PFE - Pfizer Inc at Credit Suisse Healthcare Conference

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Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

First of all, thank you very much for the invitation and let me remind everyone that I'm going to make some forward-looking statements and actual results may differ. So, coming to your questions. Look, we have been very encouraged with our interactions with FDA and we have been very encouraged with the strength of the data. Let me give you some context on that. The palbociclib study proves that palbociclib is not only having statistical significance, but also has clinically meaningful results. We are talking about doubling the progression-free survival versus the standard of care.

And let's not forget that there is no new medicine for this patient type in a decade or more in the market, so the need is there and it is high. We have been in very productive discussions with FDA, we filed, and our file has been accepted based on the Phase 2 data. We have been granted a PDUFA date in April, which means that we got Priority Review. This doesn't mean that the product will be approved, but it is a signal that the data compelling for FDA. I think there will be an ODAC for that and we will be ready to answer any questions they may have.

I think for the same reasons that I referred to in the beginning, I think the endorsement of practitioners, when it is approved, hopefully in April, will be quite good. No new medicines, very compelling data, there would be a part of the physicians that they would be more conservative in their approach and they would like to see more data, but let's remember that more data is coming. We are already having Phase 3 studies in this population and in many other populations that will follow, early 2016. So, we are very encouraged and we look at future with optimism.
Vamil Divan - Credit Suisse - Analyst

So how important is this first indication then, both from a kind of the physician acceptance but also maybe from the commercial opportunity? I think a lot of people in Wall Street have pretty big expectations for the class as a whole and for palbo specifically, so how important is this first indication or is it really more of a matter of seeing the data that would be done in 2016, 2017 to really turn this into a type of franchise that people think it could be?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

No, it’s both. It’s significant by its own, but also is the beginning of a long journey. To give you a magnitude, breast cancer is approximately 1.7 million women that are diagnosed every year. And ER-positive, HER2-negative, but it is where palbociclib is working; it is approximately 60% of them, so 1 million; half of them in the developed world, G7. So, think about the approximately 12%, 13% of this 1 million it is the first-line advanced metastatic breast cancer that we going now. So, that means maybe 120,000 in the world, 60,000 patients in the G7.

But it’s not the only indication. As I said, we have right now with palbociclib for breast four Phase 3 studies that are running. One is the first-line advanced, but then we have two in recurrent, we have one in early, which is a very big indication. From the four, two of them are expected to come to completion in 2015 and then of course I doubt likely late-2015 for the recurrent and for the first-line is 2016 as I said before.

Vamil Divan - Credit Suisse - Analyst

Let’s me see if there’s questions in the audience. And I do want to shift gears a little bit. We talked on palbo and how to do the near-term opportunity there, I think the other exciting -- maybe most exciting area in oncology is on immuno-oncology I think. You guys certainly have some work going on there as well. So, I want to give you a chance to maybe elaborate on that a little bit. One, I guess, how do you see the landscape evolving? Certainly there are players ahead of you in immuno-oncology right now in the PD-1 side. You guys have -- I know you have some stuff you really set out, you have ASCO, you have PD-1 coming. So how do you see your position in that field evolving in terms of the lead players, how close can you get to them and how important are maybe some of the combinations it’s going to take to helping you close the gap?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

Look, I think it’s a dominant belief both in the scientific community and in the investment community that immuno-oncology has the potential to transform cancer therapy and we agree with that. And I think that we have seen some very impressive results with PD-1/PD-L1 mechanisms and I think in the near-term will be the backbone. But I think also smart combinations of other compounds with PD-1/PD-L1s will significantly enhance the immuno-oncology potential and basically efficacy.

In the PD-1/PD-L1, we are behind. We have a PD-1 that is likely going to clinic in the second half of 2015. So we’re behind the first wave. There are some advantages to be behind, because you are learning from the experiences of the science and of the others and you can become a fast and smart follower. Now, don’t take me wrong, I wish I had a PD-1/PD-L1 that I could bring to clinic now in Phase 3, I mean -- not in clinic, in Phase 3 now, and to be part of the first wave. But given that we don’t, what we try to do is to develop the second generation of immuno-oncology, which is first of all other immune-oncology agents.

We have in clinic our 4-1BB disease agonist, a different mechanism of action. That’s already in clinic and we have another agonist, which is the OX-40 mechanism that will come to clinic in the first half of 2015. Also, we are working a lot with combinations both with immuno-oncology portfolio and our other molecules portfolio with PD-1s of other companies, we announced with Merck for trials. One of this with their PD-1 with our 4-1BB, Xalkori, Inlyta and palbociclib, so we’re moving fast.

On the CAR-T technology, we announced earlier this year, actually mid-summer time, that a partnership with Cellectis. They have a very unique technology on CAR-T and in combination with our antibody technologies that we mainly developed in Rinat, it’s a wholly-owned subsidiary of Pfizer in the West Coast. We hope to advance, let’s say, this area as well. We have several ADCs that we’re working. In general to summarize,
Immuno-oncology is a high priority for Pfizer. We take it very seriously. Myself and Ian personally are looking at that front. We are hoping to be able to bring one to two immuno-oncology agents into clinic every year starting from 2015.

Vamil Divan - Credit Suisse - Analyst

Okay. I guess if you think about the — this question that I asked of other companies and you certainly put a good — I think you have a good plan for it, looking in terms of being competitive there. What is it about the PD-1/PD-L1 and maybe first wave here that you guys are behind and then didn’t kind of catch that one? Maybe that’s more of a question more appropriate for someone else, but just as you think about it is there any way you have to kind of make sure the next wave that’s coming up that you don’t miss that one and the sort of internal learning that you think about it in terms of future advancements next year?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

This is the nature of the research business that you have to make bets when very little data are available, some they get it right, some they get it wrong, usually people are belonging to the same categories because some that they get right, some that they get wrong. I mean years ago, we didn’t think that we should invest in that and we didn’t.

Vamil Divan - Credit Suisse - Analyst

Okay. I do want to switch off of oncology unless there are any questions on that specifically just in the interest of time. So maybe we can shift to vaccines a little bit. So, you already had some — you had the ACIP panel discussion around Prevnar 13 for adults a couple months ago, any early indications you can give us of kind of the interest in the community or maybe early signs of any impact that’s had on the commercial side of things. And maybe switching on to payer side, how should we think about the acceptance of that, maybe special income you will receive from Pneumovax or not, how is that franchise evolving since ACIP?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

Okay. So, let’s take things from the beginning. First of all, to put some context the MMWR, which is the official document that makes public the recommendation was issued at end of the September. And this is -- so we’re talking about five, six weeks. But we have done a lot during that period of time. First of all, we worked very intensively to make sure that healthcare practitioners are aware of this recommendation. We’ve had 800,000 touch points so far with healthcare practitioners.

And then, we are working with organized customers like wholesalers, retailers, hospitals to make sure that they stock product or the product is there. And of course, we are intensifying our communication with consumers. So, we started last month already and unbranded DTC campaign and this Monday, we kicked off a branded campaign activity. So, what are the early signs from these days? Direct purchasing customers, customers that are buying directly from us, they have significantly increased their purchases, so that’s one.

Wholesalers, they all stocked their shelves with Prevnar 13. We are monitoring the withdrawal of the product from their shelves towards clinics, practitioners and all the non-direct customers and also has increased significantly. Retailers also, most of them have stocked the product. For example, CVS, Rite Aid, Walgreens, they are all having the product and they are all actively vaccinating. So, encouraging early signs. As I said early, the opportunity is large, but the adult vaccination has its own set of challenges, they are different than the pediatric, but we have a robust plan to make sure that the product will do well.

Coming to your question on reimbursement and payers. Let me clarify the situation, right now Prevnar 13, it is reimbursed. We hope payers are including Medicare Fee-For-Service and Medicare Advantage as you said. Now, when it comes to sequential use, typically Medicare follows the ACIP recommendations. So, the previous ACIP recommendation was for immuno-compromised patients and for these patients the recommendation was that they should use both products. Prevnar 13 first and then Pneumovax. And Medicare is reimbursing both products for this population.
Now, we have a new recommendation that says not only immuno-compromised, but 65 and older irrelevant of their health status. And for that, Medicare is working now to update their guidelines to include also this group for sequential use. And that can take -- I mean, it can be done immediately or can take months. We are waiting to see. But in the meantime, there are 19 million individuals in US who are 65 years old and older, that have never received pneumococcal vaccine and those are recommended to receive Prevnar first and they’re reimbursed. In addition to this group, there is everyone who has unknown or uncertain history of vaccination, also they are reimbursed right now.

Vamil Divan - Credit Suisse - Analyst

So, one area you have moving beyond Prevnar that we’ve talked about, I guess, for last year since we’ve been covering the Company is your other vaccines. I don’t think investors kind of give you guys much credit for it yet, but you have very rapid approval for the meningitis B. If you can talk a little bit about the commercial opportunity that you see there and maybe the competitive dynamics with Novartis and then I want to touch on some of the other ones that you have.

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

Thank you for mentioning Trumenba. We are very proud and excited that it was the first and so far only product approved in US. It came two years earlier frankly than what we expected to come, but was very good news. This is a devastating disease, talking about the potential. And it is, meningitis B has very rapid transfer and has high fatality rates. So, people can die within 24 hours from getting the disease and I’m talking about 10%, 15% of the people who get it die. And additional 20% of the people -- up to 20% of people will have -- if they don’t die, additional 10% will have serious health issues. I mean brain damages or amputations, so it’s a really nasty disease. So, the introduction of the product, which is the first and only right now, is a major, let’s say, win for the patients to start with.

The commercial potential will depend on first of all the commercial landscape. We wait to see what happens within the markets. And also will depend on the type of recommendation that this product can receive. It can be big variety of recommendations that you can have with a product like that. It is a rare -- let’s say disease will have 1,200 people that are getting meningitis in US, 400 on B of this 1,200 that as I said, people die. So, very different dynamics when it comes to recommendation. We presented our information to ACIP in October. We hope that the ACIP will have a vote and so the situation will be clear in February on the recommendation. For the time being, we are projecting a modest revenue uptake given also the magnitude of our Vaccine business.

Vamil Divan - Credit Suisse - Analyst

Okay. And then maybe just so much touch on staph aureus and clostridium difficile vaccines. Again, I think, potentially very devastating diseases and potential first in commercial. How do you think about those at this point in their development? How important are they to you?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

I will tell you -- let’s start with staph, as you said, high unmet medical need in staph. This is the leading cause of surgical infections, 15% to 30% of surgical infections are because of staph, it depends on the surgery. High cost to the society, to the healthcare system, $10 billion to $14 billion only in US for these surgical infections. We have a very unique approach developing the product. Our product is unique in terms of, it has four components. So, we are trying to attack this bacteria from multiple aspects. We had a successful Phase 2a study, but it was quite large, it was 450 people. We’ve had acceptable safety profile and we’ve had -- with just one injection, we’ve had very rapid onset of antibodies that also were maintained for 12 months. So, very encouraging.

Now, we are working with FDA in the design of a Phase 2b study. We hope that we will be able to initiate this study beginning of 2015, let’s say, up to first half of 2015. Our intent is to build this study as a registration enabling study. But all of course will depend if the results are strong. So, we’ll have to wait to see the results. But we want just to cover, the case of the results are strong that we can use it, let’s say, for registration purposes. That will take two years from the beginning to see the results. Very exciting opportunity. We are looking forward.
C. difficile, also high unmet medical need; 250,000 cases only in US, 14,000 deaths because of that. So it's a big issue the C. difficile. We have a product in Phase 2. Recent update it is that we have decided to hold further enrollment and vaccination of further subject in this study, because of some redness of local reaction. So, we are reviewing our data to define the best path forward for that one, but very exciting opportunity as well.

Vamil Divan - Credit Suisse - Analyst

Okay. So maybe you want to -- I do want to touch on the Consumer side of things for the last few minutes here. So maybe just, we talked about Vaccines, we talked about Oncology, the pipeline and drug development, Consumer obviously a very different business. So, maybe just talk generally about having Consumer under your umbrella in Vaccine and Oncology, what is the synergy, what's the value of keeping them all in one business unit, does it make more sense to be on the Established side or be on its own? So, maybe just you can give us your perspective?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

It's an excellent question and I'm getting that a lot. To clarify, I think the reason why we put Vaccines and Oncology and Consumer together is not because they had a lot of operational synergies or more operational synergies among the three than among GIP or GEP. The reason we did it, it is because they are all three relatively smaller businesses and relatively high value businesses, because of their growth trajectory and the areas where they play. So, all of them are poised to organic growth, all of them are poised to multiple expansion, so we did in all of them, that's very important. They have significant milestones that comes to fruition now. For Oncology, for example, the name of the game is palbociclib, is now.

For Vaccines, the name of the game it is Adult Prevnar, plus the new introduction just coming now. And for Consumer it was Nexium launch, it came now. So, it was important to make sure that we focused these businesses and we give them the resources and we didn't want them to be subsumed if they were part of GIP or GEP, that are gigantic businesses compared to them within Pfizer. So that was the only reason. There are some -- all of them operate independently. So, they have this focus. They all share some services, particularly enabling functions like HR, Finance, these types of things, but they operate independently and that makes them winners in their marketplace.

Vamil Divan - Credit Suisse - Analyst

I guess just with what you mentioned there about the near-term kind of catalysts, as you sort of play through this Nexium now in the market and obviously the Lipitor OTC opportunity coming, is there a sense as you get through some of these near-term catalysts, then it might not make sense to keep them together or that they might get better or are you thinking as we pass through these catalysts it still makes sense to keep the focus?

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

No, still I think makes sense. We don't have any plans to, that make sense to us, to separate them either from VOC or any other way. We tried to maximize their value by executing well on all of them. Actually, the reason, so that you mentioned, what if our Rx-to-OTC switch pipeline comes through to fruition is an additional reason why we need to maintain the focus on the autonomous nature of our business, so that we can get the resources and think 100% Consumer for example.

Vamil Divan - Credit Suisse - Analyst

And just looking at your Rx-to-OTC as the big one if you think about with Lipitor data coming relatively soon, how do you -- where would you put sort of the probability or the likelihood of that finally get a statin and switching over to the over-the-counter market?
Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

Look, we know the previous attempts to switch statins were not successful and actually our program did exactly that, trying to understand what were the reasons that the others failed, so that we can try to address, let's say, the concerns of FDA, of the regulators. We had our plans in this program. Our actual use study should read early next year and based on the results, we will define our next steps for filing with FDA.

You need to understand that in this type of switches for products that have been used for years. Typically FDA's concern is not the safety profile or the efficacy profile, it is -- they want to feel comfortable that the consumer, without the intervention of a physician, will be able to self-select himself or herself accurately. So that's all about that. And we've got that from the previous failing attempts, this is what I think people failed to demonstrate and we are focusing on that. So, when I have more news, I promise I will give you all the details.

Vamil Divan - Credit Suisse - Analyst

Okay. I think we are out of time for more news today anyway. So, thank you very much for joining us again.

Albert Bourla - Pfizer Inc. - Group President of Vaccines, Oncology & Consumer Healthcare

It was a big pleasure. Thank you very much, Vamil.