REFINITIV STREETEVENTS

EDITED TRANSCRIPT

MRNA.OQ - Moderna Inc Clinical Data Call

EVENT DATE/TIME: JUNE 08, 2022 / 12:00PM GMT

OVERVIEW:

MRNA has conducted its bivalent COVID booster Phase 2/3 interim analysis.

REFINITIV

CORPORATE PARTICIPANTS

Lavina Talukdar *Moderna, Inc. - Senior VP & Head of IR*

Paul Burton *Moderna, Inc. - Chief Medical Officer*

Stephane Bancel *Moderna, Inc. - CEO & Director*

Stephen Hoge *Moderna, Inc. - President*

CONFERENCE CALL PARTICIPANTS

Cory William Kasimov *JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst*

Elizabeth Daniels Webster *Goldman Sachs Group, Inc., Research Division - Associate*

Matthew Kelsey Harrison *Morgan Stanley, Research Division - Executive Director*

PRESENTATION

Operator

Good morning. My name is Olivia, and welcome to Moderna's conference call. (Operator Instructions)

Please be advised that the call is being recorded.

At this time, I would now like to turn the call over to Lavina Talukdar, Head of Investor Relations at Moderna. Please proceed.

Lavina Talukdar - *Moderna, Inc. - Senior VP & Head of IR*

Thank you, Olivia. Good morning, everyone, and thank you for joining us on today's call to discuss Moderna's bivalent COVID booster Phase II/III interim analysis. You can access the press release issued this morning as well as the slides that we'll be reviewing by going to the Investors section of our website. On today's call are Stephane Bancel, our Chief Executive Officer; Stephen Hoge, our President; and Paul Burton, our Chief Medical Officer.

Before we begin, please note that this conference call will include forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please see Slide 2 of the accompanying presentation and our SEC filings for important risk factors that could cause our actual performance and results to differ materially from those expressed or implied in these forward-looking statements.

I will turn the call over to Stephen, who will take us through the data. Stepehn?

Stephen Hoge - *Moderna, Inc. - President*

Thank you, Lavina. Good morning and good afternoon, everyone. Starting on Slide 3. I'd first like to frame our strategy for COVID boosters and why we are pursuing bivalent boosters and the seasonal update. So the strategic rationale for seasonal booster of Moderna is based on 3 points summarized here. We see neutralizing titers will wane similar to endemic human corona viruses, which circulate every year. And that decline in neutralizing titers, we believe will increase the risk of breakthrough hospitalization for those at higher risk, including older adults and immune compromised.

We also believe that there will be emergence of new strains or variants of concern that could accelerate the impact of that waning and broadening the risk of breakthrough. In fact, we see that happening right now with the Omicron variants of concern and (inaudible).

So what are the desired features for an updated vaccine? Well, the first would be to improve the durability of protection from neutralizing antibodies against Omicron to at least 6 months and that would provide full protection through the fall/winter respiratory infection season that happens every year with other viruses, and we believe will happen again this year with SARS-CoV-2.

Second, we want to retain high and durable protection against prior variants of concern and the ancestral strains. We do not want to be opening up any gaps in the immunity that we've already achieved.

And third, we hope to broaden the cross-protective immunity to increase the potential of protection as the variants of concern continue to evolve midyear. Now in order to do that, we've been advancing a range of bivalent vaccines against different variants of concern.

And on Slide 4, I'd like to summarize the Phase II/III study, our P205 study for our most recent bivalent vaccine with mRNA 1273.214. mRNA 1273.214 is a bivalent including 25 micrograms of our prototype vaccine 1273 and 25 micrograms of mRNA 1273.529. That is an updated antigen for the Omicron variants of concern.

So the bivalent vaccine here includes Omicron and helps educate the immune system about what Omicron looks like. Now in the Phase II/III study P205, all subjects in the study had previously received mRNA-1273 as a primary series, so the 2 doses of 100 micrograms. And they had all received a 1273 prototype booster of 50 micrograms.

And on entry of the study, people then received either a fourth dose of mRNA-1273 or a fourth dose of the bivalent booster that includes the 32 Omicron mutations, both at 50 micrograms. As you can see here, approximately 370 subjects were enrolled in the prototype arm, in approximately 430 subjects, 437 were enrolled in the bivalent vaccine arm.

Now we have another study ongoing in the United Kingdom with about 1,500 participants per arm, where there are mixed primary regimens, not just mRNA-1273. The arms were enrolled sequentially, but very quickly after each other in February and March this year.

Now on Slide 5, I'd like to quickly remind you of the primary objectives for the study that were consistent with regulatory guidance. So the first set of endpoints we evaluated were day 29, immunogenicity and we tested first noninferiority against the ancestral SARS-CoV-2 strain as well as non-inferiority in seroresponse rates. Having met those criteria, we then moved on to superiority in terms of geometric mean ratio against Omicron at day 29. And I'll cover that data in just a couple of moments.

But first, on Slide 6, quickly, I want to summarize the demographics and baseline characteristics between the 2 groups, and they were generally very consistent. The mean age, as you can see, between the bivalent vaccine recipients, 1273.214 and the middle column, and those who received a prototype vaccine on the far right column was 57 years old in both cases. The percentage of participants over the age of 65 was 39.8% in both cases. There was a good gender balance.

And in terms of the duration between doses, those who received the 2 vaccines had very similar. It was 8 months median duration between the completion of the primary series and the first booster dose, the 50-microgram booster dose of 1273 in both groups. And between the first booster dose and the dose received in this study was approximately 4.5 months in mRNA-1273.214, the bivalent, and 4.4 months in the prototype, again, very similar.

The both groups also had very similar percentage of baseline seropositive participants. So 22% of those in the bivalent arm had a prior SARS-CoV-2 infection, either documented based on nucleocapsid antibody or a PCR test that was positive upon baseline testing in the study. And the comparable group in the prototype arm was 26.8%. So very similar overall in terms of characteristics.

Moving on to safety very quickly. The solicited adverse reactions on Slide 7 were consistent with prior doses. And so first, looking on the left at local solicited adverse reactions reported within 7 days of the dose. And on the right, as systemic, we presented the complete data here across our range of doses. So quickly to orient you to this slide. The grade 3 are in orange, grade 2 in green and grade 1 in blue. And you've got 3 pairs of bars in each case. The furthest bar on the left is the solicited adverse reactions from our Phase III study after a second dose of mRNA-1273. As a reminder, that was a 100-microgram second dose.

The middle of the 3 paired bars is the P201 Phase II data from the first booster that was form the basis of our approval of a 50-microgram booster of mRNA-1273 or Spikevax. And then the third of the 3 bars is the reported reactogenicity in the current study, the Phase II/III study here for the bivalent vaccine. As you can quickly see, across all of the solicited local and systemic reactogenicity parameters. Generally, they were broadly consistent. In fact, there was a numerical trend towards lower reactogenicity for the 214 bivalent booster, prototype booster compared to either the prior booster dose or the second dose of the primary series.

In addition to frequency and types of unsolicited adverse events were also comparable between the groups and there were no vaccine-related serious events in the bivalent vaccine group up to 28 days after booster dose, all very reassuring and consistent with prior experience.

So now moving on to Slide 8 are the immunogenicity results against Omicron, the variant of concern that we are principally trying to develop this improved booster 4. So here, I'm showing you the pseudovirus neutralization titers against Omicron for all of the different groups in a few different groups.

So just to orient to the slide quickly. On the far left are all participants in the study, those who are both seropositive and seronegative. In the middle, as denoted, there are the seronegative participants, those who were baseline seronegative to SARS-CoV-2 prior to boosting. And on the far right, those participants who were baseline seropositive who has had a history of a SARS-CoV-2 infection.

In the lighter purple color is the prototype vaccine and in the darker purple color is the bivalent Omicron-containing vaccine. As you can quickly see, the baseline titers pre-booster titers across all participants, seronegative and positive were very similar between the groups. And as I think you can quickly appreciate the resulting boosting of day 29 titers led to higher, numerically higher, significantly higher neutralizing titers across all 3 subgroups. Focusing first on the seronegative population, you'll see that the total titers got to 2,400 approximately, and that compares with 1,473 for the day 29 titers of those who received the prototype vaccine.

But importantly, if you look at seropositives, there was also a benefit with significantly higher titers up to 7,600 compared to 3,800 for those who are seropositive. And in the all participant group, which is a blend of the 2 to the right and may accurately represent the population of folks, who will be boosted this coming fall, we still saw a significantly higher rate of neutralizing titers despite very similar starting baseline titers and similar demographic characteristics.

So moving on to the statistical testing on Slide 9. The first question as per protocol is and as per regulatory guidance with, Can we get the superior neutralizing titers against Omicron? So this is now looking only at the baseline seronegative participants and is the per protocol statistical analysis. You can see here again in the middle column, the bivalent booster data in terms of neutralizing titers and then in the far right column of the 3, the prototype vaccine. Pre-booster titers were similar, approximately 300 in both cases.

As I covered a moment ago, an ANCOVA model estimated GMTs were significantly boosted in the case of the bivalent vaccine to 2,400 and GMFR, geometric full mean boosting was approximately eightfold 7.96 in this calculation. That compares with the prototype vaccine, which did succeed in boosting titers against macro on dose.

And again, this is a fourth dose, whereas prior results have been published with the third dose, and boosted from 300 approximately to about 1,400. That's a fourfold boost. And the geometric mean ratio between those 2 was 1.75, so a point estimate above 1, but importantly, the lower bound of the confidence interval was only -- was as high as 1.49. So a statistically significant superior result.

Now in terms of serial response rate, at day 29, where we wanted to demonstrate noninferiority. There was really no difference between the vaccines, although numerically higher seroresponse rate for the bivalent vaccine that was not statistically significant, given the strong seroresponse that we see with 1273 prototype.

So in summary, all primary and key secondary immunogenicity objectives were met on the study. and the bivalent vaccine data elicit superior neutralizing antibody responses against Omicron compared to prototype. It also elicit noninferior seroresponse rate as was the objective. And so mRNA 12 -- and lastly, the bivalent vaccine induced potent neutralizing antibody responses against Omicron in all seronegative response in individuals tested.

Now quickly on Slide 10, just to show that as we look at a population that might be more representative of the broader population who are going to be boosted this fall, which is all participants, including those who are seropositive, the results are remarkably similar.

So while pre booster titers are numerically higher, and the post booster titers are also numerically higher, heading to 3,000 in this case, for the bivalent vaccine 3232. The GMFR and geometric mean ratio are very, very similar. In fact, geometric mean ratio here was still statistically significantly superior at 1.78 with a lower bound of 1.56 compared to 1.49 in the other group. And you can appreciate, those are remarkably consistent. The seroresponse rate was also numerically higher for the bivalent vaccine but not significantly so. And again, very reassuring in the context of this study.

So the bivalent vaccine resulted in superior neutralizing GMT, therefore, against Omicron compared to the prototype for all the participants subgroups, both seronegative and seropositive participants as well as the combined cohort. Very reassuring for the direction of this booster.

Last thing on Slide 11, just to orient you to the data is we did want to confirm that the vaccine -- the bivalent booster continue to have noninferior protection against ancestral SARS-CoV-2 strains. In this case, the D614G bearing ancestral assay. And this is the same assay in which we've consistently been testing our samples throughout our clinical trials over the last several years.

On the left, you're looking at the all participants and on the right, baseline to your negative participants. On the left, I think you can appreciate the geometric mean ratio was 1.2, as highlighted in red there. and the lower bound of the confidence interval excludes 1 to 1.08, meaning that the bivalent booster also demonstrated superior neutralizing protection in terms of neutralizing antibodies against the ancestral SARS-CoV-2 strains, even though the only goal was noninferiority. Again, very reassuring that the bivalent vaccine is not only significantly improving protection against Omicron as measured by neutralizing titers, but it is also retaining strong protection, in fact, providing slightly superior protection against the ancestral strains of the virus.

So on Slide 12, briefly, just to summarize the conclusion mRNA-1273.214, the bivalent Omicron-containing booster, the 50-microgram booster was well tolerated, and the safety and immunogenicity profile was similar to what we've seen with prior doses of the prototype.

All the primary and key secondary immunogenicity objectives were met. We listed the bivalent vaccine elicited a superior neutralizing antibody response against Omicron compared to the prototype and it elicited noninferior neutralizing antibody responses against the ancestral SARS-CoV-2 strains, which was the objective.

We also elicited strong neutralizing responses against all individuals regardless of whether they had a prior SARS-CoV-2 infection or not, clearly indicating there is a benefit to boosting even in those who have been infected with SARS-CoV-2.

So overall, we believe this very encouraging data clearly shows that the bivalent booster is a superior booster. And as we look to the fall infection season with respiratory viruses, with SARS-CoV-2 and the ongoing circulation of Omicron and its subvariants. We believe strongly that this data supports an update of the vaccine from the sequence that we've been using from years ago to the bivalent Omicron containing booster demonstrated here.

Modena is preparing regulatory filings based on the data, and we expect to submit them in the coming weeks, and we're very optimistic given that we have met those regulatory guidance and the prespecified criteria in the study that we'll be able to have a vaccine available by the late summer and early fall for protection against SARS-CoV-2 in the winter infection season.

So with that, I think we'll be happy to take any questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Our first question coming from the line of Salveen Richter with Goldman Sachs.

Elizabeth Daniels Webster - *Goldman Sachs Group, Inc., Research Division - Associate*

This is Elizabeth on for Salveen. Regulatory-wise, could you just walk us through the next steps post this candidate working and expectations for the June 28 meeting?

And then could you also comment on how Moderna is working to get a supply of this candidate ready for the fall?

Stephen Hoge - *Moderna, Inc. - President*

Absolutely. Thank you for the question. So we have obviously been engaged with regulators globally, including the FDA and the United States about the criteria for the study since the early part of this year and have reviewed those protocols and designed the study to meet that guidance. And the question we've been asked to demonstrate was is there really a benefit? Is it superior to update the vaccine with Omicron containing buster. And I think the data as we have here clearly shows that.

So it becomes a pretty straightforward process of having not only we've met all of those primary and secondary endpoints that we need to provide the filings to the FDA and regulators across the globe with this data. But having had those initial exchanges with them on the design of the protocol and the criteria for success here, we expect those to be relatively straightforward discussions and submissions.

We've been working on those contemporaneously, and so we're working on them throughout. And we expect to be able to submit them in just a few weeks here. And we're looking forward to that VERPAC on the 28th of June that you're referencing. That VERPAC has been called by FDA in the United States, to make recommendations based on strain and sequence of whether or not it's necessary to update the vaccines and if so, towards that.

We feel strongly the data we have is -- shows that it is appropriate. In fact, we think strongly desirable to update the sequence of the vaccines with an Omicron containing variant because of the ability to achieve significantly higher titers, which we think will correlate with better durability and better protection against Omicron subvariant throughout the winter.

Those -- we have -- we've been invited to provide a brief update. The VERPAC meeting on the 28 is not around our product, it is around sequence change. And so we will be looking forward to sharing this data and other data that emerges over the next few weeks with the VERPAC as they make their deliberations and decisions on behalf of the United States.

Similar exchanges are going on to not through advisory committees globally with other health authorities, where we are providing them this information real time alongside our submissions so that everybody can make the best decisions about what is the best updated booster we can have for the fall this year. And so we are looking to complete those exercises, I said over the next few weeks.

In terms of availability of the vaccine, we have been working hard to scale up manufacturing throughout the last several months. And we've been -- while we haven't guided to the amounts of vaccine that will be manufacturing, we are confident that through the next several months of hard work, we will be able to supply substantial large, large amounts of the updated bivalent booster, hopefully sufficient to meet all demand that's out there for this updated vaccine through the fall season.

Stephane, do you want to provide any specific comments on manufacturing?

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Sure. I mean on manufacturing, just a few words. We have been getting ready for a typical fall launch like in a seasonal flu. So we want to be ready as early as August to be shipping. And so what we have done over the last few months is we have been making a lot of 1273 half of the component of a product. And now for several weeks, we have been making the 529 components. And so we are really on track to be able to supply customers across the world with 214 for the fall.

Operator

Our next question coming from the line of Matthew Harrison with Morgan Stanley.

Matthew Kelsey Harrison - *Morgan Stanley, Research Division - Executive Director*

I guess similar vein is around regulatory requirements because I think that's the big question for everybody. I guess a 2-part question on that.

So the first 1 is -- do you have a sense -- obviously, you picked what I'll call, ancestral Omicron, but we know there are a lot of subvariants of Omicron now, and the prevalence of them is quite different than and may be quite different in the fall. So do you have a sense of how the regulators -- or are the regulators going to mandate a certain strain requirement? And if they did, do you think you'd have to run another experiment? Or would you be able to just switch out the strain?

And then secondly, you didn't address durability here obviously because you don't have that follow-up, but obviously, 1 of the key points of the bivalent is potentially longer durability. Is that going to be a key component of what the regulators are going to want to review.

Stephen Hoge - *Moderna, Inc. - President*

Great questions, thank you, Matt. So let me take the first 1 on Omicron subvariant. That is an emerging field. Omicron has launched its own strength of SARS-CoV-2 virus, as we all know. We're following that closely. We're going to be testing our samples across a range of subvariant assays, but it's important to note those assays, we've all lived this are still research grade assets. And so there's a high degree of variability in how they're performing. They need to be qualified, compared and validated so that we can go make informed decisions about the relative performance of vaccine.

However, the early data that's out there from the academic literature, mostly academic literature with very small sample numbers suggest that there is a two to threefold decrease for some of the most recent strains, BA.4, 5, in the level of neutralizing titers from BA.1. And so there is a chance that there's approximately two or threefold decrease we will have to test these samples and see.

Now the good news, I think, here is that the titers that we're achieving, for instance, in the all participants groups, the neutralizing titers we're achieving against Omicron are above 3,000. And 3,000 is a much larger number even than we were seeing against the ancestral strain out of the Phase III study 2 years ago, and it is fivefold higher as a reference point than the approximately 600, 700 that we were seeing after a third dose of 1273 against Omicron this past winter.

So we've got fivehold higher neutralizing titers, absolute number at 3,000. Even if you divide that by two to threefold, we think we're still going to be in a very comfortable place because of how high those neutralizing titers against ancestral Omicron or BA.1 are now.

And so for that reason, we're pretty confident that this vaccine is going to provide a benefit even against the family of Omicron variant subvariants. We're going to have to test in these research assays. But I think the most important question is what's available to the tune of hundreds of millions of doses to provide protection to those who need it this coming fall.

And I think that's where there's also a pragmatic factor that will have to come to play. We're going to be in a position to deliver very large volumes as Stephane said of Omicron updated vaccine, a vaccine that we know can produce. As I said a moment ago, fivefold higher titers than the third dose levels up to 3,000 and that has much more room to give in terms of dealing with the evolving virus throughout the potential fall.

And we think that's the right path. I mean, this is a clearly superior booster statistically significantly so, including against Omicron, and we think the right path is deploy this booster to give us the best immunity chance we have.

Now if we -- you asked a question about regulatory path, if there's a call for updating it. There is definitely, I think, going to be an evolution we expect in how SARS-CoV-2 seasonal vaccines are handled. As you know well, as we all know, in the case of flu, another respiratory virus that's seasonal.

There's generally a strain recommendation made. It tends to be made early in the year, sort of February, March time horizon for the coming fall. And data is not -- you do not need to develop the kinds of data that we've developed here in every case. In this case, -- this is -- we've gone and done by no vaccines for a while. This is the second time we've been able to demonstrate superiority. We do believe the bivalent provides better breadth and durability because of the diversity of antigen it's presenting. And so we've shown that with our prior beta containing bivalent 211.

And so we're quite -- we do believe that the data started to pull together across our clinical trials that would support more of a flu-like model, where you just select a strain and then rapidly update the manufacturing and do some parallel testing but ultimately roll forward without having to run these sort of pivotal superiority studies.

Whether that is going to be in play for this fall, which is the kind of the subject to your question, Matt, I do not know. That's a question for regulators. That will be a big step forward in terms of our ability to rapidly deploy new vaccines. And given the strength of our M&A platform, we think we will be pretty well positioned to provide those updates very quickly.

But for now, we're working on the established regulatory guidance for what it takes to update the vaccine sequence. And that regulatory guidance calls for demonstrating superiority against the variants of concern, and that's what we did here.

And so for now, we're going to -- this is the regulatory framework we're working in. Obviously, if there's opportunities to speed things up in the future, we will.

And the second question you asked was about durability. And thank you for making that point. We have achieved superiority at 1 month, day 29 here. Now we're going to continue to follow these participants and so we'll see whether that superiority is still -- is better or the same at 3 months, day 90 and at 6 months day 181.

The real goal is to get to that 6 to 9 months the duration of protection, which gets you through the whole respiratory virus season, right? I mean, we'd love even longer than that, but really what we need to get to is something that protect us from October to April in the Northern Hemisphere.

And the data we have from our prior bivalent vaccine, which we've obviously presented and is publicly available also published. The bivalent vaccine for 211 showed better durability at 6 months against the included beta variant concern. And so we have good reason for optimism based on that data to suggest that actually we think that the bivalent Omicron-containing vaccine here or 214, is going to have better durability at 6 months. And that what we're seeing is this 1 month peak titers, while it's really encouraging and already is better, that some of that gap will even widen as time plays out.

Now we need to develop the data to see that and no but it will -- it is based on that prior experience, that published data on our bivalent platform that we're actually pretty confident that this Omicron-containing bivalent will provide protection through the season and that's of course, the virus does as a new curve and that we will see good durability for those who are boosted in September, October that can last against Omicron for the better part of the winter.

Operator

Our next question coming from the line of Michael Yee with Jefferies.

Unidentified Analyst

This is (inaudible) on for Michael Yee. Can you hear me okay?

Stephen Hoge - *Moderna, Inc. - President*

Yes.

Unidentified Analyst

So this is excellent data as we head into the kind of the fall boosting season. I had 1 or 2 questions. My first question being Modena has submitted for approval for a wild-type vaccine for the pediatric population under 5. What plans do you have to develop a vaccine that's going to be Omicron based or bivalent based for the pediatric population? Because it seems like 1 part of the population is going to get the wild-type vaccine, which is the peds population and the other population, which is the adult seems to be getting this newer booster dose. So can you kind of give us some insight into that?

Stephen Hoge - *Moderna, Inc. - President*

That's a great question. And so again, it's 1 that is beyond Moderna's control, it's really a question for, first and foremost, for regulators and the public health officials, how they will deal, how we will deal with this. As a starting point, you're correct. We submitted for pediatric authorization. There will be a VERPAC next week as has been previously disclosed. And we'll be discussing our prototype vaccine in that context, the basis approval of the prototype vaccine is based on comparison to its prior performance against other prototype. And that's something that, as we've said before, we're very confident that we've met those criteria, and we'll go forward.

We are -- it's obvious, though, that the viruses have all in the last 2 to 3 years, and we need to update the vaccine. In this case, we're talking about a booster for adults. But we are going to go study a booster dose for Omicron containing bivalence in 214, in the pediatric population as well, including the population in our clinical studies. And so we are going to go evaluate the booster in that population to try and demonstrate there's an advantage there as well. And obviously, we want to characterize the safety profile of that.

We were also in the pediatric population in that study trying to looking at a primary series and so we have patients in our under 5 studies who have received placebo, and we have an opportunity to cross them over and give them a bivalent vaccine. And so we're going to be looking at how they perform with Omicron. And that will be our responsibility as a developer to create that data.

But there's a more general question, which you could ask, which I think is really for regulators and public health officials to decide, which is, does it just make sense to update the vaccine broadly, including primary series for young children, once we have an approval of an updated sequence, for instance this Omicron-containing bivalent 214.

And that is actually precedented. If you think about it, that's what happens with the flu vaccine every year. So seronegative kids, who've not previously gotten a flu vaccine, get 2 doses of a flu vaccine, and they don't get the vaccine from 10 years ago or 5 years ago or 2 years ago, they get the vaccine from today. And that model is a model that we think will ultimately be the right model for how we address SARS-CoV-2 as a seasonal virus as we come to live with it much like flu.

But the question of when folks are comfortable, particularly regulators and public health officials, are comfortable switching over to that model is really for them, not for us. We will develop the data through clinical trials that provide confidence we can do that. And I personally believe that the

data we've already developed across these booster vaccines provides a high degree of confidence that it probably is appropriate to just update the sequence of the vaccine broadly, they are performing as we would expect.

The safety profile is consistent and the immunogenicity against the variance of concern is superior when you better match the sequence of what's actually circulating. And so I hope that happens sooner rather than later. But obviously, that's for public health officials [student] side.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Paul, do you want to add anything.

Paul Burton - *Moderna, Inc. - Chief Medical Officer*

Yes. No, Stephane. So look, just on the charging because I think it's a very important point. Clearly, these youngest kids are unprotected. There's no other option for them today. And caregivers, moms and dads clearly want to get their kids protected. They also act as a reservoir rate for potential transmission vector to older adults. As we've talked to those people, and we've talked to population health decision makers, I think what's become clear with the data that Stephen alluded to, very strong safety data, which is so important, obviously, to parents, caregivers, physicians, excellent antibody data, too. So we believe that our 2-shot regimen here, which is simple, easy, very protective is important now, if authorized, to get those kids vaccinated so that they can get through the summer and then get back to school protected.

We think this will be a very important part of the armamentarium in our fight against this virus in those young gist kids because it will give that simple solution. So we think if authorized get those kids vaccinated now. And then as Stephen says, we can think about updating booster strategies in the latter part of the year. But this will be a quick, simple, safe way to protect those children.

Unidentified Analyst

Got you. Okay. So just to kind of capture all that, basically, what you're saying is that there is precedent according to the flu vaccine that once you do kind of your efficacy study in the booster Omicron-based booster website, you don't need to do another efficacy study every year for each different variant that comes out. Is that correct?

Stephen Hoge - *Moderna, Inc. - President*

That's correct in the flu precedent. Again, subject to regulators deciding that we're at that state with -- we do.

Unidentified Analyst

Right. So my next question then comes when can we expect kind of updated data or some sort of catalyst for that pediatric Omicron or bivalent boosting dose?

Stephen Hoge - *Moderna, Inc. - President*

So those studies are just starting now. Obviously, we waited until we had the superior data here with 214 to initiate them. And we're -- we don't have timing on when those when those will read out. I also think it's important that before we go too far down the path of deciding that data is necessary, we do need to hear from regulators, including the FDA and VERPAC next week as to whether or not they believe that's necessary or whether they're or not we've already cross that threshold such that we should really be updating the vaccine for children as well.

And so those are important questions over the next, I'd say, 2 weeks that will be answered that will then determine the size of the studies we need to run and when or whether we need to run them. And I think that we should wait until we have those answers before we start sort of specifically planning for when we'll have data on an update of vaccine for pediatrics because it may not be necessary.

Unidentified Analyst

Got you. Got you. Okay. And just a broad-based question. It was noted, I think, in a press release either earlier this week or at the end of last week that countries that have ordered doses will be eligible for the new bivalent Omicron boost. So there's actually going to be a one-for-one exchange if they have 1273 boosts left over, they can send it back to Moderna and Moderna will send an updated booster dose. Is that accurate?

Stephane Bancel - *Moderna, Inc. - CEO & Director*

This is Stephane. So this is not accurate. What we announced last week is an agreement with the European Union to delay some of the Q2 shipment of 1273 into Q3 for shipment of 214. So it is not getting vaccine back. It is shipping products that is of a newer version, which makes sense to protect people.

Unidentified Analyst

I see. Okay. So they ordered 1273, however, that is no longer -- that's still only going to happen. They're going to get to Omicron or bivalent boost in Q3, Q4 instead of the orders for wild type.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

Correct. Exactly. That's what -- as you can imagine, help ministers want from a public standpoint to protect people. And given for us, it's the same as total. As Stephen explained, of 50 microgram, 25 of 1273, 25 of 529 of Omicron containing mRNA. So what we want to do is to be a partner of choice to the government...

Lavina Talukdar - *Moderna, Inc. - Senior VP & Head of IR*

Okay. We will take our last question. Olivia, can you please queue for the last question.

Operator

Last question coming from the line of Cory Kasimov with JPMorgan.

Cory William Kasimov - *JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst*

I actually have two of them for you. First, can you clarify the comments on superiority versus non-inferiority in the study and getting some investor questions where there's some confusion. -- if it's a statistically significant superior result or numerically superior. So any clarity there could help.

And then my other question is, do these results impact how you think about the potential privatization of the U.S. market this fall? Was the government waiting to see these data prior to determining a path forward? Or is that more driven by the evolution of the virus and pandemic itself?

Stephen Hoge - *Moderna, Inc. - President*

I'll let Stephane take the second half with Paul. But first on the superiority. Unequivocally, these are statistically significantly superior for Omicron and the ancestral strain. And so I think if I was confusing in my framing of that, we tested noninferiority, and then we tested superiority. But in terms of neutralizing antibody titers, the primary endpoint for a demonstration superiority, we were significantly superior against Omicron. And incidentally significant against the ancestral strains, although that's not of a substantial importance.

The only place where I might have confused a little bit is in describing the seroresponse rate. Seroresponse rate is just the number of people who had a response, people have a response even to the prototype vaccine. So it's near 100% in both cases. We were not specifically trying to demonstrate superiority there ever. That was not something that was an objective nor is it necessary to demonstrate superiority there. So Unequivocally, the results are significantly superior on neutralizing titers against Omicron, which is the primary endpoint for demonstrating superiority against that or any concern that was established with regulators.

Stephane Bancel - *Moderna, Inc. - CEO & Director*

And Cory, Stephane, for the second question. So I don't think this has anything to do with prioritization. It is relied to funding from Congress. As you can imagine, we have shared with the U.S. government and the regulators, of course, but all the key public health leaders in the U.S. government, the 211 data when we had it, as you remember, a couple of months ago.

And of course we have been sharing that data. I think the opinion in the U.S. has been exactly the same thing we've heard outside the U.S., which is as we proceed the data, they are very interested to get this product bivalent versus the ancestral vaccine. But the prioritization from me is really driven by the funding in Congress.

Operator

Thank you. I will now turn the call back over to Mr. Stephen Hoge for any closing remarks.

Stephen Hoge - *Moderna, Inc. - President*

Thank you, operator. Well, thank you all for joining and listening. I think we believe the data unequivocally shows the bivalent Omicron-containing booster is significantly superior in terms of neutralizing protection it more accurately reflects the circulating strength and the data clearly shows it's time to update the vaccine that we can improve the durability of protection, the magnitude of protections that's coming into the fall.

We look forward to seeing with regulators -- thank you all for taking time this morning to review it with us, and have a good morning and good afternoon.

Operator

Ladies and gentlemen, that conclude our conference for today. Thank you for your participation. You may now disconnect.