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EDITED TRANSCRIPT

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CORPORATE PARTICIPANTS

William Pao *Pfizer Inc. - Executive VP & Chief Development Officer*

CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

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

Good morning, everybody. Let's start on time. I hate to penalize people who are on time, especially in the morning. So welcome to day 2 of the Goldman Sachs Healthcare Conference. I hope everyone had a very positive and productive first day experience. Jet lag is kind of a bummer, but off we go.

Very pleased to have Pfizer join us this year, and in particular, a year under the belt of Chief Development Officer, William Pao. William, thank you for joining us.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Thanks for having me.

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

Unfortunately, Dave Denton, the CFO, couldn't be with us here. So we're really going to focus a lot on the pipeline. I know obviously, for Pfizer and for investor communities, there's a lot of big picture questions here, but I think personally that this can be an interesting snapshot to really focus on the expertise of the person who's joining us for this conversation. After all, they're on the brief side anyway.

So I always like to also start again because you're a relatively new face to the Pfizer side, you have a long history at some very distinguished academic institutions and a lot of top shops, especially in the cancer space globally. So tell us a little bit about your background, your professional journey.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Okay. Yes, Chris. So basically, MD, PhD. I was in the lab of Adrian Hayday at Yale, where I studied the function and development of mirroring gamma-delta T cells. Then did internal medicine at Cornell Medical Oncology and Memorial, did a postdoctoral in the lab of Harold Varmus, where then we and others found EGF receptor mutations as the genetic basis for why EGFR tyrosine kinase inhibitors work in only 10% of lung cancer patients, then also found the T790M mutation, which mediates resistance. So I have a patent on that with Memorial and some other people.

Then I had my own lab at Memorial, where I saw patients, helped run trials and do research. And then got recruited to Vanderbilt, where I eventually became the Division Chief there of hematology/oncology, continued to see patients, run the lab, helped run trials, helped AstraZeneca develop osimertinib. Also cofounded MyCancerGenome, which is an online tool to enable genetically informed cancer medicine.

Basically then in 2014, got recruited to Roche to head up oncology drug discovery there in the Pharma Research & Early Development unit, the pRED unit. And after 4 years, became the head of all of pRED, helping not only in oncology, but immunology, infectious diseases, ophthalmology, neuroscience and rare diseases. And then basically joined Pfizer last year as the Chief Development Officer.

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QUESTIONS AND ANSWERS

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

Okay. Great. So obviously, incredible background in terms of the academic experience, very relevant clinical experience as well, nested to a great extent, obviously, Roche, the home of Genentech, and the discovery side of it. So there must have been -- basically you've been surrounded by a lot of smart, challenging people perpetually. And so your time at Pfizer is actually quite a crucible for the company. Thinking about everything that's happened, obviously, there's a lot of moving parts here in terms of what we know, the portfolio, a lot of the LOEs coming in back end of the decade.

Along comes COVID, completely changes the trajectory, the revenue profile, almost creating 2 companies in essence, right? And investors have a lot of debate. We won't focus on that with you. I'll try not to torture you too much, although I will be asking you from like your development standpoint, sort of like what could come next in terms of developments from a clinical perspective.

And then there's this pipeline of assets layered on top of a base business, including things that you've acquired, things that have been developed, et cetera. Very important, and I kind of have made an analogy with investors that it's like being handed this black bag or this pouch, let's call it a velvet pouch, full of all these coins, and The Street is sort of perceiving that there's a lot of nickels and dimes. And therefore, the task is to sort of find where are the quarters, where is the Susan B. Anthony Dollar in here.

So a lot of progress points, a lot of things that could add up and to try and get conviction around that. So I'd like to make sure that we, in our discussion, given your expertise, circle in on some of the pipeline aspects here.

And I think the highest profile opportunity here that is very time-relevant from the standpoint of where we are is the vaccine business, but particularly, the next iteration of opportunity. It threads in COVID, but obviously focuses on RSV. So tell us a little bit about where you see we are with the RSV vaccine opportunity. It's really at this juncture now where we have quite a bit of conviction in terms of the profile. We don't know everything. And like all great scenarios in the industry and for investors, it's kind of a 2-horse race currently in the leadership and there's others that follow as well. So obviously, clearly dynamic opportunity. Perhaps outline for us where you see your RSV vaccine in a way that will help us understand how we can relevantly compare and contrast with the GSK product. That would be very helpful to start.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Sure. So as you know, we have the RSV vaccine. It's a protein-based vaccine. And we've had multiple readouts, including older adults, where we've shown great vaccine efficacy against lower respiratory tract infection. We also have a great result in maternal immunization, which then protects newborn babies.

So right now, we're very focused on -- basically, we passed the VRBPAC for the older adults. We anticipate the ACIP very shortly and then approval. And then later on this year, similarly for the maternal vaccine, we anticipate approval and then an ACIP recommendation.

So we feel very confident in the vaccine efficacy of our respiratory syncytial virus, most notably -- vaccine. Most notably, it also has a very good safety profile. So you may remember, we're unadjuvanted. And so we have high vaccine efficacy, but the reactogenicity is very tolerable. And we think that will make a huge difference in terms of acceptance by patients and participants across the globe. So -- and we'll be the only ones with the maternal vaccine as well.

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

When we think about the overall profile, no product is perfect, pros and cons, relative advantages and disadvantages. But at this juncture, I think investors are thinking about what is the uptake going to look like, how big can these get, what's the ultimate market share. So from a clinical development leadership standpoint, as you look at this version of the RSV vaccine that you have that's going through these key gating factors that will then become the product that's unveiled commercially to the public for the first time, where would you say the key strengths are that are

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relevant from a commercialization standpoint? And where might they possibly still be able to improve as a function of putting on your R&D hat and saying, okay, well, the next iteration of this, where else can we go? Strengths, same question on potential shortcomings because as I said, obviously, no product has a perfect profile for such a heterogeneous population. So talk about both of those.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Sure. Yes. I mean, I think, obviously, we don't like to compare against any other products because we've never had a head-to-head comparison. But as I said before, we have a very high vaccine efficacy both in the older adults as well as in the maternal immunization. We'll be the only ones with an indication, assuming regulators approve that in the maternal immunization indication. And again, we have a very tolerable safety profile.

So in terms of acceptance by people getting it, we think that they'll, first of all, recognize that respiratory syncytial virus is a serious infectious disease problem. We heard last year on the news, not only did we have COVID but increasing cases of respiratory syncytial virus. It does cause significant hospitalization and death, particularly in older adults as well as infants, particularly in the newborn period of 0 to 6 months of life. And so we think we'll have a very differentiated product that's accepted by the community.

Now in terms of the next steps, we have, as Mikael Dolsten has communicated earlier this year, plans to do additional studies in patients at high risk from 18 to 60 years old as well as from 2 to 18 years old. So we feel that those in higher risk for RSV will be amenable to immunization as well to protect them from hospitalization and death.

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

One incompletely answered question as of yet from a data reveal standpoint is on durability of the benefit here. I think there are scenarios where we could possibly be dosing on an annual basis, which is an inherent sort of public health commercial logic, versus compelling enough durability to perhaps make it every 2 years. Help us understand sort of how we should be understanding what the ultimate outcome of that data scenario and commercial implications could be.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Well, again, the study is ongoing particularly in older adults. But at the VRBPAC, we did release a 2-year data where we showed, I think, about a 70% continued vaccine efficacy there. So we'll have to see how the data play out. But it's possible, you can imagine a scenario where it's every 2-year vaccine, although then possibly the people who are at high risk may want to go for an annual vaccine. We'll have to see how the data play out.

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

Fair answer from the development guy. Ultimately, the question I think investors will be looking to explore as well is given that potential for flexibility on the dosing or different scenarios or populations, there's a bit of a pricing question that would come out, which I'll agree is probably not fair to ask you but nonetheless is something that's quite relevant. And if you had to guess what you think makes sense, again, from the arc of -- including being a clinician and taking care of patients, your wish list would be once a year or once every 2 years?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Well, I mean, I think we have to do what's medically correct. So there's no wish list in terms of the commercial value. I think we do what's medically needed and fulfills the unmet medical need.

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

Okay. Fair and safe. Let's go on into the vaccine portfolio here and think about flu. And here, again, we're trying to actually flex the mRNA-based platform. Talk about the data that you have thus far and your views of likelihood of success for this opportunity because there's some nuances to thinking about flu, picking strains, advantages, et cetera. So talk to us about the profile of your product and how you think it could stack up.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes, sure. So we have mRNA vaccine in development for flu. We haven't revealed a lot of data, but internally we're very excited on what we see. As you mentioned, it's a more complicated virus in the sense that we have 2 against -- 2 components against this A strain as well as 2 components against the B strain. And to get vaccine approval, you need to have vaccine efficacy against both the A and the B strains.

So what we did announce was that we opened an additional study in the Southern Hemisphere. This year in the Northern Hemisphere, just by chance, there were very, very few B cases. And so we've expanded in the Southern Hemisphere to gather not -- additional B cases. And hopefully, by the end of this year, we'll be able to release additional data.

Theoretically, an mRNA vaccine has lots of advantages over a protein vaccine. For example, an mRNA vaccine, first of all, you can, much closer to the time of launch, decide on what strains you want to have. So for COVID, for example, last year with the bivalent vaccine, we were able to go from construct to launch within less than 100 days. With a protein vaccine, that usually takes 8 to 9 months or so. So with the shorter time period, we think you can get -- match the strain much more readily and then potentially have a much higher vaccine efficacy.

So before COVID also, the standard for flu vaccines used to be about 30% to 50% vaccine efficacy, and still about 50% of older adults would get the vaccine. So with COVID now, we know that the vaccines that we developed have 80% to 90% efficacy. And we would hope to see high rates of that as well. You also get some advantages with the mRNA vaccine, not only do you elicit of B cell response, but you also elicit a T cell response.

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

So you made some interesting sort of anchor and adjust type of references to the COVID vaccine. One aspect of that was this element of urgency and actual declared emergency on this. And perhaps the rate-limiting step on being able to come up with another vaccine that was more targeted toward the strain with the less than 100 days was in that environment from a scientific, manufacturing, regulatory sort of fervor and willingness to accept and sort of turn things around. Is that dynamic, that pacing, that tone still valid today? And on the forward when we think about flu, it certainly seems like it would be an advantage in this scenario, but is that practical? Or should we anticipate some tempering of that tempo?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Well, first of all, for COVID, just since we're on the topic, we -- very shortly this week, we should know what the strain selection is for the fall. So that is becoming entrenched in terms of picking the strain in June and then having it ready for launch in September in less than 100 days. And Pfizer is committed to having the next strain available. And we think that for flu, pending the data, if the vaccine efficacy is that much more superior, then certainly, I think the paradigm shift will occur compared to protein vaccines.

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

Yes. And you mentioned paradigm shift. With the COVID vaccine, I mean, there were probably audible gasps in terms of the level of efficacy profile that was demonstrated. We were in a whole different realm. It was like going from immuno-oncology to precision medicine, right, kind of the 30-50 to north of 80%. And all of a sudden, 80% was clearly a B minus, didn't cut it. Is that level of efficacy hurdle the right way to think about for flu?

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William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. Again, I think we'll have to see what the data show. But historically, the vaccine efficacy of protein-based flu vaccines has really only been in the 30% to 50% range. So we think north of 50% will be already a significant advantage.

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

Right. But the 90% for COVID, is that valid as an expectation setter for the flu side? Or are there other parts to the equation here that...

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

I think it's early days. So again, there's 4 different strains that we have to protect against. We'll have to see what the data would look like. But north of 50%, I think, is a good estimate for being an advantage for the mRNA vaccine versus protein vaccine.

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

Okay. And then you said something partly in passing but is worthy of observation, this whole Northern and Southern Hemisphere dimension to it, and there just happen to not be as many cases, et cetera. That's part of the epidemiologic challenge, you're trying to be able to predict that. And so the mRNA platform seems to be more nimble in that regard. How much does that impact what our expectations should be in terms of what the profile in flu could be?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

I'm not sure I understand the question. So essentially, if we can match the strain better, closer to the time, then we think we'll have that higher vaccine efficacy.

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

Okay. But in terms of timing perhaps, can you discuss anything about the Phase 3 readout? I think the preliminary guidance has been about for the second half of this year. Do you expect that will continue to be the case for the data and that we could be thinking about the '24 into '25 season as the one that we hit the ground running commercially?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. So we hope to release data by the end of this year. And hopefully, we'll have ready -- we'll be ready to launch by the '24, '25 season.

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

Okay. All of these vaccines, you're looking to combine them. There's an inherent logic to doing so. But scientifically, not as straightforward. Can you talk to us a little bit about the key considerations in terms of clinical development? And anything about how the product profile might look? Is there any vulnerability of some additive changes when you combine these, particularly COVID with flu, and then potentially in addition, COVID plus flu plus RSV?

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William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. I think ultimately, for convenience sake for patients, we think a triple vaccine would be where we ultimately want to go. So you could get a one-stop shop, one injection, you're protected against COVID, RSV and flu. But to get there, we need to not only have the singletons but then the doubles. And so yes, we do have a COVID-flu study ongoing as well as an RSV-flu study ongoing. So in terms of the regulatory agencies, what they want to see is not only efficacy but also safety and tolerability. So we need to demonstrate that for both components of the vaccines.

And then for new vaccines, it's likely that the regulatory agencies would want at least a year of data before approving a combination. So for example, with the flu vaccine, assuming we launch in '24, '25, we think we have a combo ready for the following season. But right now, those studies are ongoing and we look forward to seeing the data. Again, from a scientific point of view...

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

Right, exactly. I mean we're combining mRNA-based platform from protein-based. And so get a little geeky for us and help us understand what some of the risks and things that you need to make sure that you accomplish and demonstrate when you're actually doing the work to combine the vaccines.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. I mean you need to understand if they're compatible, you need to understand by formulation. For example, if you combine a protein-based vaccine like RSV with an mRNA vaccine, you need to make sure that the protein component doesn't degrade the mRNA component and vice versa. Obviously, if that happens, then your vaccine efficacy would drop for one of the components of the vaccine.

For a double mRNA vaccine, basically, it comes down to how much mRNA can you actually give a patient by -- and not only have good vaccine efficacy but good tolerability. So we do know that the higher doses you go with mRNA vaccines, you can get more reactogenicity. So those are just some of the things that we have to think about.

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

You specifically made -- you want to make sure that they don't degrade the relative components. What evidence do you have thus far, either in early preclinical or early clinical work, that you can share to give us some perspective in terms of what that potential is?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

I think it's fair to say that we wouldn't be in the clinic if we had any issues preclinically.

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

Okay. And then when we think about the arc of the clinical benefit, each individual vaccine component has some degree of durability of the benefit, which can change or which can also be different between the 2 components. So how do you see that potential combination and the durability of benefit when you combine these playing out in terms of what, for instance, a clinician will tell a patient that this is appropriate for?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. Again, I think it's early days in terms of how long the vaccine efficacy will last just as we discussed. I think some of it will depend on how fast the virus mutates. So for example, with COVID, we know that it seems to be at least a biannual strain kind of shift, which is different from flu, which seems to be more of a seasonal thing. So basically, we know that you can get one flu vaccine and that usually protects you for the season. Whereas

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with COVID, the virus continues to mutate. And so even if you had immunogenicity and immune response to the initial vaccine, if the strain changes enough, you still need to get potentially a new vaccine. And then RSV appears to mutate at a slower rate. So I think we'll just have to see how it plays out ultimately with the data.

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

Okay.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

But the triple play is mainly for the convenience. I think patients are willing to get one. We've seen with COVID and flu that people will get a shot in both arms. But if you could ultimately have one shot that protects you against 3 and you don't have to go to your doctor or the pharmacy multiple times, we think that's the most convenient for patients.

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

Okay. Let's shift topic to something that actually became interestingly headline-generative in spite being data that had already been presented, and this is in the obesity space and diabetes with the oral GLP-1. Talk to us about the 2 assets that you have and what kind of data we might expect to see in the second half of the year.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Sure. So I think you all know we have 2 GLP-1 receptor agonists, both danuglipron as well as lotiglipron. Danuglipron was developed earlier, and so we have more patient data on that, and that was the recent publication where we showed significant decrease in hemoglobin A1c, fasting plasma glucose as well as weight loss. And then we have lotiglipron, which is earlier in development, it just came later essentially.

So the main differences, at a very high level, danuglipron is given twice a day, lotiglipron is given once a day. And so right now, both of them are in development. For both molecules, we did do rapid titration to get to proof of concept and show that we actually had significant decreases in fasting plasma glucose as well as weight. But both studies now are looking at monthly titration and ultimately to pick the right dosing schedule to move forward to the Phase 3s. So for danuglipron, we hope to have data by -- lotiglipron, we hope to have data by the end of this year and then danuglipron by early next year.

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

Okay. So the BID danuglipron is a first quarter or early '24, whereas the QD loti, the one that's a little bit further behind in terms of overall development, will have data. Some perspective because it seems as if the communications have been about having these 2 horses in the race and ultimately making a decision to lean in more one versus the other. And so will the datasets have some aspect of comparability in terms of the N, the kind of the protocols, the dosing ranges that are studied? A lot of nodding on your part.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. No, I think we would -- we're doing the studies particularly so that we can pick the winner, so to speak. Again, we want the best dosing schedule with tolerability in terms of the main side effects in this class of molecules, which are the GI symptoms, nausea, vomiting, diarrhea. And then obviously, we want safety and then we want to pick the best molecule to move forward. Moving forward is a huge investment, right? So we want to make sure that we have the right molecule when we move forward with the ultimate studies in both type 2 diabetes as well as obesity.

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

And obviously, there's other leading players out there, Lilly, Novo, developing orals, et cetera. What kind of profile would be adequate in your mind in terms of committing to continued investment? Obviously, the market opportunity is potentially vast. Pfizer was very explicit in their December Analyst Meeting, identifying the full scope of this, put a $90 billion number out there in terms of the broader market. And here, you have these 2 assets that are poised. One will eventually move forward. What is kind of the bogey or the threshold level that you're going to use to decide which one will go forward and also how it will compare at a comparable time point of development with other products that are out there?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes, sure. So yes, we did put out there that it was $90 billion market, and even some analysts since then have gone even higher. I think an oral small molecule GLP-1 receptor agonist will be a new class. We do know from market research, for example, that many people would prefer an oral versus an injectable. Also, most of the injectables are given by endocrinologists and there are a limited number of endocrinologists. Whereas if you had an oral that was safe and easy to give, you could get to all the primary care physicians, just like they prescribed statins.

So I think the profile ultimately we want to match is to be equivalent to the injectables, just a single class. But it's possible that -- we'll just have to see what the data look like and what's accepted by patients and caregivers. But ultimately, we would like to have a profile very similar to the oral injectables as a single class.

The other advantage, for example, of a small molecule is that we don't have any fasting requirements. So that could be an advantage over the oral injectables. And then we've also seen that the peptides are very difficult to produce basically with high cost, whereas a small molecule should be easy to produce -- mass produce, and the cost of goods would be much less.

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

One of your favorite phrases, we'll just have to see how the data reads out, and it's one of my least favorite responses. We'll just keep on asking you going forward. As you think about designing the Phase 3 program, the reality is that there's going to be products that are out there. There's expanding concept of segmentation of the market. Also, there's hypotheses about how these therapeutics will work in the obesity market, in particular with kind of the thought of induction and maintenance kind of thing, standard mirroring that we see in all sorts of like chronic diseases, metabolic, immune-mediated, et cetera.

So with that in mind, help give us a sense for the William Pao view on strategic Phase 3 development given where you are and where the market is and where you'd like to eventually be at the end of those studies?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. Again, you're not going to like the answer, but depending on the data, obviously, we would like to get into type 2 diabetes as well as obesity. I think if you have an oral small molecule, there's also possibilities in the future where you could have an injectable, followed by an oral. There's lots of different kinds of parameters that can come into play.

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

But to be clear, you guys do not have an injectable that's in the clinic or in terms of thinking about a portfolio, priorities on the oral.

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William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes, yes.

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

Okay. And so as a result, are there particular segments of the -- to get to that $90 billion and to actually also get to the high single-digit billion potential scale revenue number that was put out in print on the slides of the December meeting, again, is there a thought of where will these patients come from? Is it just a matter of muscling share and grab because there are so many numbers? Or is there a particular profile, again, you, as Head of Clinical Development, think is smart, is stealth, could position you for an opportunity that could give you some sort of competitive advantage to be able to grab that?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. Again, I think the -- if we want to move into type 2 diabetes as well as obesity, there may be other indications that are secondary to obesity such as sleep apnea or other things that are consequences of obesity. Again, though, yes, I think we have to get primary approval in both type 2 diabetes as well as obesity before considering those additional areas. And I think one other advantage, again, if you can get to the primary care physicians, you can really have an advantage. And then there, Pfizer's powerhouse marketing team can really help get market penetration.

You probably remember that last year, we did reorganize the biopharma organization to have Primary Care, Specialty Care and Oncology. So within the Primary Care business, we already have molecules like the CGRP antagonists for migraine, PAXLOVID is in there, many other molecules. And having a GLP-1 in there would also be an advantage.

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

And then again, as a clinician/scientist in your background, outcome studies, when we're thinking about what seems to be very logical derivatives biologically, clinically with weight loss and potential benefits, cardiovascular outcomes, sleep apnea, et cetera, what is your view on sort of the most likely outcomes trial type scenario? What makes sense to you that you would come to the table at the committee at Pfizer and say, okay, if we get to this point where we're figuring out an outcomes trial, here's what I think is a smart approach for us to take because there's a lot of directions you could go. What would William Pao sign off on?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. Well, there's what William Pao would sign off on and then there's also what regulators would require. And particularly, for example, in type 2 diabetes, they would require cardiovascular outcome studies. And then we've seen also in obesity that there is...

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

So specifically for the obesity side, what are the directions that you would want to go? Because if you look and sort of see what the 2 leaders are in that space, they kind of mapped out slightly different strategies with that. What's the slightly different strategy that you think would be smart?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. I would say, Chris, we're not ready to disclose that.

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

I know. Again. Okay. You're not going to want to sit up here with me next year, are you? That's okay. That's fine. I'll try to be nice. Let's move on to some aspects. We're just coming on the back end of ASCO, you're a former Memorial Sloan Kettering guy, as am I. Harold Varmus, very distinguished time at MSK. Elranatamab, you guys are in the mix, bispecifics here. It seems like a tremendous opportunity, a lot of different players that are out there. Talk about this asset. Certainly, it's fitting within a landscape where people want to see what is the monotherapy profile, and what is this opportunity in combinations given the serial treatments and the multiple, multiple combinations of this patient population. Tell us specifically about elranatamab's profile so that we can distinguish it from the other bispecifics that are out there.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Sure. So elranatamab, we're very excited about that molecule. It's a B cell maturation antigen CD3 T cell bispecific. So it's an antibody basically that brings a myeloma cell together with the T cell, and then the T cell kills the myeloma cell. Multiple myeloma, as you know, is a huge burden, big hematologic disorder for which there's still a huge unmet medical need.

So we have released data both at ASH as well as ASCO this year, about a 60% overall response rate but a very tolerable safety profile. Notably, we have predictable cytokine release syndrome, which is the main side effect of this class of medicines with no grade 3 cytokine release syndrome.

Compared to -- we feel that our MM-3 study, the main one for which we should get approval later this year, does have a much better reflection of real-world patients. For example, we can go down to platelets of 25,000, creatinine clearance of 30, performance status of 2. We have many more patients with extramedullary disease and we have many patients who are even penta-refractory in terms of treatment.

Also this -- at ASCO, we just released new data showing that it works post-BCMA treatment. So whether you've had a BCMA CAR T cell or a BCMA ADC, we showed a 50% response rate. And notably, as a single agent, again, we haven't reached -- for those who responded, we haven't reached a median duration of response or a median overall survival. So we continue to see very, very promising efficacy there. I would note that we have got breakthrough designation and priority review despite another agent being there on the market. And I think that's an independent validation of the excitement about the molecule.

So we do plan to move into earlier lines. We have multiple studies ongoing. So we have triple-class refractory, which assuming regulators approve, that should read out later this year. Then we'll have double-class exposed -- study in double-class exposed patients. And then moving into first line, we'll have a study in transplant-ineligible patients as well as first-line maintenance studies. We even plan to potentially move into earlier lines and then do a number of combinations, some of which we're not ready to disclose.

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

It's really setting up -- obviously, the natural evolution is to migrate into earlier lines of treatment. CAR T has been doing this with quite impressive data. And there's kind of this decision dynamic often of what is the ROI on investing in some of these earlier studies and when can you get there. In particular, how do you feel about these earlier line opportunities, which are really, in many respects, the brass ring, more patients, longer duration of use, et cetera, for a bispecific? Compared to the CAR T profile, what kind of data needs to be presented? What does the profile need to look like to be able to go nose to nose or nose ahead of CAR T?

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. Yes, I think the efficacy of the CAR T cells, the chimeric antigen receptor T cells, is very impressive. However, it takes a lot of personalized treatment as well as manufacturing, et cetera, and there's still limitations to that. I would note that I recently saw some market research which showed that even the BCMA CAR T cells have maybe 2% market share, whereas teclistamab already has 7% market share in the third-line setting. So even in its short introduction, it's already surpassed the market share of CAR T cells. Also notably, CD19 CAR T cells have been on the market since 2017, as you know. But none of them have gotten to first line yet. And in the second line, I think they only have about 6% market share.

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So I think just given the manufacturing and other challenges, it will be very -- and the cost, it's going to be challenging to get to first line. Whereas if you have a T cell bispecific that's an off-the-shelf option antibody that's available throughout the globe, I think it's just going to be much more convenient.

I did forget to mention, for elranatamab, we also have a unique hospitalization schema for our step-up dosing. So we have 3 step up -- 3 doses in the step-up dosing, a 48-hour hospitalization just for the first dose, 24 hours for the second dose and 0 hours for the third dose. And we think, compared to the competitors, that's going to allow you to treat double the number of patients actually by having such a short hospitalization requirement. So again, compared to CAR T cells, that's also a huge advantage.

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

Yes. I think the rubber meets the road, as you just described, with the clinical actual administration requirements, physicians getting comfortable with that. So we appreciate that detail. Less than a couple of minutes left. I just want to do some quick...

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

By the way, also on CD19 CAR Ts in lymphoma -- so again, they haven't had any competition and only recently mosunetuzumab, glofitamab should get approved as well as epcoritamab. So I'm looking forward to seeing the CAR T versus T cell bispecific issue play out in the next couple of years.

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

Okay. Good. And I gave a fair amount of time to elranatamab because when we were over in headquarters last month, Angela, the Chief Commercial, picked this out as sort of like making the podium beyond some of the other stuff that we talked about. So very quick hits. TALZENNA was also data at ASCO, HRR-mutated subpopulation. Discuss your confidence that the combination will ultimately receive a broad label in spite of that suboptimal performance.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Yes. So at ASCO, we released data on the combination of talazoparib plus enzalutamide in metastatic castration-resistant prostate cancer in those with homologous recombination repair gene mutations, which account for about 25% of the population. So the data were very specifically significant, and we do expect a label at a minimum in the HRR gene-mutated population compared to just BRCA1 and 2. That's going to be, we think, about 20% to 25% of the population, whereas BRCA is only about 10% or less of the population.

Right now, the overall survival data, as we announced, is immature. So we're waiting for that, and we ultimately are confident that, assuming regulators approve, that we could get an overall -- an all-comer population down the line.

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

Okay. Felt like we just took a sliver of even the pipeline and the portfolio. And I feel like there's pros and cons, some disadvantages to that. But I do appreciate the opportunity to go more in-depth on some of the near term and kind of the higher profile needle movers. We'll just consider this another chapter in the dialogue that you and I will have at various forums. So thank you for being a good sport. We look forward to your continued progress.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Thanks a lot, Chris.

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

Thanks.

William Pao - *Pfizer Inc. - Executive VP & Chief Development Officer*

Okay.

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