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MRNA.OQ - Moderna Inc at Jefferies Healthcare Conference

EVENT DATE/TIME: JUNE 08, 2023 / 2:30PM GMT

OVERVIEW:

None

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PRESENTATION

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Very good. Well, thank you, everyone, for joining us on our next session up here. I think our next guest needs no introduction. He's the President of Moderna, Stephen Hoge. It's good to be here with you. We just came away from ASCO. So there's some cancer topics to discuss. I'm sure the audience would love to start off with some of the respiratory disease updates.

QUESTIONS AND ANSWERS

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

And so maybe it would be a great place to start would be sort of your sense or Moderna sense of the state of affairs with where we are with COVID. You have guidance for COVID vaccine revenues this year. Market is a bit uncertain about that. We got RSV, and we'll talk about other stuff and also oncology.

So why don't we just start off with COVID? There's guidance. What is Moderna's sense of the state of affairs with COVID this year and your confidence around guidance and where we're going with COVID vaccines?

Stephen Hoge - *Moderna, Inc. - President*

Yes. So first, again, thank you. It's a privilege to be here. It's always fun to sit with you. I'm sure the questions are going to be great and challenging.

I -- so let me start with the COVID bit. As you said, so we haven't actually issued explicit total revenue guidance, as you know. We've said that we have approximately $5 billion worth of signed agreements for delivery this year. And we haven't revised that up or down. We've said that pretty consistently since late last year. And that really represents a floor.

The incremental sales that would come on top of delivering just those prepurchase agreements would come from the United States. It's obviously the largest market and as well as Europe or Japan, other markets. And so a lot of the focus right now, as you might imagine, is on those additional sales and pushing that number up. We -- the biggest market and the one to really talk about, obviously, in the United States. I think we, as our main competitor, continue to believe that's about a 100 million dose market in this country this coming fall...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Way higher than consensus by the way.

Stephen Hoge - *Moderna, Inc. - President*

Higher than consensus, but both Pfizer and us are saying the same. We get there because that's less than flu. And so it is less than flu in this country, but still, we think that there's going to be pretty strong recommendations this coming winter season for people who have protected against COVID.

And so the population of higher-risk individuals, whether that's from cancer or autoimmune disease or other things they have as well as those over the age of 65 is actually quite sizable in this country.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Can I ask a question on that?

Stephen Hoge - *Moderna, Inc. - President*

Yes, of course.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

So let's start with that because -- so you have guidance for the APAs, $5 billion. Those are contracts we'll assume that stays in place or some uncertainty about that. I know Europe sort of revised some of their stuff with Pfizer. But in terms of the upcoming announcements, you guys feel pretty confident that U.S. will engage in purchasing on a commercial basis. So I don't think that's a government contract per se. So what is your confidence on announcing something with U.S.? How would that work? How would the pricing work? And how does that go into revenue this year? So U.S...

Stephen Hoge - *Moderna, Inc. - President*

So great questions all. So the U.S. is a fully commercial market now at the end of the public health emergency. And so as you know, there's a set of contracts that you entered with certain integrated health delivery networks, but the majority of the volume will probably move through traditional channels like pharmacy, some doctor's office as well.

So you'll -- we're out negotiating with groups like the VA or some of the integrated large health networks around supply to those groups. And we're finding real appetite and demand. Obviously, they all want to procure supply to the updated vaccines. We expect within a week, actually next week at VRBPAC that the FDA will recommend that you update the vaccines to the current -- if they follow European -- the European example just this week to an XBB-containing variant. That will mean just like flu vaccines that all the existing supply is, therefore, obsolete for last year's flu vaccine.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

And they can't return that. That's like -- so if we do no XBB, which we're going to hear about like in a week or so, Moderna would contract to start shipping X amount of doses of XBB to the United States.

Stephen Hoge - *Moderna, Inc. - President*

Correct. And the difference here is...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Which is not in the guidance, of course, yes.

Stephen Hoge - *Moderna, Inc. - President*

That's correct, with the caveat being that in the United States, that shipment will no longer be just to 3 CDC government warehouses where they distribute it out but actually to pharmacist -- pharmacies to health systems. And so those are the contracts that everybody is engaging in right now.

If you take the last, last winter, which was a weird winter because a lot of people got COVID in the summer going in, and it was a fatigue winter. There was 50 million, 60 million doses that was administered in the United States of the COVID vaccines between us ourselves and Pfizer. And so at a minimum, you need to get some multiple of that into the channel so that those folks can show up and get a booster again.

We do believe there's going to be strong public health recommendations. We do believe that, that will come first from the FDA and then from the CDC and then from your providers and your provider networks because the truth of the matter is, we know if you're -- let's say, you're Medicare or Medicare Advantage plan or a hospital system, we know that you can prevent costs by administering COVID vaccine that year because the health benefits are sufficient. This is still third leading cause of death in this country. It caused a huge amount of hospitalization, caused a huge amount of health care costs. And so there's going to be, we believe, a pretty strong -- not longer from the central government in the same way but actually pulling through from payers and providers, a demand for the vaccine.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Let me quantify that. So you're estimating 50 million to 60 million jabs in the sort of second half of last year as a proxy for this year going in, right?

Stephen Hoge - *Moderna, Inc. - President*

Because that was a time where you're facing the Omicron surges BA.4, 5, and there were at least that many in not quite so many...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Let me -- so 50 million to 60 million, and how did you guys get to 100 million because the 50 million to 60 million was done last year? I think there will be 100 million into the system into the channel.

Stephen Hoge - *Moderna, Inc. - President*

Yes. So there's -- we think 100 million will get used, so the channel might have a little bit more...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Does that include what already happened in the first half of the year?

Stephen Hoge - *Moderna, Inc. - President*

No, that's seasonal. So let me give you a sense of how we think about this. So last year was actually a pretty exceptional year because so much infection was happening. And so many people had received the spring booster, right? So a lot of people received their booster and recommendations in the spring, and they were only a few months out, and then there was a Omicron BA.4, BA.5 wave and the updated vaccine. So actually, we see that 50 million to 60 million dose number in the U.S. market from last year as a low ebb.

As you look forward and you say there's going to be strong recommendation language similar to what you see with flu, you might say, "Well, why not the flu number? That flu number is north of 150 million." And the answer there is, actually, we still think that this will be a little bit less than that

-- than the flu but not as low as last year. And you kind of get between 50 million and 150 million, and you kind of say, "Well, about 100 million." Now we've done more work than that. But we continue to have pretty high conviction that those high-risk populations are going to get strong recommendations. Those Medicare populations are going to get strong recommendations. That is substantially (inaudible).

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

So let's quantify that, and then we'll move on to the next topic. 50 million to 60 million last season was jabbed. The...

Stephen Hoge - *Moderna, Inc. - President*

U.S. number.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Yes, U.S., that you think it could be a multiple of that. That's how you got to 100 million. It's not formal guidance. It's just a guess. I mean...

Stephen Hoge - *Moderna, Inc. - President*

Market size. By the way, this is not Moderna...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

100 million, yes. 100 million, start with 50 million times a rough $100 price is $5 billion. That would be split between 2 companies. There was 100 million times $100. That's $10 billion split between a couple. (inaudible) so the -- do you think there will be billions, plural, to Moderna for this year?

Stephen Hoge - *Moderna, Inc. - President*

Absolutely. That's our intention.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Okay. All right.

Stephen Hoge - *Moderna, Inc. - President*

It's now subject to things we don't control. That's the expectation.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

The market thinks it's subject to how demand of jabs is going to be less this year than last year. So even though you said 50 million to 60 million, people feel that there's -- the urgency is less.

Stephen Hoge - *Moderna, Inc. - President*

Yes. I mean -- I think that's completely fair. I think we -- but we would say we actually think the number is going to start approaching the flu number over time, and we'll...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Yes. So I think the more relevant question is rather than just sort of guesstimating this year, which we walked through, 2024, do you think the same math applies to whatever degree that is, in the U.S. alone, 50 million to 100 million for 2024 and beyond every year and that the numbers outside the U.S. would mirror something around your APA guidance because you think those are something of recurring contracts? I would say the $5 billion is a mix of some deferments in today [or so]. Without getting into complication, it's a few billion from OUS and a few billion from U.S. That's a recurring tail every year.

Stephen Hoge - *Moderna, Inc. - President*

We have not specifically guided on a recurring revenue number, but I would agree with the logic you made out.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

The math. Right. Okay. Good. Okay. So that's that. We will see some of that play out. And the next announcement would be possibly some U.S. progress. Would that be the next thing people would hear about?

Stephen Hoge - *Moderna, Inc. - President*

So those are going to be -- the market [that's outside] -- quite differently in the U.S. is no longer like the government does a single contract. And so what you'll see us doing is -- we'll be doing deals with the channels and with the health systems. And I don't know if we will provide an update in the future on those specific things where we'll just look to perform financially over the next couple of quarters.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Here's an interesting question -- the last question, I promise, on COVID. So if you're going to announce -- and it's not -- you're going to be shipping into the channel, you're going to be booking that as revenues, for example, in the third quarter, it's into the channel. What happens if only half of the vaccines into the channel were shipped? Do you have to account for stuff getting shipped back or, hey, they purchased it -- it's a little bit of accounting thing because I don't want to see like "uh," and then it was a negative $1 billion the following year because you have to actually rebate that back.

Stephen Hoge - *Moderna, Inc. - President*

Yes. So first of all, you don't naturally -- it depends on the structure of relationship. There are situations where obviously, we don't get reimbursed, and therefore, it's not used until somebody gets injected in the arm. And so I think it's a more -- slightly more nuanced analysis -- and I would let you follow up with Lavina, but we're fully aware of it, and we would not want you to be surprised.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

That's a great question because normally drugs are booked generally as it's shipped in the channel. There's some accounting thing for it. But because this is a guesstimate based on the user stockpile limit, that's more of a guesstimate.

Stephen Hoge - *Moderna, Inc. - President*

And so our financial team and Lavina, we were fully aware, but we're going to try and avoid any surprises in that in how we report these numbers.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Okay. RSV. So this is something the team here at Jefferies, just a big global report. We have obviously a team covering GSK and Sanofi for the antibodies. And Pfizer, another analyst covers Pfizer. And so here we are here with Moderna with your high-end efficacy RSV vaccine. Two people are about to launch an RSV vaccine this year. What is your thought around the uptake and then how more Moderna will play for that in 2024? Because this could be billions of dollars for you according to the Jefferies report. What is your estimate?

Stephen Hoge - *Moderna, Inc. - President*

Yes. Well, look, I think we've come out and said, we see it as a very large market. If you look at the big 3, very round numbers, COVID, RSV and flu, they're all trending towards $10 billion, maybe more as health care burdens -- cost burdens. Don't forget that when you really want to get to those total addressable markets, you got to CAGR out the aging of populations, right? And populations are actually aging faster across all of these markets. Then population is growing, and then economies are growing. And so that's -- it could go up from there. I would just make it as a comment.

Now your question about how do we see that playing out. We see this as a huge opportunity. We're very proud of our product right now. I think there's a lot of good news in RSV. There -- we believe there will be 3 products in short order. And that's good news because this is a huge burden of disease and a lot of costs can be offset as we play in that market.

Now our own products, we're very pleased with the efficacy profile you mentioned. We're pleased with the safety and tolerability profile, which, to date, we have not seen the acute demyelinating events of concern that have been reported with some of the others. And the tolerability profile is, we think, quite strong.

And then the last bit is we like our presentation. We're moving towards single-dosage forms, prefilled syringes. We think that, that will also be really important as a large portion of the product in this country, which is the largest market, will likely go through the pharmacy channel. We'll have to see that as it plays out.

So the combination of things, we're actually really pleased with. We still have to file, and we're doing that shortly. And we have to get approved. And we will be 1 year behind the first 2. I think that's sort of the part of your question.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Well, it's a seasonal thing, not a cure, so it's not a race to get the first year.

Stephen Hoge - *Moderna, Inc. - President*

We believe it's a seasonal thing. There is some question out there in our minds and everybody's mind about, is it possible that the efficacy lasts 2 seasons? I don't know. Like literally, we don't -- nobody knows, and we'll follow the data in that. If it is, then maybe it's in every other year, or maybe people give the vaccine every year anyway because it's just easier for people to remember.

And so that will be a public health decision, not ours. But either way, to your point, launching a year late, if you know and believe as we do that there's going to be a regular recurring vaccination, boosting of older adults and high-risk adults across markets, we want to go and compete and when we think the product profile is really strong.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

So let's quantify some of that. So COVID, you said 50 million to 60 million just for the seasonal COVID in the U.S...

Stephen Hoge - *Moderna, Inc. - President*

That was last year in the United States.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Last year, and you short of put some numbers around 50 million to 100 million for this year for COVID...

Stephen Hoge - *Moderna, Inc. - President*

We think the market in the U.S. is going to be about 100 million doses, the market.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Okay. For RSV, we know that the elderly population in the U.S. is roughly 80 million (inaudible) this is mostly for elders. So 80 million is sort of the opportunity. If you do half of those people -- you probably think it's more than half, but if it's half, it's 40 million, right?

Stephen Hoge - *Moderna, Inc. - President*

We always wanted to be more than half. But the half, I agree that 80 million -- half of 80 million is 40 million.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Okay. So but you think it's more? So now that's -- there's your guy. So more than 40 million. How do you think about price? What is the COVID price ballpark? And what is the RSV price, presuming it's higher?

Stephen Hoge - *Moderna, Inc. - President*

So we haven't announced the list price on RSV. We don't have one. We are -- it would be premature. We're also waiting to see what Pfizer and GSK will do because that will obviously be important in the market to understand as well. We're not the only product there.

In the case of COVID, as we previously said, we're approximately $130 a dose as the list price. There are discounts, either the channel or individual payers that will happen around that. But I think if you look at what GSK and Pfizer have indicated in some of their health economic analysis and even some of their commentary, they're seeing price in that similar sort of range, $150. I'm just taking a rough -- somewhere between $100 and $200 of the numbers. And I think we're fully aware of that and would expect that although we have a very -- we really like our product profile, we'll also be cognizant of the competitive environment as well. So I think that's probably as much as I can say because that's as much as we have at this point because it's similar.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

So you think it's more than half, but 40 million to 50 million, then times $100 to $150, it's like $7 billion...

Stephen Hoge - *Moderna, Inc. - President*

You're trying to give me your revenue forecast up here with the...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

And then split that between 3 ways is sort of your thinking. Okay. I'm trying to do the sum of the parts here. All right so that's COVID. [I'm sorry].

Stephen Hoge - *Moderna, Inc. - President*

We see a very large recurring market, and we want to have a large share.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

And then third is flu in combination. So let me put these 3 together because flu, the market is very confused. The flu data came out. It wasn't statistically noninferior. It was very confusing for people on the B strain. People are like, okay, how do we do that because it's a market. Do you have a flu vaccine? Are you going to file something? And does that lead to a combo?

Stephen Hoge - *Moderna, Inc. - President*

Yes. So we are still running -- well, actually, we've enrolled and hope to read out flu this year. I won't say more because I don't think we've got it more on timing. A final Phase III study in flu an immunogenicity study that we believe, we hope or expect will answer the B question and resolve it.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

You're talking about the infection [setup].

Stephen Hoge - *Moderna, Inc. - President*

No. This is the P303 study. We've described it as the -- but this is the study that enrolled in the United States in the second quarter to look at immunogenicity in the B strains because...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

With the improved B strain, yes. Okay.

Stephen Hoge - *Moderna, Inc. - President*

With the improved B strains. But just to paint that picture for those who don't follow it that closely, we ran -- this is our third Phase III study that we've run -- a program that started 2 years ago, less than 2 years ago. So we were able to move incredibly quickly. In the first one, where we're pursuing accelerated approval, we ran into a surprising result on the B strains.

Now 99% of the disease is in the A strains, and so we weren't as focused on the B strains, but it was a bit of a hiccup because at the end of the day, it became a question we were going to have to address. We had run in parallel an efficacy study, 302, that read out and we shared at our Vaccines

Day, actually, we were good on the B strains, and we were superior in the As. And in that study, we didn't -- it was in the Northern Hemisphere. It was much larger. It was the populations we mean principally to commercialize the product in, but we didn't look at the B strains statistically because it was mostly an efficacy study.

So we're running this P303 study quickly to just plug that question. And then we would pursue, as we said before, approval out of that combination of those 3 studies because we have the answer, we hope, which is superiority on the As in terms of neutralizing titers, which is where we want the product to be, noninferiority on the Bs or better. We'll see what comes out of P303.

And our goal is to get that product launched next year. Now we haven't got the P303 data, and we haven't yet, therefore, been able to sit down with regulators and talk about that plan. But if everything went perfectly, our goal would be to launch that product next year.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

And what -- there are combination studies going on right now, like COVID-flu, RSV-COVID, [RSV-flu] and a triplet.

Stephen Hoge - *Moderna, Inc. - President*

It's like 5 or 6 combination vaccines (inaudible). That's correct.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

So all of those are going on. Will Wall Street hear about the results of these combination studies from immunogenicity standpoint and from a tolerability standpoint? I think Icosavax just put out some combination data. They showed the antibody levels. Are we going to see levels that say you can inject COVID and RSV in the same injection, the antibodies are just as high here it is, guys, see, we have a combination?

Stephen Hoge - *Moderna, Inc. - President*

Yes, yes. So we have previously shown that we can do combinations. The COVID, flu, RSV 3, and you pointed that we have almost every doublet. We've got a triplet, and we've got multiple generations of product, including our second-generation COVID vaccine, which will be refrigerator-stable. We've got that also in a combo study.

To the question on Wall Street. So the path forward on this, we're running a bunch of Phase I, Phase II studies to find the optimal combo product, first-generation combo product. The -- it's competitively quite important for us that we don't share too much as we're doing that. And so we've been pretty coy about releasing the early clinical results as we kind of identified the one that we want to take into a pivotal study.

That pivotal study will be a registrational study for the first-generation combo. It's not an efficacy study. So this is relatively small, maybe 3,000 people for a 6-month kind of study if it falls to previous precedent from an FDA perspective. No specific guidance I'm going to offer on that, again, for competitive reasons. But if that's the case, that's a pretty quick study. And as we move into a pivotal study with a leading formulation, we would obviously be transparent about that decision.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

2024 pivotal-type combination study, immunogenicity to antibody levels showing that the antibodies are comparable to your approved products, that would be a valid combination.

Stephen Hoge - *Moderna, Inc. - President*

Yes. So we've said that we expect to launch the first generation combo in 2025. That requires us to be [finishing] the study.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Finishing then filing in '24, and you're confident because everyone tells me, Mike, the reactogenicity, putting these 2 things together. They can't do it. They're knocked out for 3 days. No one is going to do that.

Stephen Hoge - *Moderna, Inc. - President*

Yes. We are...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

People think that.

Stephen Hoge - *Moderna, Inc. - President*

Well, I understand. I can't disagree with people's own thoughts. But...

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Tell me what you guys think, yes.

Stephen Hoge - *Moderna, Inc. - President*

Look, so I think that it's a little bit more nuanced than that, which is that for different populations, you generally don't see that reactogenicity, particularly the higher -- the older you get, you see much less reactogenicity than you do with younger populations.

So it's a -- who's having the thought? Where do you think about it? For high-risk populations, those that are immunocompromised. That is a large population, highest value. Actually, it's -- they really don't generally see as much. And then the different combinations of different things. Our RSV reactogenicity profile are -- was 1% grade 3s above placebo. So just contextually, I don't know what RSV is going to do to make that more difficult. It certainly seems like it's quite a favorable one.

So we are aware of those. One of the things we're looking at in the Phase I/IIs is the -- in the combinations is both, can we combine the [entrance], and we find the optimal formulation for different populations. I do not believe at this point, but we'll see. We'll have to prove it to everybody. I do not believe that reactogenicity is going to be limiting for the creation of [combination].

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

But everything you said is the -- I believe the people who are getting a lot of these are the older populations. And you just -- your point is not only do they need the highest efficacy stuff, they have the least reactogenicity because of their weakened immune system. So Pervein, the average 35-year-old for side effects is not the same as Pervein with a 75-year-old that's going to be taken this.

Stephen Hoge - *Moderna, Inc. - President*

Correct, which is where the most of the value is.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

They have lesser side effects.

Stephen Hoge - *Moderna, Inc. - President*

Most of the value is. And if you're delivering better efficacy, it's worth it. Remember, there is an adjuvenated flu vaccine that actually is in this country that's actually used for populations recommended preferentially actually.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

One last nuance too about that is I understand the whole competitive thing. Yes, Pfizer is doing flu-COVID combination. Their RSV is not mRNA. And so even though they talk about combination, the RSV, I don't know if they can mix that in the same injection. No, it wouldn't (inaudible) combination.

Stephen Hoge - *Moderna, Inc. - President*

The combination of proteins and lipid nanoparticles in a product, nobody has released any clinical data on that ever.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Yes. So an RSV combination is really a Moderna thing?

Stephen Hoge - *Moderna, Inc. - President*

We believe we're -- well, I believe that we're pretty uniquely positioned, we think, to put RSV in the product.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

I know I'm 1 minute over. On PCV, we just came out of ASCO. So you're going to have to summarize in 1 minute. ASCO had great PCV data in adjuvant melanoma, people like that's great data, awesome. Don't know what to do it the. Merck's is in the other room, and they say, we're going to run Phase III, see you in a couple of years is Wall Street thinking. What is the next step there? Do we have to wait a couple of years or you think we can file?

Stephen Hoge - *Moderna, Inc. - President*

I -- look, I think it's -- I think I'll try to be consistent. It is an evolving picture. If you saw the ASCO data, I know we spoke about it there. We are now seeing -- I don't think there's uncertainty in the benefit that's been seen in the DMFS curves. And again, that's a primary analysis of the alpha transferred to that secondary endpoint, and the hazard ratio is .34. The p-value is .006. That's distant metastasis free survival. So if you play the movie forward 6 months, as we had hoped, the data is maturing, and it's maturing more clearly towards a benefit for the INT for the combination.

I think the question is where are we in 6 months and 12 months? Because if that continues to happen, and as we do -- we're going to do a follow-up analysis, as you know, on 51 events, let's say that's at a median 3 years. And those hazard ratios continue to mature in that direction and the stats continue to go there. The question is, is there a residual equipoise or uncertainty about the benefit? Now the good news is there's not much uncertainty about the safety profile. This has a vaccine-like safety profile, like your COVID booster, and as was presented by the discussant -- the folks at ASCO, the investigators and discussant at ASCO, it's really not adding anything in terms of safety or tolerability concerns over KEYTRUDA. So benefit and risk are clarifying. In the meantime, our job is execute the Phase III. Get the Phase III enrolls. [It makes sense] for everybody.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

(inaudible) the agency, starting the Phase III, take the second cut that you will have later to (inaudible) 51 events. Hazard ratios are getting better. I hope that you and your partner, Merck can have a great discussion with the agency. Thank you.

Stephen Hoge - *Moderna, Inc. - President*

We will look forward to it.

Michael Jonathan Yee - *Jefferies LLC, Research Division - Equity Analyst*

Okay. Thank you guys very much for the update. Appreciate it. Thank you.

Stephen Hoge - *Moderna, Inc. - President*

Thank you.
