

Vaccine Progress and What's Next

JAKE SIEWERT: This is Exchanges at Goldman Sachs where we discuss developments currently shaping markets, industries and the global economy. I'm Jake Siewert, Global Head of Corporate Communications here at the firm.

It's been a big week in the news across the board, but particularly in the race for a COVID-19 vaccine. To get to the latest on that and what's still ahead, we're joined by Salveen Richter, Lead Analyst for the US biotech sector for Goldman Sachs Research. Salveen, welcome to the program.

SALVEEN RICHTER: Jake, thank you for having me.

JAKE SIEWERT: So, you know, there was huge news earlier this week when Pfizer released encouraging vaccine results. What do those results tell us? And how have markets reacted?

SALVEEN RICHTER: Yeah, so on Monday Pfizer and BioNTech released positive data from their phase III COVID-19 vaccine study for their asset known as BNT162b2. And they showed us vaccine efficacy of greater than 90 percent in terms of preventing COVID-19 in patients without prior evidence of SARS-CoV-2 infection. This did occur at seven days post the second dose. The results were based on the first interim analysis per an evaluation of 94 confirmed cases of COVID-19. There were no serious safety concerns. On the forward here, there will be more interim analyses for the final look at 164 cases.

Given this was the first demonstration of phase III efficacy for a COVID-19 vaccine, the markets, understandably, reacted quite positively.

JAKE SIEWERT: So Salveen, you closely cover Moderna, which also has a late stage vaccine in development. Does the Pfizer news imply anything about the likelihood of Moderna to be successful? And is there a way that we can read across that success to think about Moderna's vaccine?

SALVEEN RICHTER: Yeah, so my colleague Terence Flynn covers Pfizer. With regard to Moderna, we should view this as a positive read through given the technology is identical and the constructs are pretty similar for these vaccines. Basically how they work here is that they introduce an mRNA molecule into the body through an injection. And this provides the body with directions to make a specific protein. In this case it is the

spike protein that is on the surface of the SARS-CoV-2 virus. This then elicits an immune response in the body to the SARS-CoV-2 virus in order to prevent the defend against future infection. Both Moderna and Pfizer/BioNTech have developed their vaccines to be administered in two doses. One to prime the immune response and the second to boost it.

For COVID-19 though, we've noted, and this is kind of a nice feature here of the mRNA vaccines, Moderna designed the vaccine in two days after the genome sequence was published and took two months to manufacture the vaccine for clinical trials. So the speed of development is really possible given Moderna's modular manufacturing capabilities that leverage AI and machine learning.

JAKE SIEWERT: So, with the success that Pfizer announced and the potential for success on the Moderna front, a lot of the attention has now turned to sort of production, distribution, approval processes. What's the best-case scenario timeline look like for vaccine approvals and distribution in the United States?

SALVEEN RICHTER: Sure Jake. So, a best-case scenario here would involve emergency use authorization. This is a process by which during an emergency the FDA can determine that the vaccine is worth approving for use, even without the full evidence to establish its effectiveness and safety. Which would lead to the December/January approval potentially for high risk groups. Remember, despite the positive interim and efficacy data released by Pfizer and BioNTech, a median of two months follow up on safety is required following the second dose of the vaccine. We believe the safety data will be available by the third week of November for Pfizer/BioNTech and by November 24th for Moderna post which they can file for emergency use authorization.

Dr. Scott Gottlieb, the ex FDA Commissioner and a member of Pfizer's Board of Directors recently did project that it could take the FDA about two to four weeks to approve a vaccine after an EUA filing. So we expect full approval for these two vaccines in early 2021 based on the full efficacy analysis of the trials. And then distribution to the broader population in 2Q '21.

In terms of supply and distribution, we estimate for population wide or 100 percent vaccination, that the US, EU, UK, Canada, and Japan would have a surplus of vaccines contingent on the totality of agreements and these vaccines working. If you look

at the US by year end, Moderna guides to availability of 20 million doses. Now each individual needs two doses. And Pfizer/BioNTech guide to 30 to 40 million doses with potential for 100 million doses by March 2021.

If you think of a more global picture for 2021, Moderna does expect to deliver COVID-19 doses of 500 million to 1 billion. Pfizer/BioNTech expects to have greater than 1.3 billion doses available. And other phase III vaccines, such as Novavax will have supply of 2 billion. AstraZeneca has signed contracts for over 3 billion. And J & J expects to have greater than 1 billion. And we know J & J is the only vaccine potentially that could be available with a one dose regimen.

JAKE SIEWERT: So, I'm an optimist, so I like to focus on best-case scenarios. But why don't we run through some of the risks that could delay that rapid, relatively rapid, distribution.

SALVEEN RICHTER: There is the possibility that FDA does not approve a vaccine based on emergency use authorization. But the Expanded Access Program is another path in discussion for granting early access to a vaccine. You know, per your optimism, we did really just have some excellent data for Pfizer and BioNTech's vaccine. Also we are monitoring for safety events as these phase III trials progress.

Per Dr. Moncef Slaoui, the Chief Scientific Officer of Operation Warp Speed, about 90 percent of adverse events related to vaccination take place within the first 42 days. So that is positive in that sense. And so, we'll be watching for rarer side effects that occur in larger populations over time. A challenge could also be in convincing the broader population to get vaccinated. That's going to be a key focus here on the forward. And one thing we'd be look at is on distribution. We know cold storage infrastructure is required to various degrees. This does exist in developed countries. And that while frameworks for tiered access prioritizing high risk populations do exist, we will want to see execution on this front.

JAKE SIEWERT: Okay, so you've covered a lot of potential deadlines, some risks to those deadlines. What are you going to be focused on looking ahead to determine the course of action going forward?

SALVEEN RICHTER: So, we await more interim and final looks from the phase III studies. And in light of the positive data we've just seen, we would expect the focus to shift, and our

focus to shift, to a few key factors. We're looking at the regulatory approval path and timing to market. As we mentioned earlier, December/January approval seems likely for high risk groups. We'd be looking for the additional data from the phase III trials, including impact on severe disease, potentially prevention of infection and durability here. Are we looking at a situation where we need to take an annual vaccine on the forward? We'll also be looking at the outlook for the other phase III COVID-19 vaccine candidates. So, apart from Pfizer and Moderna, we're watching AstraZeneca, which guides to providing X US data for their vaccine by end of 2020. J & J we'll be watching, as well as Novavax. And then we're looking at Sanofi GlaxoSmithKline, given these are two traditional vaccine players, where they're going to have phase I/II data likely by December with a phase III trial initiation by year end '20.

In addition to all of this, we do anticipate focus on COVID-19 vaccine manufacturing capacity and supply dynamics, distribution, as well as supply chain inputs such as syringes and vials.

JAKE SIEWERT: All right, well, that's a lot to keep track of. You're going to have a busy winter. And you've had a busy year. And it doesn't sound like it's going to let up any time soon. We'll have to have you back on to check in on the progress in a couple months. But Salveen, thanks for joining us today.

SALVEEN RICHTER: Jake, thank you. It was my pleasure.

JAKE SIEWERT: That concludes this episode of Exchanges at Goldman Sachs. Thank you for listening. And if you enjoyed the show, we hope you subscribe on Apple Podcast and leave a rating or a comment. And please tune in later this week for our weekly markets update where we'll be talking to David Costin of Goldman Sachs Research who will share his latest outlook for US equities.

This podcast was recorded on Wednesday, November 10th in the year 2020. Thank you very much for listening.

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