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PRESENTATION

Jami Rubin - *Goldman Sachs - Analyst*

Okay. Good morning, everybody. We're going to kick it off this morning with Pfizer and I am pleased to host a session with Geno Germano, who is President and General Manager of Specialty Care and Oncology at Pfizer, clearly, probably the most exciting division at the Company today.

So, Geno, it's a real pleasure to have you. Before I begin, I'm obligated to read disclosures. We are required to make certain disclosures on public appearances at Goldman Sachs' relationships with companies that we discuss. The disclosures relate to investment banking relationships, compensation received or 1% or more ownership. I'm prepared to read disclosures for any issuer now or at the end of this call if anyone would like me to, but again, this is not a really good time for that. However, these disclosures are available in our most recent reports available to US clients on our firm portals.

So, with that, Geno, just as a reminder for everybody here for Q&A, Geno again is responsible for, if I think, some of the most exciting parts of Pfizer's pipeline and commercial opportunities, including the vaccines business, oncology and immunology with Xeljanz. So, again, real happy to have you here.

I'm going to just sort of launch right into it. We've got a whole lot of material to cover and I know Eliquis is not under your purview, but I think everybody here is interested in your perspective of the launch trajectory today. I think some of us are a little bit surprised, given the strength of the label, the strength of the field force between you and BMS and that's why I think that the trajectory is a little bit may be below what some of us had anticipated. So, just as a commercial guy --

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Yeah, sure.

Jami Rubin - *Goldman Sachs - Analyst*

I'm interested in your thoughts on that.

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

So, I think, in general, we're actually not disappointed at all with Eliquis. We'd love to see it go faster, but the profile of the drug is very, very strong as you mentioned. I mean we have the superiority on stroke prevention, on all-cause mortality and major bleeding, which differentiates our product from the other products in the category. And I think that's being recognized more and more everyday by the physicians that we're talking to.

If you think about the dynamics of the market, you have a well-established therapeutic approach to these patients that was well ingrained for many, many years and you had a couple of new entries over the last few years. And so I think some of the low-hanging fruit has been kind of taken by the entries that came before Eliquis. I think ultimately we have the data, we have the product with the profile and ultimately, I think that the Eliquis will be the leading product in the category.



Right now, we're focused on fundamentals, getting the formulary placements, getting reimbursement in place and getting physicians comfortable and knowledgeable about the product profile and I can tell you the progress has been really good. From a reimbursement standpoint on the commercial side, we have about 80% to 90% of lives are covered. On the Medicare side, it's probably between 70% and 80% coverage. And then in hospitals, importantly, a significant proportion of patients are started in hospital and getting hospital formularies in place takes a little bit of time.

We're having great success. We see a continued adoption within the hospitals as these formulary committees meet and make decisions. So, there's really no red flags out there. It's just a matter of getting things in place and picking up and really it hasn't been that long since we've been in kind of full-promotion mode. So, we're pretty comfortable. We think that ultimately the profile will prevail.

Jami Rubin - *Goldman Sachs - Analyst*

What is your timing of your DTC campaign? Is that something that you're planning to do soon?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

We will do DTC for Eliquis. We generally will wait for a six-month period before launching DTC, but it won't be too much longer.

Jami Rubin - *Goldman Sachs - Analyst*

Okay, great. So, again, more of a high-level question, given the position that you have at the Company, just curious to know what operational changes you have seen in your business units that would get Pfizer closer to a full separation of innovative and established businesses along the lines of what Ian and you and others at the Company had been discussing publicly? And just what are the key challenges to accomplishing a full breakout from what you see from your perspective?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Well, our model today is already somewhat of a hybrid model. I mean we have, in the US and Europe, almost separate businesses already and then in the emerging markets, it's more of a kind of a combination of innovative and value businesses. So, we have some experience, because we have the two different models that work today. And I think from a commercial standpoint, it's not a massive effort to separate the businesses and realign, so that we have an even more focused operational approach to these two business types.

I think the challenges, from a kind of a full separation over time, would involve the supply chain and in the way that we manage shared services throughout the organization. And I think it's tricky there, because you want to be efficient and you don't want to create duplication, but some of the same operational capabilities are necessary to support both businesses. So, those are the things that we're kind of working through.

Jami Rubin - *Goldman Sachs - Analyst*

Are you on target to make a decision about how to manage the emerging markets' business this year, whether that would be managed as a geography or managed as a separate innovative versus value business?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Yes, we're in the evaluation stage. So, I think you'll be hearing more as the year progresses.



Jami Rubin - *Goldman Sachs - Analyst*

Okay, good. So, let's move onto vaccines, which is probably the biggest chunk of the revenues that you are running and vaccines came from Wyeth, which is where you came from and I think it's around \$4 billion in sales and again one of the most important growth platforms for the Company. And also with a pretty neat pipeline right behind it, meningitis B and staph aureus, just from a high-level perspective, right from the days of Wyeth, I don't recall there being much of a pipeline at Wyeth. And I'm just curious to know what has happened at Pfizer in R&D since you've joined, since the merger in 2009, which has led to a broader vaccine pipeline?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Yes. Well, I think Pfizer identified vaccines as a key asset from the Wyeth portfolio and I think it was one of the parts of the Wyeth acquisition they were most excited about. So, in bringing the companies together, they, I think, took very prudent steps to ensure that there was an appropriate allocation of resources for the vaccines research organization, did a great job of maintaining a lot of the talent that was in the organization. And I think, frankly, with my experience, I ran the vaccines business years ago, and in it spent a lot of time with the other vaccines companies in the industry and I can tell you, I think our research talent in the vaccines area is among the best in the world certainly.

And there were -- actually some of these programs did have their origins at Wyeth. I mean the meningitis B vaccine and the staph aureus vaccine was in the pipeline of Wyeth. It was just really early and it probably wasn't getting as much attention and as much resource as it needed. And so, I think Pfizer being excited and enthusiastic about vaccines put the pieces in place to ensure that we will be able to move forward and then expand it beyond the prophylactic vaccines into therapeutic vaccines. So, we have the anti-nicotine vaccine that we're working on and a vaccine for asthma and anti-immune IgE vaccine and even experimenting with some oncology vaccines.

Jami Rubin - *Goldman Sachs - Analyst*

Prenar 13 is again around a \$4 billion franchise today and most of those revenues are for children, the pediatric indication, but it seems to me anyway that the growth opportunity in the franchise is with adults. Can you help us to think about this franchise because Prenar has also been quite lumpy recently as well and we're waiting for new data to expand the adult indication, but talk to us, how do you see this franchise over the next three to five years?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Yes, I mean, obviously, Prenar is I think clearly the most successful vaccine ever been developed and it is about a \$4 billion business today. We do think there is still some room for growth in the pediatric market, primarily in emerging markets. We're pretty well established now in the major developed markets, but we do see some continued opportunity for expansion in China and some of the other emerging markets, but you're right, I think the adult opportunity is really substantial. The disease burden is significant. There is between 600,000 and 800,000 cases of community-acquired pneumonia caused by pneumococcal pathogens that are covered by our 13-valent vaccine.

So, the health benefit, the financial benefit of preventing those infections is pretty well established, so, I think the opportunity is. I also think that we're going to see an expansion in the use of adolescent and adult vaccines in the future. I think there's a lot of environmental factors that are supportive of that. I mean, first of all, there are more vaccines that are being developed and introduced for adolescents and adult individuals, number one.

Number two, the infrastructure is changing. You're seeing more vaccination occurring in pharmacies and in urgent care centers and many clinics and things. So, availability of vaccines, without having to make an appointment with your doctor, it's going to be easier to access vaccines. I think with reimbursement in place in a lot of places, again recognizing the value of vaccines, reimbursement is generally pretty good. And then I think consumers are just becoming more aware of the importance of taking ownership and responsibility for their own healthcare. And as they start to recognize this is a good thing for me to do, I think that all those factors will lead to a greater adoption of again adolescent and adult vaccines.

Jami Rubin - *Goldman Sachs - Analyst*

So, let's talk about the CAPiTA trial, just to say, a large 85,000-patient outcomes trial that's being conducted and I believe, it's The Netherlands, designed to show that Prevnar 13 can prevent pneumonia. Talk us through this trial, when it reports out and what a positive outcome would mean to the franchise?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Right. So, this trial has been ongoing for a number of years and it's an event-driven trial, meaning there are 85,000 -- roughly 85,000 patients and half of them been vaccinated with our vaccine and half of them not. And as cases occur, as community-acquired pneumonia cases occur, they are evaluated to determine whether -- what the causative pathogen is. And there is a process of evaluating that patient and evaluating the causative pathogen that takes a little bit of time and then it has to be confirmed that if it's a pneumococcal pathogen, whether it's one of the serotypes that's within the 13 vaccine.

So, as cases occur, they are categorized on the basis of what the causative agent is and whether it's pneumococcal or not. And we accumulate these cases and based on the statistical analytical plan, we know how many cases we have to accumulate before we can determine whether or not the vaccine is having the intended effect. And we're getting very close to getting the final number of cases that we need. We anticipate that we'll have that by the end of this year, hopefully sooner.

We tend to have peaks and valleys in the rate of accumulation. So, sometimes, we get a bunch of them and sometimes, a period of time goes by, we don't get many, but based on our projections right now, we think that we'll have the required number of cases by the end of the year.

Jami Rubin - *Goldman Sachs - Analyst*

And this is a pretty robust flu season all over the US and Europe.

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Right.

Jami Rubin - *Goldman Sachs - Analyst*

And I seem to recall a conversation I had with you or Ian or somebody that if we did get a robust flu season, then that trial would likely report out even earlier than anticipated. Doesn't seem that that's happening. Is there anything to read into that?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Yes, I don't think so. I mean, as I said, we do have peaks and valleys in the number of cases that we see and I think we have seen an uptick in the number of cases that would be associated with a period of time that corresponds to the flu season. So, I do think that that association of a robust flu season in more cases is panning out. There is a delay from the time that the flu season occurs to when you actually analyze those cases and identify them though. So, we're moving along.

Jami Rubin - *Goldman Sachs - Analyst*

And so, if it's positive, what will that mean to the franchise?



Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Well, I think that -- our expectation is that the data will show that the Prevnar prevents community-acquired non-bacteremic pneumonia and then that will be -- that will establish Prevnar as the only vaccine that's able to do that. And this is where there's a significant disease burden, because we have the invasive disease and then you have the non-invasive disease and both Prevnar and the polysaccharide -- pneumococcal polysaccharide vaccine have effectiveness against the invasive disease.

We think Prevnar has an advantage there, but suffice it to say there is some protection there. It's in the community-acquired disease, where there doesn't seem to be the same level of protection. So, if we were able to establish that you have that protection, then we think that will mean that recommending bodies will preferentially position Prevnar as the pneumococcal vaccine for adults. And once those guidelines are in place, in the United States with the ACIP guidelines, then it will be much easier to drive the adoption of the vaccine.

Jami Rubin - Goldman Sachs - Analyst

So, let's move on to that meningitis B trial, how is this vaccine different from Novartis' vaccine? And help us to think about the commercial opportunity, is this something that would have the magnitude of importance as Prevnar 13 or how should we think about it?

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Well, I mean it's a different -- I mean simple way to think about it is -- I mean it's a different construct. It's a different vaccine. And we think that because of the construct of our vaccine, it may have a broader coverage -- broader spectrum of coverage. So, just like there are different serotypes in pneumococcal disease and meningococcal disease, there are a whole range of different strains or sub-types of meningococcal B pathogens. And we think that our vaccine has the potential to cover a much broader range than Novartis' vaccine. It's just based on the construct of the vaccine. We'll have to demonstrate that, but we think based on what we know, that that'll be the case. So, we think it'll be a vaccine that has more value and has more coverage.

The second biggest difference is that we're developing our vaccine for adolescents and young adults and that's important, because these are the individuals that are not only at the highest risk for meningococcal B disease, but they're also carriers of meningococcal B organisms. And so in a way, if we can vaccinate a large subset of those patients and if the vaccine is effective at preventing the carriers, then you actually have a reverse kind of herd effect and you'd be protecting infants and neonates. And for instance, the highest incidence of disease is in the very, very young neonates and you can't vaccinate them.

So, the best way to protect them is actually by reducing the carriers in the younger kids and preventing the transmission of the organism. So, two differences, we've different construct of our vaccine, we think it will result in a different pattern of coverage and a different patient population that we're going after. The mening B adolescent population is also a population that gets vaccinated with the quadrivalent, the meningococcal quadrivalent vaccines. So, it's an already established practice of vaccinating those individuals. So, we think that that could be an advantage as well.

Jami Rubin - Goldman Sachs - Analyst

So, how large is the trial, how long will it -- I mean, it took a long time to go from Phase II to Phase III, like a couple of years I think.

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes.

Jami Rubin - *Goldman Sachs - Analyst*

So, now that you're in Phase III, I believe, what will be the critical development path forward look like?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

So, it will take a few years. I mean these are large trials. There's three Phase III trials and it will take a couple of years to complete those trials and then analyze and report the data and have the regulatory review process. So, we're looking at probably three to four years before introduction.

Jami Rubin - *Goldman Sachs - Analyst*

And how many patients do you need to recruit?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

I don't remember off the top of my head.

Jami Rubin - *Goldman Sachs - Analyst*

Okay. So, you then can get back on that.

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Yes, we can get you that information.

Jami Rubin - *Goldman Sachs - Analyst*

So, the staph aureus vaccine is also exciting, but also I think a difficult area, we've had failures of this type of vaccine before. And again, why are you confident with yours when I think the most recent was the Merck vaccine failed and a positive again, how do we think about this opportunity?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Well, remember, I told you we had great talent in our R&D organization. I think we have a great vaccine. I mean the Merck vaccine was a vaccine that targeted a single virulent property at the staph aureus organism. Our vaccine is a quadrivalent vaccine. So it targets three different virulent processes. And we think based on what we've seen pre-clinically and in early clinical trials it is going to be effective in preventing this disease.

So, we're completing right now the Phase II work and we'll be reporting that out this year and then we're -- actually at the moment, we're involved in discussions with regulators around the world on the path forward. Our goal is to identify a patient population that would be representative of patients at high risk, demonstrate efficacy in that patient population and then look to expand to other patient population through the establishment of the relationship between immunogenicity levels and efficacy. So, to provide additional safety information and immunogenicity information in other patient population as opposed to having to repeat efficacy studies over and over again, that's our goal.

Jami Rubin - *Goldman Sachs - Analyst*

So are these patients that are being hospitalized, or at risk --?



Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes, elective surgeries, hospitalized patients, patients at high risk.

Jami Rubin - Goldman Sachs - Analyst

So the idea is that these patients are admitted that they would get the vaccination.

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Well, the idea is initially, it'll be elective surgery. So, you'd be vaccinated ahead of being admitted for the surgery. And then over time, we see the potential to expand beyond these elective surgeries to other high-risk patient populations.

Jami Rubin - Goldman Sachs - Analyst

So you mentioned to others C. difficile and smoking cessation, before we move on, do you want to -- is there anything you want to say about those opportunities?

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

I mean I think we're excited about both of those. C. difficile is a very significant problem in hospitals around the world. Again, we have a unique vaccine construct that in our early experiments that looks to be effective and have the ability to control the disease that work through the toxin, the C. difficile toxin and we're encouraged and excited. We're looking forward to going forward with that vaccine. The anti-nicotine vaccine, the vaccine is intended to prevent nicotine from entering the central nervous system and reducing the euphoria or the psychological effects of nicotine. We think that that also could be a very important vaccine.

Jami Rubin - Goldman Sachs - Analyst

And these are what, three to five years out?

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes, we're in Phase I with both of these vaccines.

Jami Rubin - Goldman Sachs - Analyst

So, it's early.

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes.

Jami Rubin - Goldman Sachs - Analyst

So, Xeljanz, that's an opportunity upon us right now and again, I think that you said it a year ago expect to slow ramp, but you probably aren't.

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes, I did.

Jami Rubin - Goldman Sachs - Analyst

Yes, I remember, I remember. And so, you probably aren't surprised to see how this drug is ramping, but again, if you could kind of take a step back and what is your assessment so far? I mean, again, from our perspective, it does look a little bit slower than I would've thought, particularly given the second-line label that you received.

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes. Well, it's interesting, because everybody is excited about Xeljanz. You talk to rheumatologists and they exude excitement about this drug, about this mechanism of action and they're anxious to use it and to try in patients. But the reality is, RA is not a growing area, I mean RA patients are actually fairly well recognized and fairly well-treated today and a lot of the agents that the doctors have are effective.

So, we're looking really at the opportunities for them to use Xeljanz on patients that they're switching from existing therapy to something else. That's a modest size patient population. We're getting a large percentage of those patients, the ones that are switching and what I think particularly exciting to me is we are getting patients that are switching from methotrexate to a new agent. Normally, they would go to a TNF inhibitor. We're seeing almost half of our business for Xeljanz so far are people that are going directly from methotrexate to Xeljanz before a TNF inhibitor and then the other half of the business that we're seeing is coming from patients that have been on multiple TNF inhibitors and they are still looking for better results and we're getting a lot of those patients as well.

So, everything that I see and hear is positive. Changing practice just takes a lot of work and there are ingrained practices and habits. You talk to rheumatologists about the fact that Xeljanz works well with or without methotrexate. I was with rheumatologists last week and I asked them, I see people at Pfizer tell me that patients hate methotrexate, is that true? And he says, yes, absolutely they hate it. And he says about 50% of them just want to get off of it and a lot of them just take themselves off of it. So, it's a big problem, isn't it? He said, yeah, and I said, well, now you've got an option where you don't need the methotrexate. And he said, yes, I'm going to think about that. So it just takes a while to get that --

Jami Rubin - Goldman Sachs - Analyst

Seems obvious to me.

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yeah, me too. But --

Jami Rubin - Goldman Sachs - Analyst

Are there impediments to a stronger launch, I had a conversation with another CEO at a competitor company and he mentioned to me that Xeljanz just isn't available to a large percentage of patients, because PBM's insurance companies are limiting access to Xeljanz unless they have failed other TNFs. Even though that's not in the label, it seems to be practiced with a lot of these formularies?

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yes, there are some of that out there. There are some formularies where there is a requirement for a step edit and let's say it's a small proportion of the formularies that we're on today. There is some of that and that is an impediment. We would like to find a way to remove that. In some cases, it's going to take time for us to build enough market share ourselves whether we have enough volume of business where we have some more negotiating power.

But, in the majority of our formulary positions, are the same as they would be for other biologics. I mean there's always a prior authorization required, because these are expensive medicines, but in the majority of cases, a physician can prescribe it as a second line agent or third line agent. And I was looking at some data -- last week that looked at the percentage of prescriptions that are written and filled, the percentage of prescriptions that are written and rejected, and then the percentage of prescriptions that are written and refused, and written and filled and written and rejected are pretty self-explanatory, right. So written and refused are the physician wrote the prescription, the patient went to the drug store to get it and found out the co-pay was really high and refused it. So if you look at the pattern that exists for those three segments for biologics for the whole class, and you look at the pattern for Xeljanz, it's nearly identical. So these are issues for all of us. So, I'm not going to say we don't have those issues, but we don't seem to have a pattern of reimbursement that's different from the other agents.

Jami Rubin - Goldman Sachs - Analyst

If I guess what's on everyone's mind is can Xeljanz then still be a multiple billion dollar asset, which is I think can meet its expectations?

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

I think so. I mean, Jami, I think that some of the things that are happening in the marketplace, both for Eliquis and for Xeljanz, you have established markets, you have multiple agents available and at the end of the day, it's going to be the kind of horse power of the drug that's going to determine where it's ultimately going to get to.

I think we're seeing the trajectory isn't what we would have liked it have been. We're in a different environment today than we were five or 10 years ago. I mean with REMS, you have a heightened focus on benefit risk, safety adverse event profile. From a marketing and selling standpoint, it's a different day today.

Even speakers and speaker programs are not as impactful as they once were when a physician could go to a speaking engagement and describe his personal experience. Today, speakers are viewed as agents of the Company and have to speak within the confines of the label. So, it's not a bad thing, it's just the different thing. So I think that -- what that means is, the trajectories particularly in really competitive markets are going to be a little bit slower than what we saw five or 10-years ago, but I think the plateau, I think where the drug ultimately gets is dependent upon the profile of the drug.

And I think Xeljanz, the fact that it's effective as monotherapy, the patient reported outcomes that we see suggests that patients are going to really feel good, taking this drug. They have less fatigue, they have better quality of life, they have better sleep patterns and I do think that there are some real good reasons to believe that -- and it is a pill, I mean that's not the first reason when the physician is going to choose it, but you put those things together and once we get to the point where we've got some momentum, I think you can really take off.

Jami Rubin - Goldman Sachs - Analyst

And is this also something you would do direct-to-consumer ad campaign?

Geno Germano - Pfizer Inc. - President and General Manager, Specialty Care and Oncology

Yeah, we started our direct-to-consumer advertising about a week ago.



Jami Rubin - *Goldman Sachs - Analyst*

And just one last question and then I want to move on to oncology pipeline, which I think is very exciting. What is going on in Europe? And it seems that an appeal is -- your ability to appeal the decision is probably a low-probability event. So, do you think you have the sufficient data to address the concerns of the European regulators?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Well, we think we have the data and we think it's worth going through the appeal process. I will agree with you that I think it's a relatively low probability event, but here's the situation. I mean in Europe, we had a rapporteur who took a fairly negative view of the drug right from the start and wasn't as supportive as we would have liked. He had some concerns about the safety profile of drug that were frankly identical to the concerns that the US FDA had.

The difference is the FDA went to an Advisory Committee and had a dozen rheumatologists discuss this drug and reinforced the fact that these were adverse events that were predictable, that were understandable, that were manageable and within their practices, this is what they do every day and obviously they convinced the FDA that going forward, patients were better off having access to this medicine, note that the benefit risk was acceptable. They don't have that process in Europe. So what happened was, when the CHMP met, the rapporteurs were kind of cool to that product and the CHMP kind of responded that way. We think it's worthwhile going through the re-evaluation for a couple reasons. One, it's a relatively quick process. We're not going to delay anything for a year. The process is going to occur over the course of the next couple of months, number one.

Number two, we think now we can focus on the handful of issues that were identified as the reasons for the negative opinion and we can bring our data with greater focus, okay. Number three, there's a new rapporteur and the rapporteur that has been selected has experience with rheumatology products. He had actually been a rapporteur for a rheumatology product in the past. And number four, we're going to bring more European rheumatology experts, experts in structure; experts in immunology; experts to the CHMP. So, we think we have a good game plan and if we don't win it, we think that we can at least overcome some of the objections and will have an easier time focusing on the kind of remaining, our outstanding objections as we go forward. So, we thought it made sense.

Jami Rubin - *Goldman Sachs - Analyst*

In our remaining time, I want to focus on the oncology pipeline, which I think is really exciting for the Company, particularly PD-991 or palbociclib. Walk us through the development timeline, I mean what we saw I guess back in December was a PFS of 26 months in the Phase II study versus 7.5 months by the standard of care. What is the next dataset that we are looking for, when will we see it and what should our expectations be for that?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Right. So those were preliminary data or interim data from the Phase II program. We are now completing that Phase II program. All the patients are enrolled. The program is completing. We think it may -- and again it's an event driven study, so we think it could complete by the end of this year and once we have those data, the first thing we're going to want to do is to meet with the regulators, who've taken a very high interest in the program and in the data and discuss with them the implications of the outcome of the trials and determine what the regulatory path forward will be.

So that's kind of the most important thing on our minds. And we had dialog with regulators before, they encouraged us to proceed immediately with a Phase III trial. That trial is up and running. It's actively recruiting. We have sites open and it's moving rapidly. So we're excited about that. Sometime in 2014, we will be presenting the data from the Phase II. I think the kind of most optimistic opportunity would be San Antonio by the end of this year. I would give that a low probability personally, I mean we would love for that to be the case, but -- and maybe it will be. And if we have the data, we'll bring it there and will present it.



Jami Rubin - *Goldman Sachs - Analyst*

I mean I guess it's the best way to look at it, if people -- it's an event driven trial, so patients are still alive and they haven't progressed, that's probably good news. I mean is that the way to look at it?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Exactly, yes. So that give you an idea where we were at.

Jami Rubin - *Goldman Sachs - Analyst*

And what have been the practical implications of receiving breakthrough designations?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Well, breakthrough designations are a new kind of process and primarily the implication is that you get a lot more attention. The FDA is working more closely with companies. There is more interaction, there's more meetings.

Jami Rubin - *Goldman Sachs - Analyst*

Does it mean there is a desire to get this to the market more rapidly?

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

I mean I think that there is an implication that that's the case.

Jami Rubin - *Goldman Sachs - Analyst*

And just in our remaining one or so minutes, help us to think about the commercial opportunity for this drug.

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Well, we think that again our initial focus is on breast cancer. We have the trials going on in advanced breast cancer. We're looking at possibly starting two additional Phase III trials either later this year or beginning of next year in resistance disease and in earlier disease and high-risk patients. So those three patient cohorts encompass about 200,000 patients in the developed world and in the major markets. So we think, just in breast cancer, this is going to be a pretty substantial drug and then of course we're exploring where a PD-991 would fit in and in other cancers and we're collecting data today and determining where to go beyond breast cancer in the future.

Jami Rubin - *Goldman Sachs - Analyst*

Great. All right. With that, thank you very much.

Geno Germano - *Pfizer Inc. - President and General Manager, Specialty Care and Oncology*

Okay. Thanks, Jami.



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