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EDITED TRANSCRIPT

MRNA.OQ - Moderna Inc hMPV+PIV3 Interim Data Conference Call

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Moderna hMPV and PIV3 Interim Data Conference Call. (Operator Instructions) As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's conference, Ms. Laura Schneck, Investor Relations at Moderna. Ma'am, you may begin.

Laura Schneck - *Moderna Therapeutics - IR, Associate Director*

Thank you, operator. Good afternoon, everyone, and thank you for joining us today to review the top-line interim clinical data from our Phase 1 study of mRNA-1653, our human metapneumovirus or hMPV and parainfluenza virus type 3 or PIV3 vaccine. You can access the press release for these data and the slides that we'll be reviewing by the going to the Investor section of our website at www.modernatx.com.

With me today are Stephane Bancel, our Chief Executive Officer; and Tal Zaks, our Chief Medical Officer. Lorence Kim, our Chief Financial Officer, is also here and will join us for Q&A

Before we begin, I would like to remind you that today's discussion would include forward-looking statements based on our current expectations relating to among other things the future clinical development of mRNA-1653 and its ability to protect against hMPV and PIV3. These forward-looking statements are neither promises nor guarantees and are subject to a high degree of uncertainty and risks.

Please see the press release issued today 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 the forward-looking statements. We undertake no obligation to update or revise the information provided on this call as a result of new information or future results or development.

With that, let me pass the call over to Stephane.

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Stephane Bancel - *Moderna Therapeutics - CEO*

Thank you, Laura. Good afternoon, everyone and thank you for joining us today. We are pleased to have the opportunity to review the positive interim data from our Phase 1 study of mRNA-1653 we have gathered. This mRNA vaccine candidate was designed to prevent respiratory diseases associated with hMPV and PIV3 infections, and this one is wholly-owned by Moderna.

This vaccine candidate consists of two distinct mRNA molecules encoding for key antigens of hMPV and PIV3 viruses. The interim Phase 1 data suggest that in healthy adults a single mRNA-1653 vaccination is sufficient to boost serum neutralization titers against both hMPV and PIV3 at all dose level tested, and that vaccination was generally well-tolerated.

As such, [there who are] growing existing body of clinical data with Moderna mRNA-based prophylactic vaccines and it provides support for our respiratory vaccine strategy. Importantly, the data also provide validation of the ability of [platform] to successfully combine mRNAs that include proteins from multiple pathogens into a single vaccine and with a potential to protect against substantial burden of a respiratory disease.

I'll now turn over to Tal to review these data in more detail.

Tal Zaks - *Moderna Therapeutics - CMO*

Thank you, Stephane, and good afternoon everybody. First, I'd like to comment on our prophylactic vaccines modality a bit more broadly. We designed this modality to prevent or control infectious disease. It includes programs for both commercial and global health uses. The goal with any of our vaccines is to safely pre-expose the immune system to a small quantity of a protein from a pathogen and antigen, so that the immune system is prepared to fight the pathogen if and when exposed in the future and thereby preventing infection or disease.

Much of our commercial vaccine work is focused on addressing major causes of respiratory infections including respiratory syncytial virus or RSV and human metapneumovirus and parainfluenza virus 3 or the hMPV and PIV3 combination. Now these infections show many of the same clinical features often causing upper and lower respiratory tract illnesses characterized by wheezing, bronchiolitis and pneumonia. Infection with hMPV or PIV3 is associated with a substantial burden of hospitalization and outpatient visits among children within the first five years of life.

Notably, there are currently no approved vaccines for either RSV, hMPV or PIV3. With the mRNA-1653 data announced today on top of the prior clinical data on our RSV vaccine, we have now shown that we're able to create potentially effective vaccines against several respiratory viruses, suggesting we have the opportunity to prevent respiratory illnesses in healthy individuals who are exposed to these pathogens.

As a reminder, although RSV, hMPV and PIV3 share common clinical manifestations, we are addressing them with two separate vaccines that are aimed at different initial target population. For RSV in collaboration with Merck, we are developing mRNA-1777 as a vaccine for use in older adults. Each year the United States alone, more than 177,000 older adults are hospitalized due to RSV-associated respiratory infections and as I mentioned a moment ago, there is no vaccine approved for use to prevent this disease.

We have previously disclosed Phase 1 data indicating that the MRNA-1777 was well-tolerated at three-dose levels in both younger and older adults with no treatment related serious adverse events. Moreover, we have seen promising immunogenicity data with neutralizing antibody titers observed in both healthy younger and older adults. Based on these results, Merck has initiated plans for a Phase 2a trial for which they will serve as the sponsor.

Separately, we are independently advancing mRNA-1653 as a vaccine against hMPV and PIV3 for use in the pediatric populations. hMPV is one of the most frequent causes of upper and lower respiratory tract infection and it's associated with an estimated 1 billion outpatient clinic visits in the U.S. and more than 250,000 emergency department visits annually among children less than 5 years of age.

Of the four PIV types identified, we're focusing on PIV3 that is the most common cause of respiratory infection and appears to lead to more serious lower respiratory tract infections. The combined hospitalization rates of hMPV and PIV3 in children in this age group is roughly two-thirds that of

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RSV. So part of the rationale for a combination vaccine against hMPV and PIV3 is that they present with the same clinical symptoms, and a physician like myself cannot distinguish the two baseline clinical features when a child shows up at the emergency room.

In recent years, awareness of hospitalizations due to either hMPV or PIV3 infections have risen with hospital admission rates highest among children under 2 years of age. We believe this creates a significant opportunity to vaccinate infants against both infections. So, we're excited to be advancing mRNA-1653 as the first combination vaccine to focus on both viruses together.

We designed mRNA-1653 as a single vaccine consistent of two distinct mRNA sequences that encode the membrane F proteins of hMPV and PIV3, co-formulated in our proprietary lipid nanoparticle technology. As with all of our vaccine programs, we started by identifying the antigens most likely [in use] the protective immune response and then tested these animals in multiple animal models.

We were pleased to see that the immunogenicity we observed in the animal models translated into humans in the current study as has been the case with four of the five other vaccines for which we already have Phase 1 data. As an example, here in the preclinical study shown, we demonstrated that mRNA-1653 induced a humoral immune response in mice. These mice were immunized twice with the mRNA-1653 vaccine and we were able to detect antibodies in the serum that neutralized or blocked hMPV and PIV3 infection of the cells.

Neutralizing antibodies are thought to be important for protection against both viruses. In addition, we've also shown that our hMPV, PIV3 vaccine can protect both cotton rats and nonhuman primate for hMPV and PIV3 infection as measured by reduction in detectible viruses in their lungs.

So based on these and other preclinical data, we advanced mRNA-1653 into this first-in-human study this as a randomized, observer-blind, placebo-controlled study to evaluate the safety reactogenicity and immunogenicity of the vaccine in 124 healthy adults.

The study is being conducted in two phases, first the dose escalation phase designed to evaluate four-dose levels of mRNA-1653, mainly 25, 75, 150 and 300 micrograms in five subjects each per cohort. And then, followed by dose selection phase with 26 subjects per dose level cohort. Subjects in the dose selection phase were randomized to receive either a single vaccination of mRNA-1653 or two vaccinations one month apart.

Because these are healthy adults, they have been previously exposed to these viruses and so we do not expect the second dose to substantially boost antibody titers. But it was included in the study design to assess the safety in preparation for eventually testing this vaccine in children and infants, which we expect to require two doses as they will be naive to the virus.

The objectives of the study include evaluating the safety and humoral immunogenicity of mRNA-1653 through 12 months after the last vaccination and selecting a dose in vaccination schedule for further clinical development.

So, today, we are pleased to announce the positive top-line data from the first planned interim analysis of all subjects through two months, which is one month after the second vaccination.

So, let me start with safety and tolerability. mRNA-1653 to date appears to be generally well-tolerated on the basis of this interim analysis with no serious adverse events, no adverse events of special interest and no adverse events leading to withdrawal reported. Injection site pain was the most common reported adverse event and is the most common grade 3 adverse events.

The immunogenicity data showed that a single mRNA-1653 vaccination boosted serum neutralization titers against both hMPV and PIV3 and that the magnitude of the boost was similar at all dose levels tested. Consistent with the prior exposure to hMPV and PIV3, all study participants had neutralizing antibodies against both viruses at baseline.

One month after a single mRNA-1653 vaccination, the hMPV neutralization titers were approximately six-fold out of baseline. While at the same time, the PIV neutralization titers rose to approximately three-fold out of baseline. In both instances, the fold increases are based on geometric mean ratios as is common in these types of studies.

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A second mRNA-1653 vaccination done a month after the first vaccination did not boost antibody titers further suggesting that a single vaccination maybe sufficient to achieve a plateau of neutralizing antibodies in this pre-exposed population. We expect to present these data in a full format in upcoming conference and we plan to advance mRNA-1653 into a Phase 1b study in seropositive pediatric patients.

Now this study would be designed to assess the safety and immunogenicity in children as part of the standard vaccine development program where our target population will be healthy infants. Additionally, we will be following the subjects in the healthy adult study for a full-year after vaccination and we'll publish the complete results at such a time.

Let me now hand it over back to Stephane.

Stephane Bancel - *Moderna Therapeutics - CEO*

Thank you, Tal. As you can imagine, we are excited about these interim data both in terms of what it means, what is important vaccine candidates and for our broader portfolio. We have now dosed 945 subjects across several infectious disease vaccine program in Phase 1. We repeatedly have seen consistent results. Safety and immunogenicity profile have support further clinical development and potentially has [achieved] targets product profiles.

For (inaudible) public health programs where [code] of protection is known, 96% of subjects in Phase 1 trial of mRNA-1851, the vaccine against H7 influenza and 100% of subjects in Phase 1 of mRNA-1440, a vaccine against H10 influenza, (inaudible) [delivers]. For the programs where immunological correlates are not known, we achieved multiple [14] (inaudible) in neutralizing antibody titers over baseline.

So this is data from hMPV and PIV3 program, are particularly meaningful given this is our first prophylactic vaccine without -- from a program using our proprietary lipid nanoparticle formulation. We developed these formulations specifically for intramuscular delivery of mRNA molecules.

We have other programs of [vaccine] well in this (inaudible). For instance, we look forward to presenting the interim results of our Phase 1 cytomegalovirus vaccine study which is progressing well in our [month]. [Continuous] CMV infection is a major cause of birth defect in this country and a significant unmet medical need. Our CMV vaccine is another wholly-owned Moderna program in our proprietary lipid nanoparticle formulation.

Of note, for those of you interested in our lipid formulation, we published a few weeks ago in Molecular Therapy a new scientific paper about this novel vaccine formulation and you can find the link on our website.

Taking a step back, I'd like to highlight the diversity of targets in the vaccine portfolio which speaks to the power of Moderna's mRNA platform. In this modality, we started with single membrane-bound antigens like influenza H10, H7 and RSV. Once we have confidence in our ability to elicit an immune response against those single membrane-bound antigens in clinical trials, we move on to more complex programs.

Chikungunya and Zika are virus-like particles antigen or VLPs, [they're] most self-assembled in human cells and then it's secreted from the cells in order to be presented to the humoral immune system. And as we discussed today, hMPV and PIV is a combination of two membrane-bound antigen.

Even more complex is CMV. This is a vaccine combining six mRNAs, five anchored pentamer, a membrane-bound protein with five subunits and one anchored, [the gB], another membrane-bound antigen. We have demonstrated the ability to layer our technical competency within the modality and will expand to other [modalities].

The hMPV, PIV3 interim data will present another step forward to demonstrate what Moderna mRNA platform can do and [then a single relief] in an entirely new class for medicines.

With that, we'd like now to open the call for Q&A.

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QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions)

Our first question comes from Matthew Harrison with Morgan Stanley. Your line is now open.

Matthew Harrison - *Morgan Stanley - Analyst*

Good afternoon. Thanks for taking the question. I guess -- I guess two for me, can you first discuss, do you need to step down through a young adult population and then into a pediatric or an infant population before you move into Phase 2 or can you move directly to infants in the Phase 1b?

And then second, can you just talk about the titer levels that you saw in adults and what we should expect in terms of translation into infants or do you think you can just pick a single dose to move into the Phase 1b? Thanks.

Tal Zaks - *Moderna Therapeutics - CMO*

Thank you for that, this is Tal Zaks. So the -- we're going to have to do the age de-escalation as is routinely done in this type of vaccine. So, we expect now to go down through the age cohorts until we get to the infants and we have to step through seropositives to demonstrate safety before we go into seronegative population. So, I think we expect to follow the traditional paradigm here.

In terms of -- your second question was around the dose. I don't think we can extrapolate from the dose in the seropositives who had been previously exposed to what it's going to take to immunize naive subjects. So for us, we had a pretty wide range of doses that we studied to ensure we can go in with the appropriate dose ranging ultimately when we end up at the target patient or subject population here of seronegatives. And so in that regard being able to describe the safety across this cohort I think is very helpful for further development and in getting confidence that indeed we are immunogenic against both viruses despite the fact that people have a preexisting immunity I think was helpful to show.

Matthew Harrison - *Morgan Stanley - Analyst*

Okay. Tal, can I just ask you to tell us what the age de-escalation procedure is because some of us are not as familiar with certain vaccines? Thanks.

Tal Zaks - *Moderna Therapeutics - CMO*

So, I don't want to commit to specifics. I think that ahead of us, we'll also going to have make sure we get full regulatory buy in to that. But you can look at typical paradigms of what others have done, so you basically define the different age cohorts and you go and expose them sequentially to define safety.

Operator

Thank you. Our next question comes from Salveen Richter with Goldman Sachs. Your line is now open.

Ross Weinreb - *Goldman Sachs - Analyst*

Hi, thanks for taking the question. This is Ross on for Salveen. Just in terms of the trial design for the Phase 1b study, can you describe the patient population? I know you said that you won't be able to commit to patient age, if you can give some more color around the dosing, the treatment

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-- the dosing schedule. And then secondly, given the -- in terms of durability, do you expect this to be a two-dose vaccine and that's it or would this be a yearly boost post those two vaccinations?

Tal Zaks - *Moderna Therapeutics - CMO*

So, let me answer the second question first. I think that the schedule is ahead of us, so I think it's too early to comment. Typically in naive subjects, you get additional protection from a booster shots and most vaccines have at least one and sometimes two boosters. Since the -- most of the morbidity in the pediatric age group is before the age of 5 and indeed even younger than that, then I think a single immunization series we expect will protect throughout childhood, but that's ahead of us to prove.

In terms of the current trial design, these were adults. As typical in the study, adults is 18 to 49. The vaccination routine was a single intramuscular injection or two intramuscular injections followed by typical observation period and solicitation of adverse events.

Ross Weinreb - *Goldman Sachs - Analyst*

Great. And then just lastly, over the next 6 to 12 months, what additional datasets can we see from the other modalities outside of prophylactic vaccines?

Lorence Kim - *Moderna Therapeutics - CFO*

Hey, Ross, it's Lorence. So, we're not guiding on that at this time. This has been consistently [their] practice during the -- during the [IPO].

Operator

Thank you. Our next question comes from Cory Kasimov with J.P. Morgan. Your line is now open.

Cory Kasimov - *J.P. Morgan - Analyst*

Hey, good afternoon guys. Thanks for taking my question. A couple for me as well. So first of all, were you expecting to see similar titers at all dose levels tested in the Phase 1? I'm wondering how this is similar, different to other prophylactic mRNA vaccines you've tested. And then second question I have is, I'm curious whether you saw a dose response on the safety front at all?

Tal Zaks - *Moderna Therapeutics - CMO*

So the way I characterized it is yes, I expected to see some dose response [proven]. It seems that we have a very potent vaccine and that we hit the plateau very early on.

In terms of safety, I think we're still looking through the data. This is just an interim analysis. I'd say overall, the safety profile we see is consistent across the doses. There maybe a slight dose response curve to the safety profile but I think it's too early to give you the full discretion on that. This is the first interim look and we'll be combing through it with a lot of secondary analysis and eventually presenting this at a medical meeting.

I think the important thing to state here is that all the way up to 300, includes above 300, we didn't see anything unexpected. What we see is a safety profile consistent with that of other approved and marketed [adjuvanted] vaccines and the safety profile we see is consistent with that which we've seen in our prior Phase 1 experience across the board.

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Operator

Thank you. Our next question comes from Ying Wang with Bank of America. Your line is now open.

Ying Wang - *Bank of America - Analyst*

Hi, thanks for taking my questions as well. So first of all, given the lack of dose response and can you talk about how you decide to select the dose moving into the Phase 1b and then later Phase 2 trials? Secondly, can you give us some color on what kind of therapeutic threshold you need to reach in terms of the titer?

Tal Zaks - *Moderna Therapeutics - CMO*

Yes, so both excellent questions. I can't comment yet on the dose selection for the Phase 1b because I don't think we've fully made that decision yet, so that's still ahead of us. Of course, we'll take a look at that. Remember that the goal of the Phase 1b is still to bracket the sufficiently-wide safety margin to ensure that we can do the appropriate dose ranging studies ultimately in the seronegative infants. And there maybe a difference in both safety profile and immunogenicity between adults and pediatric population, so it's something that we need to explore.

And I apologize the second question was?

Ying Wang - *Bank of America - Analyst*

Yes, so I know there's no current treatment approved by FDA for this indication but what do you think you need to see in terms of titer?

Tal Zaks - *Moderna Therapeutics - CMO*

Yes. What do I need to achieve? Great question, nobody knows the answer to that. I wish I had a wiser answer to tell you. I think people generally look for sort of a fold increase over baseline to guide further development. The challenge with any respiratory virus vaccine that has not -- no approved one yet on the market is that you have no correlate of protection because nobody has ever been able to protect. And so nobody knows what a correlate of protection is which means you're developing your overall confidence that you have protective titers based on a lot of corollary inferences from other vaccines from the animal work that you have and ultimately we'll need to demonstrate that in an efficacy study. It's not a very reassuring answer, but that's true of every pioneer of a new vaccine and a new indication.

Operator

Thank you. And our next question comes from Geoff Meacham with Barclays. Your line is now open.

Unidentified Participant

Hey, this is Scott on for Geoff, maybe just some clarification here. So in the permanent outcome measures for the study it's -- one of them was the proportion of subjects with a four-fold increase in neutralizing antibodies and you guys obviously hit that with the six-fold in the hMPV. But how should we think about the three-fold increase in the PIV3? Thanks.

Tal Zaks - *Moderna Therapeutics - CMO*

So, there's a slightly different measures, so that gives you an overall description of the population. It doesn't give you the percent and the distribution within a dose who hit that four-fold increase. So, people typically look at a four-fold increase as something across the board in respiratory viruses and that's where it comes from.

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So it gives you the magnitude overall, if you will, that level of granularity of detail will require some additional secondary analysis that we're not ready yet to share, it's still work ongoing.

So, I'm giving you the overall picture of the entire population for [these]. You're asking a granular picture of how is the behavior within that population and I think we'll share that as part of sharing the full data.

At a high level, I'll just state that I'm pleased with the results that we see and it's consistent with expectations. Recall that these subjects are all pre-exposed and obviously all had baseline serum to a varying degree, baseline immunogenicity to varying degree against both viruses.

Operator

Thank you. (Operator Instructions)

Our next question comes from Ted Tenthoff with Piper Jaffray. Your line is now open.

Ted Tenthoff - *Piper Jaffray - Analyst*

Great, thank you very much. Congratulations on the update on a growing body of [evidence of] mRNA vaccines therapeutics. So quick question, when it comes to ultimately registrational endpoints, would you be required to show a study that is actually demonstrating protection or would this be something where you think actually neutralizing antibody levels could be recognized as a surrogate or a tolerated approval endpoint?

Tal Zaks - *Moderna Therapeutics - CMO*

It's a good question. Those conversations are still ahead of us. I'll give you my expectation today which is since there is no vaccine on the market there today, there's no accepted correlate of protection, therefore, it will be very challenging to obtain accelerated approval based on that surrogate endpoint.

So today, my current expectation is that it will require demonstration of efficacy against infection or disease and I will say that you're -- this is just a first interim result. There's a lot of work ahead of us and obviously discussion with the experts and their regulatory authorities to define what those endpoints are going to look like.

Ted Tenthoff - *Piper Jaffray - Analyst*

It makes a lot of sense. And how large, I know it's again still early and maybe too early to consider, but how large do you think a potential pivotal study or registrational trial in [inference] might be? Thanks for taking the question.

Tal Zaks - *Moderna Therapeutics - CMO*

Yes, so I don't think we're ready to commit to that point at this stage. Registration trials are going to be a function of the magnitude of effect, the epidemiology and the safety database required to get a vaccine approved, those are all variables that are still off in the future. But I would expect our overall pivotal [paradigm] here to be consistent with that of previous vaccines.

Operator

Thank you, and I am showing no further questions at this time. I'd like to turn the call back over to Stephane Bancel for any closing remarks.

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Stephane Bancel - *Moderna Therapeutics - CEO*

Thank you, operator. In closing, I'd like to thank you all for the ongoing support and interest in Moderna. I also want to thank Moderna employee (inaudible) work [recently] to rapidly advance how many programs forward. And of course and finally, I know our entire team joins me in thanking the clinical investigators and all the healthy volunteers who have participated in this study. Have a nice evening and see you soon.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This does conclude your program and you may all disconnect. Everyone, have a great day.

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