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CONFERENCE CALL PARTICIPANTS

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

PRESENTATION

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

Welcome to our session here at the Goldman Sachs Healthcare Conference. I'll have to let Keira know that we observe that 8-hour, 5-minute time difference between here and London. We're super pleased here to have Pfizer join us. My name is Chris Shibutani. I'm a member of the Goldman Sachs research team covering pharmaceuticals and biotechnology. Pfizer here is strongly represented by the tour de force the R&D group, Mikael Dolsten, who's been heading up that effort for many years now. And the newest member of the team, Dr. William Pao, welcome.

And I think it will be as an introduction. I think many of us are familiar with Mikael, but give you a chance to sort of tell us a little bit about your story, your background. I know you're coming over from pRED at Roche, a little bit of shift in sort of like the stage of things that you're looking at. Give us a sense for what your background and what your mission is, why you're the right guy for Albert to tap you as he continues to shape the C-suite?

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

Sure, Chris. Thanks for having me here. I'm delighted to be here. So by way of background basically, MD, PhD at Yale, then I did internal medicine at Cornell in New York Hospital, and then medical oncology at Memorial Sloan Kettering, where I was a fellow in the laboratory of Harold Varmus, and then we and others EGF receptor mutations at the time as a genetic basis for why drugs like gefitinib and erlotinib work best in patients with lung cancer.

Then we found the T790M mutation as well and then had lab, saw patients, ran trials, then I got recruited to Vanderbilt where I eventually became the Director of Personalized Cancer Medicine as well as the Director of the Division of Hematology Oncology, then I got headhunted and asked to head up oncology for pRED in Basel. So I took the plunge, And then for 4 years, headed up pRED Oncology there. And then for the last 4 years, headed up all of pRED, which included therapeutic areas outside of oncology, including neuroscience, rare diseases, ophthalmology, immunology and infectious diseases.

Yes, so then I got headhunted and got asked to be with Albert. And I did tell him that I had early stage experience, not the CDO experience. And I think he appreciated actually coming in from the outside and taking a fresh look at how development works and really seeing if we could transform Pfizer to even greater heights. And one of the things that really attracted me to come into Pfizer was what Pfizer and Mikael and others had done in terms of PAXLOVID and the vaccine, really working at the speed of science and accomplishing what they accomplished or we accomplished in record time to basically help society get back on its feet.

So it's been very impressive, and the mission moving forward will be to maintain the high quality, but also see if we can be even better in terms of speed and cost and really get patients the medicines that they need.

QUESTIONS AND ANSWERS

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

Right. Now you're coming in at a fascinating transition, one, where certainly the company is not at any shortage of being resourced and yet amongst the many companies in the industry and all the folks in this room, we're all paying attention to sort of what is the revenue profile, what is the patent loss exclusivity exposure that everybody has. And all the companies go through cycles where there's tremendous franchises, but it's that double-edged sword of this industry, where you have this date with destiny, people trying to figure out what could fit in. And there seem to be 2 tools to that in terms of the internal aspects of it in terms of the R&D pipeline. And certainly, we've seen across the pillars, Mikael, that you have, there's been that building process, but now you have perhaps almost boundless access to be able to do some business development, and we're going to be discussing some of those assets, which essentially come from other people's hands that will be transitioning towards yours.

So Mikael, maybe I'll just start in general at this juncture with where you're at, there's a pretty big task. The bar has been set pretty high. I think the team and Albert have not relented from saying, 6% CAGR going through. Also, there's been a lot of leaning in, in terms of the scale of revenues that you think you can develop and post when we get to the end of this decade that will come from business development activities. Talk to us about how you're feeling with this...

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I think it's an extraordinary time, and I'm so grateful to have Will, see him joining Pfizer, bringing new fresh eyes and great partner in thinking how we can both internally and with external assets accelerate our journey. So we build on what we call this light speed experience as a competitive factor with the best internal products or we become a partner of choice for biotech. We have more or less 2 science and commercial engine in the -- coming from the R&D organization, the COVID on its 2 legs of vaccine and pill and prevention and all the other areas that are up for internal/external augmentation.

So we look at how to optimally fill that LOE goal of 25 billion to maintain that steady growth, and that can be both accelerating internal and from business development. And I think we have seen, and obviously, one of Will's great mission, as he spoke to having a clinical development that now have shown twice that we can break barrier, bring quality and speed to unprecedented magnitude that can allow us to look at external assets and see how we can get more out of them in a partnership.

And we have done deals more recently by having an interesting migraine drug that is pending close. We have Arena to bolster our immunology franchise. We had a deal with acquiring ReViral to add on to our RSV franchise in the same way we had a treatment and the vaccine on the COVID and where the Trillium to our evolving blood cancer in oncology. So I think what you will see, we stay steady on our 6 therapeutic areas. We work to drive what's coming from internal. We blend with external, and we look for complementarity. I feel very optimistic that, that goal that Albert put on us, Will and I will succeed to take on. And like always, Albert expects us to exceed the goal. So it's not about delivering. It's thinking big.

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

Yes. Now the body language is remarkable, how much it resembles Albert, probably now that we're back in person as opposed to Zoom, I'm sure you're picking up some key efforts there. When you look, William, at the pipeline and what would be your candid assessment of sort of the needs, where there's theoretically white spaces in terms of where the science is going, but then also, obviously, very important to address the commercial organization, and we're going to talk about some of the business development assets. I see Biohaven as sort of like more of a commercial reach as opposed to going to the R&D side. We can talk about that. But what draws your eye in terms of like, let's address some unmet need, some critical unmet needs.

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

Yes, Chris, I mean, when I particularly look at the pipeline, there's a lot of exciting molecules. I can't go through all of them. Mikael can probably talk about the burgeoning vaccine pipeline.

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

Right. But to be clear on my question, where are things missing? Where is there a bit of an air pocket?

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

I see. So I mean, we're in multiple therapeutic areas. I think we need to make sure from the global product development standpoint that we remain focused on execution, increasing the speed, using the Lightspeed learnings that we've had from PAXLOVID and the vaccine to adopt to other programs where we can really accelerate development there. In terms of scientifically, I think we have multiple plays in oncology. We have multiple plays in immunology. As I said, we also have multiple plays, a huge portfolio of vaccines. So I think we'll continue to look at that and then look at the external landscape to see where we want to fill in and follow the signs.

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

Okay. Fair general answer. So far, you have been very well trained by Chris Stevo. But I'm going to keep asking because I think as you have more labs under around the track and under your belt, I think one of the things that people are looking at very specifically is just trying to understand what the portfolio management and the strategy really is with that, i.e., for instance, you brought in Etrasimod as a mechanism and trying to understand the relatively recent history of how the I&I portfolio has kind of shape shifted.

And there are components. Everyone is talking about combinations, complementarity, et cetera, what do you have, what do you need? So I will persist in asking more about what you need. So for today, I'll try to be a nice guy and give you a pass on that.

Let's shift over to something very top of mind, perhaps driven by the fact that you guys had a news update and we have your partners BioNTech up on the stage yesterday, the inevitability of needing to address things related to COVID.

And let's start with the vaccines, in part because we actually have, once again, the events, perhaps theater, but hopefully just events that are very pragmatic ahead of us, the VRBPAC meetings, FDA's decisions. The big question marks in front of us is we all think about what is kind of Pfizer's revenue profile contribution from these is about boosters that's very much what we're going to see. Maybe you can just remind us about what the update news this was this morning. It was about progress with what you are filing in terms of what type of booster, right, and what the expectation is timelines for the U.S., Mikael, can you highlight for us?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Yes. It's active weeks. I think today are the discussions on the pediatric dosing regimens and I think, once again, the Pfizer vaccine team comes with a three dose, the more optimal dosing for an Omicron environment. I think it's the 10th time or so we have been the pioneers in being first with having those next steps that's needed to protect and vaccinate age groups or the right upgraded vaccine. The upgraded vaccine is about 2 weeks from now. There will be another VRBPAC that want to discuss what should be the schedule for this fall. And we are very prepared and have data that will answer those questions, what would be the advantage of shifting to an Omicron-containing vaccine, whether it's monovalent or bivalent.

We think most experts in the field at the moment tend to believe that going to a bivalent will address the fundamental request to protect against the previous and the current existing strains and to the evolving, rapidly growing Omicron substrains. We will have data on that, encouraging data, and we also have our manufacturing engine ready to go if there is a recommendation and path forward. We can very quickly start to supply some of those anticipated vaccine recommendations for patients you need to make people feel very protected whether it's immediately or in the fall. And I think that's a unique thing with the Pfizer and the vaccine side, our end-to-end capability from the science in the lab to very large dosing supply for billions of people worldwide.

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

Okay. Let's keep it to this upcoming VRBPAC meeting, which I think is at 28th, exactly 2 weeks, et cetera. I think what I heard you say is that we expect to see data on an Omicron-adapted booster. The phraseology adapted is one that I think the partners at BioNTech use as opposed -- as well as the bivalent vaccine. And I think one of the questions is going to be as -- which I think I heard you say that the group will be addressing is the question of which will be the recommendation. Do you have any insight into what framework, what the basis of that decision will be and how they will -- the questions?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Yes. I think on one hand, we are open-minded and are prepared to respond to multiple scenario that FDA and VRBPAC may decide upon. As I said, I think most experts in the field that have been part of the public dialogue seem to gravitate towards the bivalent vaccine of the current and the Omicron.

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

But the agency themselves and this group VRBPAC, what do you think...

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I think they're here to look at that data.

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

Right. And how will they look? Do we have anything to share?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Yes, absolutely. I think they will look at like always, do you have similar protection as the wild type for previous trains with the alpha, delta type of strains? Do you have any better immune response towards the new strains within the Omicron family that would warrant strain adaptation to the current environment? And of course, overall performance of your vaccine tolerability reactogenicity. And we have always, I think, been very skilled in choosing a dose that gives good protection and premier tolerability. So that will weigh all of that in as a foundation is that we have shown several times that we can upgrade with variants and generate the same platform, tolerability and immune response. Now we will show data specific where you have Omicron mono or Omicron as a bivalent. So we are prepared to go and look forward to the path forward provided.

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

Okay. No, that's helpful. Let's just a little bit to thinking about the future as we do our projections. Ultimately, I think they agree that we're still in a pandemic state, but we're transitioning. In an endemic environment with '23, '24, '25, let me just put that out there, what is your house view? What is your view in terms of what the frequency of boosters that you think we'll need, annual and for which -- for everybody?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Great question. A minor thing, actually traveling here, Will and I had a really stimulating discussion that the term endemic has been used to describe how we move from this overwhelming pandemic to the future, but endemic actually means that the infection is localized only in certain regions. And what we really have seen over the last period, the pace of evolution with mutations of the virus, the difficulty to contain it in an open society

is that we are going to have a continuous new normal with a pandemic that we can contain through vaccine, through treatments like PAXLOVID from bringing excess hospitalization and bad outcomes for patients.

So I think we will see an opportunity for the type of VRBPAC that will do an annual recommendation on how to optimize vaccines, and we are constantly investing to improve the technology behind the vaccines to be able to respond to such needs. But there may be certain risk groups and particularly if you start to see this continued rapid pace where it even maybe twice a year cycles with new variants. So for certain high-risk groups, there may be an opportunity for twice a year vaccination to protect them. But for the majority of people, I think we will aim for an annual vaccination.

The good thing is, of course, if there are breakthrough infections, if there are new anticipated strain coming, we have shown that PAXLOVID seems to be active across all of those Strains and would provide a very good treatment strategy, and we're very pleased with the U.S. government Test and Treat and we have responded to that challenge.

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

Okay. That's perfect. And naturally, I think investors are going to have questions in terms about like the order book in U.S. and transition to the private market payers, et cetera. These are a lot of the questions that I actually asked to the BioNTech folks, where there was the partnership here and there is commercialization. I do want to capitalize on the fact that you guys have an R&D focus. So I'll keep my questions focused there. So let's transition over to PAXLOVID, this phenomenon that we're seeing perhaps the rebound, right?

Talk to us about what you think is really happening in the real world and how that compares with the clinical trial experience. And I know that you've commented previously that you believe that it's a bit of a sort of a media echo chamber phenomenon. But it is something that, nonetheless, I think that you're looking at extended dosing, redosing, et cetera? How real is it? Talk to us about this redundant?

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

Sure, Chris. So just let me start first. I think most people know that PAXLOVID has shown tremendous benefit from the EPIC high-risk study that we conducted, we showed a 90% risk reduction in terms of hospitalization and death in patients with potential for severe outcomes, high risk for developing severe outcomes from COVID. We continue to see that in additional data that we've seen that there's a benefit. And we believe that about 40% to 50% of patients in the United States actually meet the definition of high risk according to the CDC.

So we think there's a tremendous benefit. There's been over more than 1.3 million prescriptions now for PAXLOVID, and it actually has about more than 90% market share. So we think that it's bringing a lot of benefit.

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

So rebound, tell me about rebound.

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

So in terms of rebound, so there have been social media phenomenon followed by media suggesting that there are some patients who take PAXLOVID and then potentially have a rebound of symptoms. So we've taken a detailed look in our EPIC HR study and looked by a definition of if you had basically viral load decrease below level of detection at day 5 after treatment, and then if you had a half log increase at day 10 to 14. So in our data set, we see about -- in our definition, we see about a 2% rebound rate in the patients that got PAXLOVID and then a 1.6% rebound rate in the patients who actually got placebo.

So first of all, we don't think it's anything specific to PAXLOVID but something that has to do with COVID-19 in general. And second of all, the most important thing is the patients who did develop rebound, none of them had hospitalization or deaths due to COVID-19. So clinically, it may not be -- it may be annoying but may not be relevant in terms of severe outcomes.

Finally, we've taken a look in terms of molecular resistance and we also haven't seen evidence for molecular resistance. Now notably, you probably saw the media report yesterday and there was a publication from The Mayo Group which also took a look at about 487 patients, high risk who got treated with PAXLOVID, similarly, they had a very, very low incidence of a rebound. So what we think is it may happen, but at a very small patient population, and it may not be relevant in terms of severe outcomes and also, we're not seeing any resistance.

Now in terms of additional studies, we are going to be looking at patients potentially who are immunocompromised that may benefit from longer courses of treatment. Currently, it's approved at 5 days, and we will look to see, for example, if 5, 10 or 15 days might be a more appropriate course in some patients, and we have to see the data.

I would just remind that PAXLOVID has only been around for 4 months now or so, maybe 6 months, I guess, and was developed in record time, and we're still learning about the virus as we go along.

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

Right. Some of the -- still learnings that included an update yesterday on the standard risk population data that question whether or not there was a meaningful benefit. Talk to us about whether or not you see an opportunity to move forward in that indication here. And it doesn't come necessarily as a huge surprise, you kind of presaged it with this question of your clinical symptom improvement, which you didn't expect to hit. But now we have this sort of data package here, standard risk population? Does this go forward? And if so, how?

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

Sure. I did just want to add a couple of points from the previous point, which was -- there was some speculation whether it was Delta versus Omicron their new data sets now. For example, they're published from Israel as well as preprints from Hong Kong that suggests that PAXLOVID is equally effective against Omicron. So we don't think it's also just specific to the variant in terms of potential rebound.

So you asked about the EPIC-SR study. Yesterday, we did announce that we ceased enrollment. We'll continue to study the data that we have on the patients. This is patients who had standard risk. Most importantly, even though we didn't hit the primary endpoint, which was time to symptom alleviation, which was a novel endpoint that we were working closely with the NIH on, I think now we've learned over time that maybe viral load and symptom correlation don't correlate very well with COVID-19 as opposed to other viruses.

If you look at hospitalization and death, we still saw a 62% reduction in -- well, in patients, overall, we saw a 62% reduction in use of medical care related to COVID-19, which is significant for the entire system. And that was a prespecified secondary endpoint. Also in the vaccinated patients, although it wasn't statistically significant, we did see a 57% reduction in hospitalization or death. So we think the overall package is still consistent with what we've seen in EPIC-HR and that PAXLOVID was still bring benefit to patients.

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

So we'll continue to push it forward. But based upon the profile of what we've seen, likelihood of seeing use in that population, you believe would be?

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

Yes. So I think we stand by the fact that we have an EUA in patients with high risk, of which 45 -- 40% to 50% of the U.S. population could benefit from that. And overall, we've seen the death rates really not increase over time in the U.S. and elsewhere since PAXLOVID was introduced. I know that's not a direct correlation but...

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

And as R&D guys, work probably continues, next-generation version with PAXLOVID, perhaps one that might not require ritonavir booster, update us on where we're at and when, if anything, we'll learn about.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Yes. No. I think as Will alluded to, a tremendous lots of information coming forward here. And just to tag on, standard risk study data that is encouraging will be included with high-risk study for BLA filing to bring the drug beyond EUA that's now the next step for us. PAXLOVID play a tremendous role in this large population that is the one that right now are exposed to the risk of hospitalization and bad outcomes and whether they are vaccinated or not, we do have data.

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

But on the next generation...

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

So the next generation, I think, is very -- we have made a lot of progress -- we have kept the particular feature of PAXLOVID in the next generation to be resilient to resistance, which is unique for PAXLOVID. I want to say we have seen a lot of other early emerging protease inhibitor drug in the clinic in our hands, the feature of PAXLOVID to have a high barrier for resistance is unique to that drug, some specific chemistry design by our chemistry platform that was put into it. And we have been able to preserve that to the second generation, and we are able now to see drugs that are on the path to and hopefully dosing later this year that will not have ritonavir included.

I do think that those could add further growth, supplement the role in additional populations. And it could be specific populations where there could be an advantage, although I want to say the feedback we get on PAXLOVID is so robust, so positive, but there may be a few percent of the population that for them, the drug interaction is something that delays the decision to start. It's -- we think it's less than 5%. And the second generation could offer some interesting advantage. And we will also think whether there are opportunities to go back into segments such as prophylaxis, where we have learned more. So we see growth of the overall portfolio, but think PAXLOVID will be a central pillar supplemented by a second generation.

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

Okay. Great. Watching the clock here and buckle up. There's a lot of pipeline stuff I want to hit. So let's move on to mRNA flu trial. So vaccine proof-of-concept study, what's your level of confidence in the outcome for that in light of what we've seen from competitors?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I am very encouraged by our mRNA flu vaccine. We are generating, as we speak, Phase 1/2 data. And we're, of course, building on the strength of the platform. And we have been able, as you know, to design a platform with BioNTech and the dose that give a very favorable tolerability of our vaccine, which I think is unique to the Pfizer/BioNTech vaccine, reducing that dose regimen in order to target the 4 quadrivalent strains of flu. And

I think our target profile, which I'm optimistic about, is to create a differentiated vaccine versus the current protein base, differentiated in being able to have higher immune response to some of these important strains and to have a good robust tolerability. That data is evolving, and I'm optimistic that we'll progress in a near future into pivotal studies with an mRNA flu. And as part of our plans, we continue also to develop next generation of mRNA, self-amplified that can build a platform for incorporation of a large number of respiratory virus diseases because you can lower the dose even beyond the 30-microgram range that we have used for adults by maybe a factor of 10 or more.

So near term, an opportunity for mRNA flu vaccine to be better than the current, the best-in-class, that's our aspiration, followed by further new technologies coming behind it.

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

Okay. Got it. Vaccines continue to be the platform, the pillar of really primacy for you guys. Let's move on to RSV, adult setting, where do you see your vaccine potentially differentiating from competitors and I'd be referring specifically to J&J and GSK.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I think we're building a very exciting RSV franchise with 2 vaccine indication and the recent acquisition of ReViral that have 2 therapeutic agents in clinical development. I just wanted to punctuate that we are the only RSV vaccine for maternal indication, which has a high unmet need after a competitor failed with their vaccine. Our data has been very encouraging, and that data will read out in this fall. We continue to make progress to soon conclude according to plan our RSV adult study. I'm encouraged about the recent data from other companies, further strengthening what we have published that this RSV prefusion glycoprotein that's used as the antigen will translate to good efficacy. So that gives further confidence. We are the only one that actually have a vaccine that's bivalent that cover RSV A and B that has an opportunity to give a more balanced response, and we do not have either viral component as one of the other companies, nor adjuvants that may create reactogenic issues and lower the compliance.

So that's really the profile we're going for. I think it could be best-in-class coverage of the RSV strains, best-in-class for tolerability. I'm really looking forward to the readout that's coming pretty soon.

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

Yes, we are as well. And there's a question, I guess, in this environment, this new normal, as you characterized before. The case rates and its implications in terms of the enrollment that you were seeing, I think, that was expanded recently over the past few months. What's your level of confidence that you'll have sufficient cases by the second half of this year to enable reporting of data RSV again.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I'm very confident we have seen a good pace now and are very close in the adult. And in the maternal, it's not just about getting enough cases, we want to be able to have the potential to show a very descriptive broad label when it comes to activity against whether you have a moderate disease, severe disease, durability of the vaccine, particularly for protecting newborn. So all those quality features were part of our decision to create a very data we see and it's moving very well now, given our loan experience how to run such large studies as these 2.

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

Pivoting over to Etrasimod. I think we're familiar with the data that was updated at DDW. And certainly as a public company, Arena shared some anticipation there. We had some positive results. But to go into some of the details in the UC12 portion of this population, right, the percent remission, the delta versus placebo was relatively narrow and arguably because the placebo group outperformed insights into why that was the case. We didn't see that in the other -- the maintenance 52 weeks...

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

Sure, Chris, we recently reported the results from 2 Phase 3 studies at DDW, right, the UC52 study as well as the UC12. Importantly, all the primary endpoints were hit as well as all the secondary endpoints, and they were all statistically significant.

So in the UC 52 at 52 weeks, we had a 25%-plus delta between -- in terms of clinical remission rate. And then in the 12-week part of the UC52 study, we had about a 20% delta. Now you're talking about the UC12 study where there was only about a 10% delta, we're looking at the reasons potentially why that's the case. The UC52 study was more consistent with the Phase II OASIS data. Possible reasons for why the placebo rate was higher in the UC12 study could include actually COVID-related precautions. So UC52 was started first and then UC12 was started later during COVID, and then they ended up at the same time point.

So obviously, during lockdown and with people avoiding other people and other environmental -- being less environmentally exposed, potentially, the triggers for UC were changed, and we need to look at that. But we're also looking at other covariants and other variables that might have affected that rate. The important thing is the overall endpoint was met, and it was statistically significant, and we're confident that Etrasimod has a potential best-in-class profile that could move into not only moderate to severe ulcerative colitis, but even into earlier lines.

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

And with that profile, for instance, the regimen you didn't have to titrate up compared to the existing approved drugs ZEPOSIA, your confidence in being able to get a differentiated label would be?

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

Yes, it's a great question. The way the trial was going, we did not have any titration. Patients started at 2 milligrams immediately. We saw a very good safety and tolerability profile, particularly related to cardiovascular issues. So we will work with regulatory agencies, and we're confident that we can get a label without titration.

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

Okay. Cool. In Arena's hands, I think we think about additional indications. The I&I sort of playbook is about it's the molecules are a gift that keeps on giving, right? You have UC, you have other indications under Arena hands. I think they talked about having Crohn's disease data in the second quarter. There was a bit of a misstep hiccup in the atopic dermatitis trial, and they're going after a bunch of these other sort of more boutique indications, which is probably pejorative to say, but eosinophilic esophagitis, alopecia areata, et cetera. With the UC data in hand, what read across should we think about for Crohn's and AD, Mikael?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I think the UC data, of course, confirms what was our confidence in the decision to make the deal, but needed to be confirmed. It's a molecule with robust efficacy and as William so nicely outlined, good safety tolerability. So I think we should have even more encouragement across Crohn's disease, which, of course, have some related, although it's a distinct disease. And of course, the profile of the drug, that there is no need for titration, makes it also look even more attractive for some of these other indications. So we'll take one trial by itself. You can never be certain until you turn the card. But overall, I think it has strengthened the prospect of this drug.

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

Okay. Historically, cardiometabolic and I'm just racing the clock here, huge presence in the cholesterol modification realm, other aspects there. Danuglipron is arguably one of the topical assets here in the clinical pipeline. Talk about your confidence in being able to position this, the role of an oral versus injectables. What is driving the level of sort of enthusiasm within your group?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Yes. I think the ability to design a molecule, a small molecule that can mimic what a large peptide is doing so efficiently builds on all the experience on the peptide side but makes it now much more convenient.

We have seen good robust efficacy on Hb1c. It's [1.6%, 1.7%]. And we see ability to go beyond 5% body weight reduction with just short-term use 12 to 16 weeks. So we think this drug have an upside to become, by far, the most useful drug as an oral segment, and it can compete with equal footing to any of the injectable in this class. So it's really 2 great segment that we would like to see Danuglipron, including a sibling drug to it that could be a once-a-day phenomenon.

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

Help further my neurosis as an analyst, what's the next data point catalyst that we can look towards?

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

We have a readout early next year for an obesity trial, and we will be kicking off another trial to firm up dose titration later this year and preparing them for Phase 3 plans as these roll on.

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

Okay. Great. everybody is paying attention to the space quite closely. Rare diseases, provide us with an update on where you are now that we've had the FDA lift the clinical trial holds on the DMD and Hem-A studies.

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

Yes. So as you know, we had a clinical hold on the DMD study, but the FDA leave that, and we are working very actively. Hope we have multiple or if not all sites open by June. We already have one site now open in the U.S. And we hope we are very encouraged that we'll be able to hopefully enroll all the patients by the end of this year and then potentially file by the end of next year.

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

Okay. We're coming off of ASCO. One of the data highlights in oncology was Elranatamab bispecific, right, BCMA CD3. How do you compete white play in multiple myeloma?

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

Yes. I mean I think the data for BCMA TCP/Elranatamab look very, very promising. We showed a 60% response rate in a very refractory population, triple-class refractory in multiple myeloma. Also, we had a very good safety profile, particularly with the step-up dosing, we had controllable CRS and mainly Grade 1, a little bit Grade 2, but importantly, no Grade 3 CRS and very little neurotoxicity. So we think this is a very promising molecule. We're moving into earlier lines. Notably, in the design of our Majestic MM3 study, we had a more inclusive patient population more reflective of

the real world. We think, compared to competitors. For example, we can include patients with creatinine clearance down to 30, with platelets down to 25 and ECOG of 2. So we think that, again, that will reflect a more real world population, and we are planning on moving that into earlier lines.

We also plan potential combinations, for example, with other molecules within our pipeline and hope to build a franchise in myeloma.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Just to one -- I just want to add to what you said so well. So this has showcased how we can bring internal and external products together since that was one of the opening questions Elranatamab was designed with a Pfizer proprietary platform. It's 1 of the 2 leading out of a whole set of pharma by functional have shown it's been at the real frontier of science, Pfizer-originated, one of the combination we're looking at is the CD47 coming from the Trillium acquisition. So it really goes back to what you said. We're bringing together internal and external science to create unique patient options here.

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

And then so then to close, there's one I have to ask based upon recent news, Biohaven, obviously, migraine fascinating commercial opportunity, commercial. The way the deal was structured was, in fact, to have commercial rights and yet sort of the R&D pipeline that Biohaven has continues as a separate entity because I think explicitly, Pfizer opted not to take that as part of the structure. So should we interpret this as sort of like CNS as being one of the pillars from R&D is -- is it a priority? Is it not a priority? Because in the context of everything that I just said, are we rebuilding and getting back into sort of CNS R&D or...

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

I think we are picking the areas where I think we can be a winning company like migraine is in the intersection of CNS and a vascular disease and where it can utilize on the commercial side our tremendous primary care footprint. And we can, hopefully, through medical and commercial resources, be the preferred patient and physician engagement there. There are some other assets that we thought fit better in the hands of a biotech that can go really deep on some difficult areas and hopefully make progress. But we are also present in some genetic rare disease in the neurology setting where you could include DMD. We have program in ALS, Huntington, but these are related to single gene disorders where we think for a company like us, it's mature to go in and make a contribution while some other areas may need more science, and we try to deploy our resources very thoughtfully to make the contribution the world needs.

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

Okay. And with that closing comment, thank you very much for Pfizer and the contributions to many of the ways that the world need. We look forward to continued dialogue with the 2 of you about the pipeline and looking out for the balance of the decade. Thanks, everyone.

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Thank you very much.

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

Thanks, Chris.