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PFE - Pfizer Inc at JPMorgan Healthcare Conference

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PRESENTATION

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

Good morning, everybody. I'm Chris Schott from JPMorgan. I'm very pleased today to be introducing Pfizer. From Pfizer, we have Mikael Dolsten, the company's President of R&D. For the format today, we're going to do a short presentation from Mikael. Then, we're going to break to a fireside chat type format. And we will not be doing a breakout session afterwards. So with that, I'll turn it over to Mikael. Thank you.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide Research & Development and Executive VP*

Thank you very much, Chris, and a pleasure to share with you what we think is a new era of Pfizer, R&D productivity at a high level. But as always, before I go into sharing some of our progress, please look at the forward-looking statement details that are on the slides and will be available at our filings and webpages.

So we have been working since 2010 together with our CEO, Ian Read, to really look at the way to transform how we do R&D. And if I take you back to the period 2005 to 2010, you can note as an indicator of R&D productivity that Pfizer had a moderate output with 2 blockbusters, SUTENT and then Prevnar 13 Infant that was approved just after the acquisition of Wyeth closed.

So at that time point, we took a hard look at how do you impact R&D productivity? How do you transform how you work together from R&D and commercial? And we focused on rigorous science, crisp decision-making, early development for go, no go. We looked at ways to put our key biomedical innovators in the right geographies. We looked at how we get early alignment between commercial and science in the programs and how do you focus on the areas where you can win. And that led to a reduction from our rather broad therapeutic area span of 14, 1-4, to now 5 areas. And indeed, actually last week, we announced that we are exiting early research and -- research and early development in neuroscience in order to focus and reallocate our resources into the other 5 areas, where we think we can get the most value near to mid-term for shareholders and for patients. So that's part of making sure you put your resources where you can make the biggest impact and where you can win.

With all of those changes in place, we started to look at the uptick in our R&D productivity, and again, using blockbuster approval as a measure of that, you can now see between 2011 and 2016 that we got 5 products approved with blockbuster potential. Four of them actually have already reached blockbuster status in the marketplace, Prevnar 13 Adult, Eliquis, Xeljanz and Ibrance. And the fifth was approved quite recently, Eucrisa, which we think has a multibillion-dollar blockbuster potential.

At the same time, from 2011, and if I extend to '17, we actually got 30 approvals in major markets -- U.S., EU, and we got 17 of them were new medical entities. And we started 45 new pivotal study starts to refill the pipeline. So that gives us on average 4 or more approvals per year, of which 2 or more are NMEs and 6 or more pivotal studies start annually.

And we think we can now take that momentum and even augment it to project an upward exciting slope of R&D productivity to augment growth for the company. And that's really the focus of the next few minutes, our opportunity to deliver up to 15 blockbusters in 5 years, of course, subject to attrition.

You can see they are spanning the 5 therapeutic areas. And starting at the top, we have the immuno-oncology portfolio, particularly focusing on drug combinations. Combining Bavencio, our PD-L1 drug partnered with German Merck, with a variety of Pfizer targeted agents. Most recently,



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we got breakthrough designation for Bavencio combined with Inlyta in renal cell cancer. And we have started now multiple trials combining it with other targeted agents and immuno-oncology agents.

Recently, we got the readout from one of the I/O-I/O studies with 4-1BB, where we did not see any incremental gain in adding a second immuno-oncology agent. And we obviously are looking at exploratory sub-analysis to see, as the data mature, what we can learn. But it clearly shows the importance of having a broad portfolio because the ability to predict isn't always possible to perfection. And in the I/O-I/O space, we're particularly now excited about our OX40 combination with Bavencio, as we have seen single-agent activity of OX40 and interesting immuno-pharmacology profile.

You can see the third bucket related to targeted cancer agents, where you see 4 different indicated. All of them are projected to be for regulatory submissions this year.

Then, we have our 2 oncology anchor product, Ibrance going from metastatic to early breast cancer, where we have seen in our smaller focused, the adjuvant study, a promising effect on tumor shrinkage and also anti-proliferative markers.

In this setting where we are leaders when it comes to CDK inhibitors for breast cancer, I'm also pleased to share that we're starting soon a next-generation CDK inhibitor for breast cancer resistance in both breast and other non-breast indications.

We shared last year our JAK1 proof of concept and that we were the first to start the Phase III in atopic dermatitis. We are pleased with our C. difficile vaccine, and we are now the leading late-stage vaccine in this space after competitor had a setback. It's such an important unmet need and a great opportunity.

And then, we have our last bucket, where we have multiple rare disease and internal medicine opportunities.

So you can see overall it's a really exciting cohort of up to 15 blockbusters over the next 5 years, of course subject to attrition. And they are part of a larger approval cohort of some 25 to 30 opportunities, again, of course, subject to attrition.

And let me just now close with a brief touch on what's going to happen in 2018, and I think you will see that it will be a busy year. Starting at the top, we plan to be back here soon in San Francisco and share the data from the PROSPER study at ASCO GU. The study was reported to be positive on its primary endpoint, and we are on track with our partner, Astellas, to put it into filing for registration this first half of the year.

You can see filing for talazoparib, multiple readouts in the first half of the year in lung cancer, in cardiomyopathy. Please note how our JAK portfolio in the early-stage start to deliver a readout, rheumatoid arthritis with our unique next-generation JAK3 inhibitor.

And later, second half, you can see a number of selected JAKs with readout in new areas such as alopecia, psoriasis.

You can note in the vaccine space in the early phase, we have readout of the 20-valent (inaudible) vaccine to Prevnar 13.

And then during the second half, in the later stage, you can see an action date for Xeljanz in its first indication outside rheumatology, ulcerative colitis, middle of the year in U.S. later in EU; readout for rivipansel in sickle cell; and exciting novel pain class, tanezumab has a readout in a very large Phase III study, where we again are leading the development of this innovative drug class. And then finally, we have our Triplet immuno-oncology with OX40, 4-1BB at the end of the year. And our NASH portfolio that has emerged with a proof-of-concept study on ACC, and I close to mention, GLP-1. And this is one of the few, maybe the first [oral] small molecule, GLP-1, that we see an opportunity study for NASH and other metabolic disorders.

So I'll close to say 2018 will be a rich data delivery year. It will allow us to follow the progress with delivering up to 15 in 5 blockbusters and continue to augment the growth of Pfizer and the productivity gain we have seen over the last few years.

And now back to the dialogue with Chris here. Thank you.



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QUESTIONS AND ANSWERS

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Thank you for those comments. So maybe just to kick off our discussion here. I mean, it seems like the company is increasingly confident with regards to its late-stage pipeline. We've seen pretty rapid build-out of these -- the portfolio. Can you help me just understand what's happened within the organization that has allowed for this accelerated productivity that we've been seeing?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

I think it's been, as alluded to, a number of key things. On one hand, the focus on the rigor and the science and making sure that we are selecting the most promising areas where our science and technology can lead. We focus far more now on being the company that will drive with breakthrough potential than just being someone that is a follow-on company. And the ability to integrate science and business have allowed us, I think, to have an opportunity to really have the company come together and do proper risk assessment on which areas will be the most promising and do it in a very unbiased manner. A lot of efforts has been around decision-making. How do you do unbiased decision-making? How do you do multi-variant analyses on the probability of technical, regulatory or commercial success in the pipeline? And then finally, obviously, we have done a lot of work when it comes to ownership culture, that everyone in the organization needs to own the outcome of your program, whether you decide to stop or continue your own -- that important dialogue with management.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

All right. That makes sense. Digging into some of the individual opportunities here. Immuno-oncology, obviously, a huge focus across the industry. Can you just give us a snapshot of how you see Pfizer positioned in this very rapidly evolving field? And you've got a lot of assets. You're doing a lot of studies. But there are some that are a bit ahead in development. So how do you think about your role in the market? How do you catch up in certain areas, where maybe you started development a bit later than others?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

Yes. For us, we look at oncology as a comprehensive approach, and we see a future where most cancer patients will likely have 2 or 3 or more different cancer drugs addressing the immuno-oncology aspect, the cancer biology and the tumor microenvironment. So for us, having such a large portfolio of targeted therapies, of course, with leadership in breast, CDK in Ibrance, growing in urology with prostate and renal and also significant presence in lung and blood, to have a backbone of I/O agents that can be over time combined in the right fashion is important. And we think we made a lot of progress together with German Merck on Bavencio, registered in 2 smaller indications. As we noted, we have every year now a readout in various indications. And Inlyta, our breakthrough designation is a hallmark for when we get those combinations right, we saw more than 60% response rate in renal cell carcinoma and many deep responses. So that's how we're thinking to be a company that have the abilities to combine richly across our portfolio. It gives us much more flexibility going forward. Of course, we are very eager, and this is a great meeting place, to look at other biotechs or specialized pharma that may have unique assets that could fit and combine with our comprehensive portfolio. And that's really how we see oncology develop over the next years.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

So along those lines -- I mean, do you -- is a core part of your strategy monotherapy? It sounds like it's more about combinations for Pfizer as we think about this going forward.



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Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

That's true. We participate in the first wave of monotherapy, and that's where we got the first registration. It gives physicians experience with Bavencio. It's allowed us in some segment to be a participant. But we do see over time that the field will evolve. And in most tumor types and segment will be combinations, and that's where really our major focus is.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Okay. When I look at the market right now, there seems to be either I/O mono -- or PD-1 monotherapy or even some I/O-I/O combos being established to standard of care in some very large tumor types. What challenges does that present in terms of study design and trying to develop new therapies when it seems like the bar is moving a bit higher in terms of the therapies that patients are able to receive today?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

Yes. Clearly, you need to put your investments into areas where you think the field hasn't moved as much. So we feel that in most indications, you see 20% to 30% response rate. There are very few complete responses, with a few exception of indications. So I think there is still ample opportunity to build on those initial promising data but bring it to a formal meaningful level of durable and also complete responses. Obviously, there are subset of cancers. Some of them are called cold tumors. And we are putting particular efforts there, looking at combinations that could heat up those tumors, whether it's chemo combination, radioimmunotherapy or antibody drug conjugate. And more recently, we're also advancing cancer vaccines into this space. We have a prostate cancer vaccine in Phase I. Now we're planning to move a lung cancer vaccine into clinical this year as well as bifunctional antibody. Last year, we started a study in myeloma with a bifunctional antibody. So I think for each different tumor segment, we'll ask the critical question that you did, where is the biggest unmet need? How do you build on the current standard of care? But the premise we have seen is just the very start of a long journey. There is a lot more we should be offering patients over the next 5 to 10 years of progress.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Yes. When I think I/O-I/O combos -- I think you mentioned OX40, what other targets are you particularly excited about as you think about combining your PD-L1 with other agents?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

So we have an array of I/O molecules in our pipeline and working with ambition to every year put in another or so I/O molecule into the clinic. Right now in the pure I/O segment, it is the data we have seen with OX40, single agent, and its ability to activate a different arm of the immune system, the helper cells, versus the more cytotoxic cells being activated by PD-L1 and 4-1BB. So that's the reason why we see a more comprehensive immune response being engaged. A lot of our efforts is also to look at the combination of I/O with targeted therapies. And I mentioned Inlyta. We have now started with talazoparib drug combinations, Bavencio-talazoparib, Bavencio with [indiscernible in lung. And together with investigator-initiated studies, we look at combination with Ibrance, combination with glasdegib in blood malignancies. So we see in parallel a great opportunity for PD X-targeted therapies as well as trying to figure out which I/O combination can make the immune part of that equation stronger.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Sure, sure. Maybe switching gears a little bit, staying on oncology, Ibrance. The adjuvant opportunity seems to be a fairly substantial one. Can you talk a little bit about how you see that opportunity playing out and what gives you confidence that we can see efficacy for the product in this setting?



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Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

Yes, thank you very much for that question. So in general, for targeted therapies, we have seen good translation between more advanced metastatic disease and moving to earlier lines. In most cases, responses actually get better. But specifically for Ibrance, we have a number of studies, smaller Phase I/II studies that have reported out on early breast cancer patients in more a neoadjuvant setting, where we have seen robust responses of Ibrance, alone or on top of an estrogen blockade, related to tumor shrinkage or looking at anti-proliferative markers like Ki-67. So that gave us a lot of confidence. And more recently, we had a readout also on patients with early breast cancer that are on the drug for 2 years and again showing good tolerability, which is important when you move into earlier lines. So we feel very strong about that opportunity. It's a large opportunity. There are more patients with early breast cancer than advanced metastatic, and we will hopefully see them treated successfully for a longer time period. Some of the studies that we have, like the PALLAS study, includes 2 years' treatment duration. So that opportunity we see is very substantial for Pfizer and hopefully for patients, pending outcome of the study.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

And can you remind us of timelines? I know there's a couple of adjuvant studies running. But when should we start thinking about data potentially coming for these opportunities?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

Yes. I mean, the early breast cancer readouts are a few years away. We tend to say it's probably 2020 period. At the same time, we actually have a readout also of Ibrance together with HER2 blockade in tumors that are double positive for HER2 and estrogen receptors, so there is lots of opportunities for growth of Ibrance. And I wanted to close on this question to say that we have likely 100,000 patients currently treated in the marketplace with Ibrance. And of course, unfortunately, some of them will progress, as often happens, on targeted therapies. And that's why we're so excited to bring this year to clinical studies a new generation of CDK inhibitor that, based on our leadership in the science, have been tailored to particularly address major resistance mechanism that will possibly or likely happen in these patients. And we'll also identify that, that type of resistance mechanism may be present in tumors outside breast so they are intrinsically not eligible for Ibrance, non-breast cancer, and this drug in our scientific analyses, showed a lot of promise. So that's another major advance we're looking at in the 2018 and '19 period.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Sure. That's great. Switching gears, nerve growth factor, tanezumab. It seems like we're getting close to both the big data readouts. Remind us here just on the efficacy profile that we've seen for this drug, how you would see this kind of fitting into the pain landscape we have right now? And the second piece for that, I know there was some challenges initially with the study and submissions, in knee failure. Remind us how you're addressing that in the Phase III and your confidence that we can kind of maybe get around some of those issues that led to a delay in the product initially?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

Yes, it's a great question. And I think our confidence here relies very much in what it means to be a leader in developing way ahead of others these breakthrough therapies. Of course, when we were a number of years ago in the first trials, the view unfortunately externally was that maybe there isn't a lot of need for new pain medications. I think we have suffered from that conservative view as we see how the current excessive use of opioids have led to tremendous abuse and addiction. So now of course, we were pleased to see we've got Fast Track designation for this monoclonal antibody, and I think there is completely different perspective on unmet need. We had very strong proof-of-concept data earlier with that antibody that showed similar or, in some cases, better pain relief than opioids or NSAIDs. And we took all the learning from those early studies when we had to take a pause in the development after some concern about how do you develop these drugs optimally, particularly related to some rare events that was determined of -- possible deterioration of osteoarthritis. And we redesigned the next set of studies. So we went in osteoarthritis with slightly lower dose. We went with subcutaneous regimen, very convenient, every 8 weeks. And in chronic lower back pain, we didn't see that problem. We continued with the dose. We limited the use of NSAIDs, which we learned from a competitor failure seemed to be an issue when you

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have high dose of NSAID chronic use. We have limited use of NSAID, and we have introduced a number of risk minimization plans when it comes to how you monitor and have stopping rules at the individual levels for patients in this study. So the study has now performed extremely well, and we look forward to the readout early second half of the year here, we hope. And we think it has the potential to be a major transformative therapy, where there's such an urgent need. And we certainly learned a lot, but we have wished that we could have been even a few years earlier into the market to help out with this opioid addiction.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Yes, hopefully, this time around, we'll be there. There's been a lot of talk about potential consolidation across the pharma group, including large M&A. You run a very large R&D organization that's been through consolidation over time. To the extent there is activity, and Pfizer is involved, how do you think about maintaining the momentum that you currently have in the organization, again, if a deal were to happen? And we've seen in the past when you get large consolidation that there can be disruption. Are there learnings you have in place? Or your comfort that if a deal were to happen, you can kind of keep this going? How do you think about managing that challenge?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

For a large company, though, it's important to always look at opportunity to augment, accelerate growth, and whether that's smaller or midsize bolt-on or assessing larger opportunities in order to maximize shareholder value and return. So that's obviously a capability we have and do regularly, routinely. When it comes to the specific questions, and let me exemplify from the Wyeth acquisition, where I think the recipe for success is the experience that our organization have in moving swiftly and engaging, in that case, with another company. Looking at best practice across the 2 companies, rolling out the road map, how you combine, in this case, in R&D, the strengths in each therapeutic area, the technical design of drugs, and quickly create a one single pipeline go-forward. We did all of that work with the Wyeth Pfizer acquisition, basically in less than a month, and then took a firm but important and difficult decision on where to focus, which therapeutic areas, which sites and how to allocate our resources. And I think that culture, that capability is very strong at Pfizer, possibly uniquely strong in the industry. And of course, we saw that also at a smaller scale. I spoke today about the PROSPER trial, the positive readout and our on-track plans to file first half of the year with Astellas. We accelerated, after the acquisition of Medivation, that study with 2 years. And then finally, the Anacor acquisition and the drug Eucrisa, we were able at just the registration phase to resolve a number of issues, given our capability in CMC and pharmaceutical sciences that allowed a very fast registration to occur. So I think independent of scale, that's a key capability that our company have. And of course, it's important to look at such opportunities in a very unbiased manner as part of your running a business.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

Great. I think we're just about out of time, but thank you very much for the comments.

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development and Executive VP

Thank you very much. I enjoyed it.



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