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PFE.N - Pfizer Inc to Review RSV Data Presented at ID Week Call

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's analyst and investor call to review RSV data and COVID vaccine commercial update. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chris Stevo, Senior Vice President and Chief Investor Relations Officer. Sir, please go ahead.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Chelsea, and our gratitude to all of you for joining us today.

We're very happy to be presenting some exciting RSV clinical data and provide you with an update on COVID-19.

Today, we'll be making forward-looking statements that are subject to substantial risks and uncertainties. And I'd just like to remind you that these forward-looking statements speak only as of the webcast original date, and we undertake no obligation to update or revise them in the future. You can find additional information and forward-looking statements in our SEC filings, including Forms 10-Q and 10-K, under the section labeled Risk Factors and Forward-Looking Information and factors that may affect future results.

Our agenda is as follows: first, I'm going to introduce our speakers, and then they're going to discuss the RSV RENOIR older adult Phase III data. After that, we'll talk about the commercial frameworks for the RSV vaccine and our U.S. COVID-19 vaccine, and then conclude with a Q&A session.

Now let me introduce you to today's speakers. We have Annaliesa Anderson, Senior Vice President and Chief Scientific Officer for Vaccine R&D; William Gruber, Senior Vice President of Clinical Vaccine R&D; and Angela Lukin, Global Primary Care and U.S. President.

So with that, let me turn it over to Lisa to begin.

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

Thank you, Chris, for the introduction. We are very excited to have the opportunity to discuss our progress in developing a vaccine to help prevent respiratory syncytial virus, which is also known as RSV today.

We can have the next slide, please. We're focused on 2 patient populations for our RSV vaccine candidate. Maternal vaccines provide an opportunity to potentially prevent disease in infants and babies in their first months of life. The global burden of RSV disease in infants under 6 months of age is over 6.5 million, leading to approximately 45,000 deaths each year.

Our maternal RSV candidate vaccine Phase III study is ongoing and expected to read out this year. We'll evaluate the ability of the investigational vaccine to reduce RSV-associated lower respiratory tract infection in infants from birth through 6 months of age.

RSV also has a high burden for older adults and, in the U.S. alone, is associated with approximately 14,000 deaths in adults, 65 years of age and older. We recently reported positive data from our RSV older adult vaccine candidates for both safety and production of RSV-associated lower respiratory tract illness.

We're very excited to have the discussion today with you about our Phase III trial and associated interim safety and efficacy analysis.

Our vaccine candidate contains 2 stabilized RSV prefusion F proteins. The F protein assists in 2 forms: prefusion and postfusion. Only the prefusion form on the virus combined to human airway cells resulting in the virus entering the cells where it can replicate causing illness.

Similar studies by the NIH found that prefusion structure of F and identified that the F protein constrained in this prefusion form is more immunogenic compared to the post-fusion form. This advance [broker deadlock] of over 50 years of RSV vaccine development, providing a potential path forward for a vaccine.

We built upon this observation to make a vaccine candidate comprised of 2 stabilized prefusion F proteins, one from RSV A and one from RSV B strains.

For the rest of the presentation, we shall refer to this vaccine candidate as RSV pre-F. In any clinical Phase I/II studies conducted in pregnant and nonpregnant adults 18 years and older, the vaccine enlisted high neutralizing titers for both RSV A and RSV B strains. We also demonstrated that in Phase I/II studies in older adults that the addition of adjuvants did not demonstrate a substantial benefit over the unadjuvanted vaccine. RSV pre-F is therefore unadjuvanted.

Next slide, please. Our discussion today will focus on reviewing the safety and efficacy data from the prespecified interim analysis from the Phase III study of our bivalent RSV vaccine candidate in older adults. The data from this pivotal study were presented earlier today at IDWeek by Dr. Edward Walsh from the University of Rochester Medical Center, a principal investigator for this Phase III study.

We also have had the opportunity to present this data to the Advisory Committee on Immunization Practices, also known as ACIP, earlier today.

Our older adult clinical development program has been comprehensive, including 6 studies that measured safety, immunogenicity and for the one that we'll discuss today, efficacy.

With that, it gives me great pleasure to turn it over to Dr. Bill Gruber, our Head of Clinical Vaccine Research and Development, who will describe the study and share the detailed results. We can go to the next slide.

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

Yes. So thank you, Lisa. It's great to be here today.

I'm proud to share detailed safety and efficacy results from the prespecified interim analysis of the RENOIR study, a Phase III study to evaluate the efficacy, immunogenicity and safety of respiratory syncytial virus prefusion F subunit vaccine in adults. Next slide, please.

As we look at the study design, the RENOIR study is being conducted at 240 sites in 7 countries, including the United States. The study is targeted to enroll up to 40,000 participants, 60 years of age and older. Participants are randomized 1:1 to receive either RSV pre-F or placebo, and randomization is stratified by age.

Participants are eligible if they are healthy or have a stable chronic condition, including stable cardiopulmonary disease, diabetes, asthma or COPD. Immunocompromised persons are those who have serious chronic disorders are excluded. Next slide, please.

Let's review the objectives of the Phase III study. The primary efficacy objective was to demonstrate the efficacy of RSV pre-F in preventing RSV-associated lower respiratory tract illness with at least 2 or at least 3 signs or symptoms in the first RSV season following vaccination. Secondary efficacy objectives include efficacy against severe RSV-associated LRTI in the first season, efficacy against RSV-associated acute respiratory illness in the first RSV season as well as RSV, LRTI RSV ARI and severe RSV LRTI in the second season and across 2 seasons.

We continue to collect severe cases, which will be part of planned final analysis later this year. The primary safety objective was to describe the safety profile of RSV pre-F.

Next slide, please. I would now like to describe key study definitions starting with acute respiratory illness, which is defined as having one or more of the following symptoms: sore throat, cough, nasal congestion, nasal discharge, wheezing, sputum production or shortness of breath with symptoms lasting more than one day. These are the symptoms for which all participants complete weekly e-diary surveillance entries and trigger a self nasal swab and possibly a visit.

Lower respiratory tract illness is an acute respiratory illness with 2 or 3 signs or symptoms of new or worsening cough, wheezing, sputum production, shortness of breath or tachypnea. Severe lower respiratory tract illness is defined on key specific objective criteria that represents signs of serious illnesses shown.

In the case definition of RSV-associated ARI or RSV-associated lower respiratory track illness is made when a participant has at least 2 or 3 symptoms and a positive validated RSV PCR test.

Next slide, please. Looking at the safety profile, this slide shows local reactions at the top and systemic events at the bottom. This vaccine is extremely well tolerated. At the top, local reactions by maximum severity within 7 days of vaccination were more frequently reported in the vaccine group than the placebo group at 12.1% versus 6.6%, respectively. The most frequently reported local reaction was pain at the injection site, followed by redness and swelling.

Note, in particular, only about 10% of individuals experience pain, and this was mostly mild. In fact, most local reactions were mild or moderate and resolved between 1 to 2 days. At the bottom, systemic events are shown by maximum severity within 7 days after vaccination. Importantly, the proportion of participants who reported a systemic event within 7 days were similar in the vaccine and placebo groups at 27.4% and 25.7%, respectively, highlighting the favorable tolerability profile of RSV pre-F. This is a safety profile close to that of placebo, and that is a key consideration for vaccines.

Looking more closely, the most frequently reported systemic events were fatigue, headache and muscle pain and were similar across the groups. Fever was only reported in 1.4% of participants equivalent in vaccine group and placebo. Most events were mild or moderate and of short duration.

Next slide, please. For unsolicited adverse events from vaccination to the 1-month follow-up visit, about 9% of participants in each group reported any adverse events. The frequency of related, immediate, severe and life-threatening adverse events was similar in the vaccine and in the placebo groups.

At the bottom part of the table, you can see that newly diagnosed chronic medical conditions were also similar in both groups. There were 3 serious adverse events deemed by the investigators to be related to the vaccine. Adverse events leading to withdrawal from the study or leading to death were similar in the vaccine and placebo groups. Adverse events leading to death were reported in 52 RSV pre-F recipients and 49 placebo recipients. The primary causes of death most frequently reported were in the system organ class of cardiac disorders. None of the deaths were assessed as related to the vaccine.

Next slide, please. Now let's review the interim analysis efficacy results. RSV pre-F demonstrated high efficacy against RSV associated LRTI during the first season. First, let's examine less severe disease.

When looking at RSV-associated LRTI, defined by at least 2 symptoms, there were 11 cases in the vaccine group and 33 in the placebo group with an observed efficacy of 66.7% and a lower confidence bound of 28.8%. Next, RSV pre-F was 85.7% efficacious with lower confidence interval against RSV-associated LRT with at least 3 symptoms, indicating an even higher efficacy against more severe disease. The case split was 2 in the vaccine group and 14 in the placebo.

Importantly, both primary end points from the interim analysis met prespecified agreement for regulatory agencies on licensure criteria.

Next slide, please. This slide shows the cumulative case accrual curve from day of vaccination for RSV-associated LRTI with at least 2 symptoms. The blue line is the vaccine group and the dotted line represents the placebo group. Vaccine efficacy is shown after day 15 with a mean active surveillance of 7 patient months and a surveillance period up to 311 days.

Next slide, please. Looking at a similar figure for RSV LRTI with at least 3 symptoms, vaccine efficacy is shown around day 45, mean active surveillance with 7 patient months with efficacy persisting up to at least 6 months. Next slide.

In terms of the difference between the 2 groups, the figures here show the frequency of LRTI signs and symptoms for the RSV LRTI cases with 2 or more symptoms on the top figure, and it is also displayed at the bottom with 3 or more symptoms are only 2 symptoms. Among the RSV LRTI cases with 2 or more symptoms, cough and sputum production were the most common symptoms reported.

But in the dark blue bars, for cases involving 3 or more LRTI symptoms, wheezing, shortness of breath and tachypnea were more frequently observed than in the 2 or more symptom group, which is more specific and consistent with increased work of breathing and more severe disease. Next slide, please.

Looking at vaccine efficacy for the prevention of RSV LRTI by age group or prespecified significant conditions showed consistent efficacy across these subgroups. The study was not powered to demonstrate statistical significance for these groups. However, point estimates for vaccine efficacy were well above 0 for all subgroups consistent with overall results for prevention of RSV LRTI with 2 or more symptoms noted on the top half of the slide or 3 or more symptoms as noted on the lower half of this slide.

Next slide, please. Looking at a similar figure for RSV acute respiratory illness, or RSV ARI, vaccine efficacy is shown around day 45 and persist out to at least 180 days with positive trends throughout the duration of the surveillance period up to 311 days. The potential benefits of protection against ARI should not be underestimated as this has the potential to translate into reduced winter season physician visits.

Next slide. In conclusion, the interim analysis of the Phase III pivotal trial has demonstrated that RSV pre-F was well tolerated with no safety concerns. Local and systemic events were mostly mild to moderate and short life, and the AE profile did not suggest any safety concerns for RSV pre-F vaccination in adults 60 years of age and older. RSV pre-F was highly efficacious in reducing RSV-associated lower respiratory tract illness in an adult 60 years of age and older and also in reducing RSV-associated ARI in this age group. The study is ongoing, and we anticipate having additional data in the future.

We are thrilled that in the interim analysis data from the RENOIR study, our RSV pre-F vaccine candidate was efficacious, especially in the more symptomatic and severe patients, and the vaccine was well tolerated with a favorable safety profile, which is important in older adults, some of whom may be more at risk than broader populations.

Such a safety profile of the unadjuvanted RSV pre-F vaccine candidate, combined with high efficacy based upon the clinical trial results, has the potential, if approved, to encourage routine vaccine use.

And now Angela Lukin will discuss the RSV commercial opportunity as well as U.S. commercial market considerations for (inaudible) . Next slide, please.

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

Thank you, Bill. We're very excited about our RSV vaccine candidate for older adults as it has the potential to strengthen our growing respiratory vaccine portfolio, building on our success and strong heritage with Prevnar and the COVID-19 vaccine and have a significant impact on public health.

In addition to the older adult program that we just heard about in detail, we are looking forward to the upcoming readout of our MATISSE study, which is our global Phase III maternal immunization study. Pending data readout and regulatory approval, our RSV vaccine candidate may be the first maternal vaccine available to help prevent RSV in young infants, which would potentially make Pfizer the only company to have both a maternal and older adult indication.

But our commitment to RSV doesn't stop there, and we have a unique pipeline portfolio that stands prevention and treatment. Complementing our efforts to advance our RSV vaccine candidate, we have sisunatovir, an investigational RSV F protein inhibitor asset with potential to help treat RSV-related illness.

Like we have seen with COVID-19, Pfizer is deeply committed to helping prevent and treat infectious diseases. And we believe we are uniquely positioned with the best-in-class R&D, manufacturing and commercial capabilities to deliver successful launches.

RSV represents an area of significant unmet need in older adults, and we have the potential to have a real impact on public health with the introduction of our bivalent vaccine candidate, pending regulatory approval. RSV is a common, yet often underreported, cause of acute respiratory illness in older adults with similar hospitalization and death rates to influenza. It typically manifests with mild to moderate symptoms, though some patients are often more prone to developing severe disease.

Older age alone is a key risk factor, but individuals with underlying medical conditions, such as heart disease or lung disease, are also at increased risk for more severe disease, hospitalization and other complications, including exacerbation of underlying chronic conditions.

As Lisa mentioned, RSV is responsible for 177,000 hospitalizations and 14,000 deaths annually in the United States alone. And just to put this in perspective, the estimated annual cost of hospitalizations for adults with RSV in the U.S. is about $1.2 billion.

In the U.S. alone, there's approximately 61 million adults over the age of 65, who will have the opportunity to potentially be protected from RSV with our vaccine candidate, subject to regulatory approval and ASIC recommendations. And once duration of protection data is available, that data will be a key input for defining a potential revaccination schedule.

It is highly encouraging to see the progress being made as scientists and researchers have worked to develop RSV candidate with little success over the last half century until now.

We are particularly excited about a number of features of our RSV candidate. First, the Pfizer vaccine is bivalent and includes prefusion F antigens, representing both A and B subgroups of RSV. Other vaccines in development only include RSV A.

Second, our vaccine formulation does not include an adjuvant or viral vector component. Adjuvants or viral vector components have been associated with reactogenicity. We look forward to the potential opportunity to deliver our bivalent RSV vaccine candidate to older adults during the 2023 -- during 2023, subject, of course, to regulatory approval.

This slide gives a snapshot of the rapid progression from Phase III study starts to potential BLA approval, and we are excited and proud that we could potentially launch our RSV vaccine candidate for older adults within approximately 2 years of the Phase III RENOIR study starts.

With all of the milestones achieved in 2022, including achieving breakthrough designation in March, it has been a busy year. We've been moving at light speed to advance the program and are really excited for the opportunity to potentially launch our vaccine candidate in time for the 2023, 2024 RSV season, pending regulatory approval.

And now to RSV maternal. Maternal immunization would provide an opportunity for pregnant women to get a headstart during pregnancy to help protect their infants from RSV from day 1 of life. RSV is the leading cause of global infant respiratory disease. Although RSV can impact all pediatric age groups and most children will have gotten RSV by age 2, the burden of the disease is higher in infants younger than 1 year old and especially those under 6 months.

So pending positive data, we are excited about the potential to deliver our vaccine candidate to expecting mothers to help protect their infants against RSV immediately at the time of birth and during their most vulnerable first months of life. And if successful, the RSV material vaccine candidate may provide a foundation for a potential maternal immunization platform in the future.

Before we move on to COVID-19, RSV is a virus that causes acute respiratory illness in all ages, but maybe especially serious in infants and older adult populations. As the only company targeting both older adults and maternal indications, pending positive maternal data and subject to regulatory approvals, we believe that we are well positioned to be a leader in the RSV space.

We will now turn our attention to our COVID-19 vaccine to discuss some next steps for our transition to a traditional commercial marketplace. As you know, the U.S. government recently indicated that many factors should be prepared for a transition to a commercial COVID-19 market as early as the first quarter of 2023.

The EUA way environment has been new for all of us, but we will now be moving into our sweet spot of the traditional commercial marketplace. With decades of experience, launching and commercializing medicines and vaccines, we are confident that we will see the continued success of the vaccine once this transition occurs.

We believe that our best-in-class mRNA capability, coupled with our proven and reliable manufacturing network, will help ensure we are well positioned to quickly adapt our vaccine just as we did this past fall. In the first 30 days following regulatory authorization, we were able to quickly scale up and deliver more than 30 million doses of the Omicron BA.4-5 based on bivalent vaccine in the U.S. alone. This helped to ensure pharmacies had enough supply to meet demand and represented more than 70% of the doses available in the market during this time period.

As we transition to a traditional market, we expect to be commercializing a single-dose vial, which our customers have indicated is their preferred formulation and our commercial price point for the vaccine will reflect its cost effectiveness.

Over the course of the pandemic, COVID-19 vaccines have saved millions of lives around the world. If you look at the U.S. alone, it has saved hundreds of thousands of lives, tens of billions of dollars in health care costs and enabled Americans to go about their lives more freely.

For example, a recently published study conducted by the Health and Human Services showed that vaccination against COVID-19 was linked to 650,000 fewer COVID-19 hospitalizations and 300,000 fewer deaths in the U.S. alone. Additionally, reductions in COVID-19 hospitalizations were associated with savings of more than $16 billion in direct medical costs in the U.S.

We are humbled by this impact, and we believe it will be a long-standing example of how we deliver on our mission to deliver breakthroughs that change patients' lives.

As we prepare for the transition to a traditional commercial market, our goal is to continue equitable and uninterrupted access to our COVID-19 vaccine for every American and affordability for the health care system. Based on our current understanding, when we enter a traditional commercial

model, anyone with commercial or government insurance who is eligible to be vaccinated should be able to access the vaccine without any out-of-pocket payments. This is assuming continued broad recommendations supporting annual vaccination.

When this transition happens, the commercial price point for the vaccine will reflect its cost effectiveness. This will include increased costs as we transition to a single-dose vial and commercial distribution. But more important, it reflects the value this vaccine has brought to society. We believe a potential U.S. list price between $110 and $130 per single dose vial for adults reflects the value of the vaccine and as well the thresholds for what would be considered a highly cost-effective vaccine.

As I hope I have made clear today, we have been preparing for this transition for some time. And part of this planning includes a new commercial structure in which the COVID-19 vaccine and treatment have united under the primary care unit. This new organization is unique and that it brings together our full commercial and sales power under one leader, providing increased agility and flexibly across the portfolio. We believe this will unleash the power of our organization to meet the needs of our customers in a more dynamic and nimble way.

In addition to our new structure, there are 4 key areas where we believe we have significant leadership. Number one, contracting. With decades of experience and an extensive portfolio of products, we are working with private entities, including retailers, IDNs, wholesalers and other buying groups, to secure robust and differentiated contracts. It will go into effect upon commercialization.

Number two, field force. Our field force has long-standing and deep relationships with key stakeholders in the vaccine ecosystem and is already actively educating vaccinators on our vaccine profile and driving the urgency for eligible people to stay up to date with their latest booster. And with our new structure in place, we have the flexibility to be able to deploy them to the right health care providers at the right time.

Third, manufacturing and distribution. Since the earliest days of the pandemic, our manufacturing capabilities have been unmatched. And as we head into this next phase, we plan to evolve the packaging and storage of the vaccine to better meet customer needs and the commercial workflow. These include single-dose vials, last mile shipping options and more flexible minimum ordering quantities.

Additionally, we aim to build on our long-standing partnerships with wholesalers to provide ordering and stocking options that more closely resemble the normal course of operations in a commercial environment. And last but not least, consumer engagement. Today, we are using our expertise in actively educating and engaging consumers with robust communication and a leading share of voice in digital, social, TV, radio and influencer channels to drive awareness and trust in our vaccine.

We continue to find new ways to reach patients, including signature collaborations and sponsorships. We will maintain that effort to help ensure patients understand booster eligibility and the need to stay up to date on vaccination. While a commercial marketplace presents new complexities, we are confident that we have the capability to make this a successful and seamless transition for our customers, health care providers and most importantly, for patients.

I'll now turn it back over to Chris to facilitate the Q&A session.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thank you so much, Angela. We're going to start our Q&A session. We have just under 30 minutes. We have a hard stop at 5:30. So we ask you that you could be as crisp and brief in your questions as possible. Chelsea, please go ahead and start the Q&A session.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question will come from the line of Mohit Bansal with Wells Fargo.

Unidentified Analyst

This is Trina on for Mohit Bansal. I wanted to ask about the endpoints between Pfizer trial and GSKs, and kind of given the different definitions for RSV ARI, RSV LRTI. How would you -- or which end points would you compare to which?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thank you very much, Trina. Lisa and Bill, would you like to take that?

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

Yes. So thanks for the question. I think the important piece is not to compare endpoints from different services, but really rather focus on the endpoints and the resulting results. And so we designed our trials based on feedback from infectious disease experts and also working with the FDA to ensure that we really made sure that we didn't have subjective measures of RSV disease.

We are very much concerned to be able to capture the lower respiratory disease, which is where the biggest burden lies on health care and on the population. And we wanted to make sure that we had a vaccine that was safe, well tolerated and highly effective at preventing the respiratory tract illness.

And as you can see from the data that Bill presented, we saw over 85% efficacy there. But Bill, would you like to add a little bit more?

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

Yes. I think -- I mean, Lisa has characterized it well. And I think we also heard it well characterized by Michael Melgar at the ACIP meeting today. Where he made the point that you really can't compare across studies. You're better off, just in an absolute sense about what you're seeing. Are you seeing what you would hope to see in terms of the potential to protect against serious illness and keep people out of the hospital.

And I think the balance of evidence that we have shows just that. But as you start with acute respiratory illness is kind of the lowest or the most minimal sort of illness and work your way through to more specific measures lower respiratory tract illness, you see progressively higher levels of efficacy. And even though we've not seen hospitalized patients to a significant degree to get to an endpoint.

Nonetheless, this data basically supports what we've seen in every other circumstance with mucosal pathogens with a successful vaccine that proves -- the efficacy proves to be higher for the more severe disease. I would put it in that context. And as Lisa said, the other key piece is the vaccine doesn't do any good if nobody takes it. So it's important to have a very good safety profile. And as you've heard me described, the safety profile is very comparable to other commonly used vaccines that have a high degree of acceptability.

Operator

The next question comes from the line of Louise Chen with Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

So just quickly on the payer discussions on your single-dose COVID vaccine for the commercial market, that 110 to 130, have you had those discussions and how willing are they to pay for that? And then how do you think about penetration in the commercial market?

And second question is just there's a couple of different adult vaccines in the RSV market right now that are in development. So what do you think the ACIP and physicians will base their decision on a recommendation on when they look at these different products?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Louise. It sounds like a question for Angela to start. And if Bill may so want add anything, please go ahead as well.

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

Yes. So I would just say we're in the very early days, really in terms of discussions with payers from that point of view. So I think that the goal really is to ensure that we're having robust discussions. And I think, look, based on the market analysis and the cost effectiveness modeling that we have run, we know that, that price range really does represent highly cost-effective modeling.

As I mentioned before, the number of deaths and almost $16 billion worth of cost in the U.S. alone in terms of COVID was pretty substantial. So I think we feel confident that this range will be seen as highly cost-effective and definitely one that will help to enable and ensure appropriate access and reimbursement to the vaccine.

And then in terms of your second question, with regard to a lot of competitors coming now into the RSV space, I mean, look, I think the way in which we looked at it is, given our experience in vaccines, we still have quite a few milestones yet to come. Obviously, we need to make sure that we file our BLAs by the end of the year for both adult and maternal, assuming positive maternal data.

And then there's still quite a few milestones to overcome, obviously, with FDA, ACIP recommendations. But I think one of the things that we know about this category is how much the profile of the product. So for ACPs and vaccine purchasers, they really do look at and rely on the safety, efficacy and tolerability as well as contracting and supply reliability when thinking about a vaccine that they're going to use for patients. So regardless of how many competitors are out there, we do believe that Pfizer is uniquely positioned given its vaccine experience and given the profile of the product to really drive and have leadership in this space.

Operator

Our next question will come from the line of Terence Flynn with Morgan Stanley.

Terence C. Flynn - *Morgan Stanley, Research Division - Equity Analyst*

Two for me, one on COVID. I just wonder how you're thinking about predicting demand for the boosters in 2023, given where we are in the COVID cycle and given the move to the commercial markets? So maybe how are you going to go about predicting demand and providing guidance to the Street around that?

And then the second is on the RSV market opportunity. I think I was looking back when you originally talked about peak opportunity for your vaccine. It looks like the focus is more around the maternal setting. Obviously, now you have adult data in hand. So how are you thinking about the peak opportunity now that you've seen the adult data?

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

Thank you. So look, just in terms of your first question about how we're thinking about the market, it's very early days and there's many variables to consider as it relates to predicting current. By the current, I mean, even just a fall of this year, let alone the future uptake in 2023.

For this fall, variables include timing of people's eligibility to boost due to recent infection and/or when people received their last boost as well as the personal decision-making on when to boost, for example -- helping to ensure, for example, protection around the holidays that are coming up.

However, we think about the future uptake in the coming weeks and months that are certainly similar to the trends between COVID and flu. In particular, the rate of booster uptake in the first 6 weeks post launch compared to the flu in the same time period, are actually very similar. And as we move forward beyond this fall in 2023, there's also a number of factors of uncertainty, which make it difficult to predict uptake, including the precised timing of commercialization.

However, we expect that the annual COVID booster uptake may reflect historical flu uptake rates for adults and older adults. With that said, given the pediatric COVID-19 vaccine booster adoption rates that we've seen to date, the annual booster uptake rate for the ped group will likely take longer to build, to flu like pediatric uptake rate potentially later than 2023.

Encouragingly, we are seeing a positive trend in adult co-administration of flu and COVID vaccination year-over-year. Just to kind of give you a sense, last year, some day -- same day, coadministrations were in the teens. Well, this fall, coadministrations have increased to roughly 40%. So additionally, we potentially are looking at a launch of a flu and COVID combination product and we expect that this will also help to improve uptakes due to convenience for HCPs and consumer alike. So still early days and a lot of key variables that kind of have -- yet to be determined.

And then your question about transitioning to the commercial model. Currently, the COVID-19-related contracts between Pfizer and the U.S. government continue through the end of this year. So the transition were more traditional commercial model wouldn't happen until the first quarter of 2023 at the earliest. And this transition will be triggered by the expiration of current contracts, depletion of government supply and potential rollout of adapted vaccine to match any shifting strains.

And then your last question, which was really about the opportunity that we see in RSV. I mean look, we are very excited about the RSV candidate and older adults at it has the potential to strengthen our growing respiratory vaccine portfolio and address an important unmet need, of course, subject to regulatory approval, and RSV represents an area of significant unmet need in older adults.

So for example, U.S. alone, RSV infection accounted for, I mentioned before, 177,000 hospitalizations and 14,000 each year. And we have the potential to have a real impact on public health with the introduction of the bivalent vaccine, of course, pending regulatory approval.

And on the maternal side, RSV can be dangerous for some infants and young children. And each year in the United States, an estimated 58,000 children younger than 5 years old, are hospitalized due to RSV infection. And virtually all children get RSV infection by the time they're 2, and it's the leading cause of hospitalization in children less than 1 year of age. So if successful, maternal immunization could provide protection for the first day -- from the first day of life.

So we've been moving with light speed to advance the programs and really excited about being able to launch our RSV older adult vaccine in time for the 2023, 2024 RSV season. And maybe I'll just say lastly, as the only company to potentially have both the older adult and maternal indications, of course, pending positive maternal data and subject to regulatory approval, our commitment to RSV doesn't stop there, and we have a unique pipeline that also includes the potential for treatment. And for those reasons, we believe that we're well positioned to be in the -- a leader in the RSV space.

Operator

Our next question will come from Robyn Karnaskus with Truist Securities.

Nishant Shailesh Gandhi - *Truist Securities, Inc., Research Division - Research Analyst*

This is Nishant. I'm on for Robyn. A couple of questions, one for maternal study. Regarding end point for death study, what can we expect in terms of the endpoints? Will that be similar to the older adult study? And in terms of COVID vaccine, any bookends on when the COVID vaccine will go commercial? And what are your thoughts about pricing ex U.S.? Will that still be government contracts or individual doses like in the U.S.?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Nishant. I think the first question would be for Lisa and Bill, and then to the second question, that would be more of an Angela question.

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

Yes. So maybe I can take the first one about the nature of the end points for the maternal immunization trial. I think everybody appreciates women are being vaccinated when they're pregnant. And a mother's gift of antibody is passing to the infant, and then we monitor these children from the time of birth through the RSV season.

And the key endpoints are medically-attended lower respiratory tract infection and severe medically-attended lower respiratory tract infection. And again, as you heard, we anticipate having a readout on that before the end of the year, and hope to file before the end of the year.

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

Yes. So in terms of the timing of the shift to the commercial model, really we'll be contingent on the COVID-related contracts that we have with the U.S. government, as they're going to continue until the end of the year. So the transition to that more kind of commercial model won't mostly likely happen until the first quarter of 2023 at the earliest.

And this transition will be triggered by expiration of the contract, depletion of government supply and/or potential rollout of any adopted vaccines to match any kind of shifting strain that may appear.

And then your question about pricing outside the U.S. The time lines in the mechanism for a global pricing vary and will be, of course, working with local markets to determine pricing as we look to transition from the pandemic distribution model to normal procurement paradigms in those markets. However, in 2023, we have government contracts in many developed markets outside the U.S., and as such, have already agreed upon pricing in those markets.

Operator

Our next question will come from Chris Schott with JPMorgan.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Just wanted to follow up on the COVID vaccine. I'm just trying to understand the pricing dynamics a little bit better here. So I guess, first of all, do you expect that there's going to be significant discounting in this market from this list price you're rolling out?

And well, I guess, the severity of this season's COVID wave play any role? And I guess, where net price settles out, as the kind of the value of the vaccines kind of offering? And then just a really quick one on RSV, I think you're still waiting for some of this data, but what is your base case in terms of how frequently someone would have to be revaccinated in this older adult market?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Chris. So with regards to the discounting and the value and discounting, that would be a good question for Angela. And then with regard to the duration of protection that would be Bill or Lisa.

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

So maybe I'll just start. I think that we believe that this is going to follow additional modeling that we have, for example, with vaccination. The system in which the COVID-19 vaccines are purchased and distributed really will be different, that under the emergency process set up during the acute phase of the pandemic and the market for vaccines will be a bit smaller, having different purchaser requirements and more fragmented than it was in 2021 and 2022, which will lead to some higher costs, which include manufacturing of single dose, transporting of cost and evolving the commercial distribution model.

So I think as we think about the traditional rebating, it will follow what we typically do in vaccines. And it will factor into, as I mentioned before, the cost value for the assets. So I think as we head down this road, the good news is we have a lot of experience in this space with our vaccine portfolio, and we'll be able to leverage contracts, relationships and our portfolio as we look to partner with key institutions to ensure equitable and broad access of the vaccine.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Bill or Lisa? Duration of protection.

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

So maybe I can deal with the persistence and revaccination issue. We are very encouraged, I think, by the Phase I/II data that suggested persistence of antibody well above baseline out to a year. So that bodes well for potential protection. And hence, we built into the study, the ability to look at a second season protection. And once that data is available, we'll then be able to define what that level of protection is and whether it's necessary to give a second dose, a year apart or 2 or 3 years apart.

Operator

The next question will come from the line of Chris Shibutani with Goldman Sachs.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

On the COVID vaccine front, the question would be about the potential or thinking about variance and how that would influence your thinking on the final negotiated price. And then perhaps something for the RSV vaccine, how are you thinking about -- it sounds sequentially the adults population will come first and the pediatric opportunity, the maternal would be later. How do those -- that timing and the sequencing of that factor into your thinking about pricing for the RSV vaccine?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Chris. So I'll do emergence of new variants of concern, influence our thoughts on the final negotiated commercial price for COVID vaccines and then RSV vaccines how the timing of the adult indication versus the peds indication later, how that impacts pricing. Those all sound like questions for Angela.

Angela, do you want to take those?

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

Yes, sure. So as we think about the cost-effectiveness and cost savings, those have been factored in. I mentioned before about just some of the increasing costs that have gone in. But obviously, one of the factors is in the commercial list price reflects the value delivered, not just by the vaccine, but also allows Pfizer to maintain our commitment to help equity and reinvestment in manufacturing capacity and preparedness in the U.S. and across the globe.

Two, ensure that we're also staying one step ahead of the vaccine. We know that this vaccine -- we know that these variants and COVID mutates, and so we want to make sure that we are prepared to be able to address that. So from the purposes of how we're thinking about pricing, it takes into account various different costs, increased costs, cost-effectiveness and ensuring that we are prepared and ready to be able to address potentially the next possible variant.

Operator

Next, we have Tim Anderson with Wolfe Research.

Timothy Minton Anderson - *Wolfe Research, LLC - MD of Equity Research*

When will we know the answer on RSV about whether it's annual or not? That's the first question. Second question is on pricing. It's one thing if you're the only supplier out there, but you're not. So I'm wondering what your assumptions are on potential price competition? And then last question, any thoughts about telling us what the profit contribution is from COVID vaccine like you used to do?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Okay. Thanks very much, Tim. I appreciate those questions. So Bill, maybe you want to take the timing and the duration of protection for RSV when we'll know? Angela, maybe you want to take the pricing versus the competition? And then, Angela, I don't know if you want to take the COVID vaccine profit contribution? Or if not, I'm happy to discuss that.

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

Yes. So thanks, Chris. I think for the RSV vaccine as we just described, we're now monitoring these individuals that we have gone through a first season into a second season, which, as you know, is starting right now. So you can anticipate that as we get in sort of the late spring, but likely in advance of the next -- or the ACIP meeting that's going to occur in June, we would have efficacy for that second season that would then help dictate the necessity for annual or potentially a longer interval.

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

I think that's the piece -- so it's an ongoing study. And once we have the data, we'll obviously share it externally.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Bill and Lisa. And then Angela?

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

Sure. So just in terms of pricing, the price for the COVID vaccine reflects the value that we believe it delivers to patients and society based on our cost modeling, and we believe that the CDC will recommend annual COVID-19 vaccinations for a broad population, meaning that there will be no out-of-pocket costs for Americans, regardless of which insurance they have.

And though we cannot compare list prices across different vaccines without considering discounts, broader contracts that may be in place with specific payers and the level of reinvestment in pathogen surveillance and future vaccines. Pfizer is the only manufacturer to successfully have researched and developed the COVID-19 vaccine without receiving federal government funding, and the company is still reinvesting heavily in expanded manufacturing capacity in the U.S. and across the globe and adding a supply chain to ensure a steady supply of vaccines and therapeutics.

And then just in terms of the question related to level of profit. Obviously, Pfizer is committed to finding and developing vaccines to protect against COVID-19. And as I mentioned before, the only ones that successfully develop a vaccine, self-funded. That commitment and level of investment continues as we transition to an acute phase of the pandemic with construction of additional manufacturing facilities, surveillance, pathogens, and, of course, working tirelessly to develop the next generation of mRNA vaccines.

We are confident that the U.S. price points of the COVID-19 vaccine reflects its overall cost-effectiveness and ensures that the price will not be a barrier for access for patients. Christopher, if there is anything more you wanted to add about profit?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Yes, please. Tim, as you know, but just to make sure everyone is reminded, the biggest determinant of the gross margin on COVID vaccines for us is the 50-50 gross profit split we have with our partners at BioNTech. So that's the key driver there.

We also talked about how the cost per unit are very different for multiple dose vials versus single-dose vials. Logistics are very different. So it's going to be a different construct. But again, the biggest determinant is that profit split.

And I'm sorry, we forgot to answer the last question from Chris Shibutani, but that's my bad. So Angela, maybe if I can just ask you. Given the timing of when we're getting the adult data and potentially the authorization and the timing of when we begin the maternal data and potentially authorization, how does that different timing potentially impact the pricing of RSV vaccine?

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

So from the purposes of pricing, I mean, obviously, our goal is to file both with the FDA before the end of the year, and we plan to target value-based pricing to support broad routine age-based recommendations by ACIP for older adults, pending successful data readouts and regulatory approval for the pregnant women to help protect infants with RSV.

And in the older adult segment, we know that recently adopted U.S. legislation of the inflection -- Inflation Reduction Act will enable $0 co-pay for Medicare patients. So as we think about pricing and we think about the broad right now, our focus, obviously, is on older adults, but we're looking at price to value as we think about the portfolio and the indications.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Yes. And I think at the heart of Chris Shibutani's question was as Bill answered. So by the time we'd be making those decisions, we would have a good sense of duration of protection offered and we would also have a good sense of what the efficacy looks like of the maternal vaccines.

Operator

Next question will come from Geoff Meacham with Bank of America.

Geoffrey Christopher Meacham - *BofA Securities, Research Division - Research Analyst*

I just have a couple. So one on COVID. How, if at all, would the commercial model for the vaccine differ versus PAXLOVID? I'm just trying to think about pricing versus access differences. And then on RSV, what's the gating factor for the filing for this year? Are there subgroups that you guys would want to maximize differentiation on and maybe just wait for?

And then the last question is, would you expect a recommendation in older adults, say, greater than 70 years and up? I'm trying to reconcile what ACIP may ultimately recommend versus what supportive data you have as of now?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Okay. So we're going to chape up a little bit. Maybe Bill or Lisa, you can start out with your thoughts on whether ACIP will give a recommendation versus a subgroup -- older subgroup versus the entire population? And then maybe, Angela, you can take the 2 questions on RSV in terms of gating factors for pricing and differentiation. And then for COVID, how will the commercial model -- excuse me, the commercial model for the vaccine differ potentially from PAXLOVID when that goes commercial?

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

So yes. So as far as the question around, will ACIP look at specific groups? We saw today from the working group meeting what they felt was important for what a vaccine needed to differ from a public health benefit. And so many of those things apply to older adults and whereas we can't predict what they're going to do.

One can look at other vaccines and generally, one looks at vaccines for older adults as a single category, and it doesn't tend to be passed out. Obviously, risk factors come with age, and you can't always predict when they're going to come and you want to make sure that you have an umbrella of protection for that vulnerable group.

Pretty set time so that then it's much more uniform and much more easy to maintain compliance and help physicians know when people should receive their vaccines.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks, Lisa. That was great. And then Angela, with regards to the COVID, how that -- the commercial model differ versus PAXLOVID? And then for RSV, your thoughts on the gating factors for pricing and differentiation?

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

Yes, I mean just in terms of the commercial model and the difference is, obviously, from a vaccine point of view, we'll be partnering with purchasers and retailers as primary contracting opportunities. And as we think about the support that's going to be required, obviously, there, it's going to be a big focus on, of course, those people that are doing the vaccinations and the key influencers of that.

Whereas if we think about PAXLOVID, it's going to be more broader, with a broader group of payers and really the need to support also with a broad field organization, raising awareness around the high risk factors, making sure that there's testing and treating going on and making sure

that HCPs because any HCP in the United States can prescribe PAXLOVID that there is a good understanding of the benefit/risk profile and that they understand how best to use it.

So the model and the support that will be required for those 2 products will vary and be different based on the prescribers and/or vaccinators that touch those 2 different businesses. And in terms of stage gating, the pricing and how we're thinking about, obviously, need to understand once the data readout comes out from maternal to understand the profile of that as we look at it versus older adults.

And then a key factor as we set and think about the pricing will be also related to vaccination schedule. So there still are quite a few milestones and of course, recommendations that would potentially come post assuming FDA approval from ACIP. Those are all going to be key factors that will input into the final pricing within RSV.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thank you, Angela. And then Chelsea, I think we have time for one more brief question.

Operator

Sir, our last question will come from Steve Scala with Cowen.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Pfizer is likely seeing some incidence of premature labor in its maternal RSV study. There wouldn't seem to be any reason why the Pfizer experience would be different then that of GSK. And there are factors which create noise such as COVID and different incidents and different populations. So why is Pfizer comfortable with all of these factors?

And then secondly, in terms of events avoided, the degree of benefit seen in the adult RSV trial reminds me of the Prevnar adult data from CAPiTA, and that turned into a decade-long struggle to establish it in that population. So why is that not a good comparison for modeling RSV?

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Okay. Thanks very much, Steve. So I think the first question regarding the maternal study, that would be a good one for Lisa and Bill to answer. And then in terms of the ACIP recommendation and how that would be similar to PCV13 in adults for CAPiTA, I think Lisa and Bill could also take a crack at that or maybe Angela, if she has any thoughts.

Angela Lukin - *Pfizer Inc. - Global President for Hospital Business*

So Steve, sorry, could you clarify your first question around the maternal vaccines because I think you've got the wrong company when you were going through the question.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Maybe I can interpret -- yes, go ahead.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

So GSK stopped the program because of premature labor. And I'm just wondering why Pfizer can continue and feel comfortable with it given all the factors, there wouldn't seem to be a reason for a different incidence in the 2 studies?

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

Yes. So obviously, we can't comment on the nature because we don't have a window into what caused GSK to actually stop their study. But there's a recognition, of course, by our independent DMC, that GSK has stopped its study. We have looked at presumptive sorts of funding that might have been associated with the study stop.

And we have seen no signals related to still births, prematurity or anything else. The DMC has indicated that we should we enroll the full 7,400 women and follow their babies. So I can't speak to what's happening with them, but I can say that we're confident about the safety profile of our vaccine in pregnant women.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

And then the analogy between older adults for the ACIP recommendation and then CAPiTA for Prevnar 13?

Annaliesa Anderson - *Pfizer Inc. - Senior VP and Chief Scientific Officer for Bacterial Vaccines - Vaccine Research & Development Unit*

So when one looks at CAPiTA, essentially before we have the readout for CAPiTA, we have the 13 valent vaccines, but it wasn't recommended by ACIP for the adult population until we had the readout for CAPiTA. After we have the readout for CAPiTA, we actually did see very large uptake of vaccine in the older adult population.

So I think the key was to show the efficacy. And once we showed the efficacy, we did see a large proportion of older adults taking that vaccine. But Bill, of course, you were responsible...

William C. Gruber - *Pfizer Inc. - SVP of Vaccine Clinical Research & Development*

And again, we've leapfrogged here, right? So in that circumstance, we got accelerated approval based on demonstration of non-inferiority and an advantage to the conjugate vaccine in terms of stimulating memory and a robust immune response that was likely associated with protection.

But then as Lisa said, it wasn't until we had the efficacy that the uptake was quite high and with that largest of individuals that were over 65 who could be vaccinated. In this case, we're doing efficacy right from the start. So that should provide confidence for both maternal immunization program as well as for the adult program. So that should provide the necessary confidence to help the ACIP come to a favorable organization.

Christopher J. Stevo - *Pfizer Inc. - Senior VP & Chief IR Officer*

Thanks so much, Bill and Lisa. I appreciate that. Steve, thank you for the question. And thank you, everyone, for taking the time to join us this evening. We appreciate it. And please let us know if you have any follow-ups. Thank you. Bye-bye.

Operator

Thank you. Ladies and gentlemen, this does conclude today's call. We appreciate your participation. You may disconnect.