influenza, COVID-19 does not appear to be seasonal and, thus far, the frequency of major mutations is relatively low, but there is just not enough information to assess whether further vaccinations may be needed. What has been seen in recent weeks, however, are several cases of COVID-19 re-infection. Although the patients developed an immune response against COVID-19 in the first instance and then recovered, they were able to become re-infected by a particular COVID-19 strain that clearly was not neutralised by the initial immune response, suggesting either that we may need vaccinations against multiple COVID-19 strains, or that any protection against any COVID-19 strain may not last long. Different vaccines may confer different durations of protection and, also, it is not clear what the correlates of protection will be – for example, whether neutralising antibody responses at a certain level or a T-cell response, and whether one is more predictive than the other in terms of effectiveness.

9. If enough people get vaccinated, will it induce herd immunity?

Herd immunity in the context of COVID-19 remains only a theory

Herd immunity occurs when a large enough part of the population is vaccinated against a pathogen, reducing the likelihood of further spread of infections in non-vaccinated and non-immune individuals as the pathogen runs out of hosts. In this manner, the vaccinated individuals indirectly provide protection for the non-vaccinated individuals. In theory, if enough of a population is infected (and recovers) from a pathogenic infection (without vaccination), that could also induce herd immunity. However, that is a largely unproven theory and in the context of COVID-19, that course of action could be dangerous and unethical given the long-term health effects seen in many patients, even in those who do not need intensive care. If a COVID-19 vaccine or vaccines became available and there was widespread vaccination, herd immunity may be induced. But there is not enough data available yet to say with any certainty that herd immunity would occur and whether, even if herd immunity did occur, how long protection against COVID-19 infection would last.

10. Can people be forced to take a COVID-19 vaccine?

Even if a safe and effective vaccine is available, you cannot force people to take it

Even if an effective and safe vaccine or vaccines become widely available, it will be up to individuals to decide whether to take the vaccine or have it administered to their children. As these vaccines are being developed on an accelerated timeline, there are requirements to have further clinical studies conducted before full approvals are granted (after the emergency use authorisations). First, compulsory vaccination is arguably unethical and would likely be politically sensitive in most countries; and second, as these vaccines are still in clinical development, the administration of any vaccine – whether by the choice of the individual or by the legal mandate of any country – would be covered by the principles of the Declaration of Helsinki.

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