

# FINAL TRANSCRIPT

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## **PFE - Pfizer at JP Morgan HealthCare Conference**

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## CORPORATE PARTICIPANTS

### **Geno Germano**

*Pfizer, Inc. - President and General Manager, Specialty Care Business Unit*

## CONFERENCE CALL PARTICIPANTS

### **Chris Schott**

*JPMorgan - Analyst*

## PRESENTATION

### **Chris Schott** - JPMorgan - Analyst

Good afternoon, everybody. I'm Chris Schott, pharmaceutical analyst at JPMorgan. Very happy this afternoon to be introducing Pfizer. From Pfizer, we have Geno Germano, Pfizer's President of the Specialty and Oncology business units. Again, looking for him to -- very interesting presentation. As a reminder, we have a breakout session directly across the way directly following the presentation.

So with that, turn it over to Geno.

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### **Geno Germano** - Pfizer, Inc. - President and General Manager, Specialty Care Business Unit

Thanks, very much, Chris. Let me just start out by reminding you of our forward-looking statement on our website where you can get more information about our business.

This is a slide that, hopefully, you've seen before. This is our organizational structure at Pfizer, the way that we're managing the business today. This structure has been in place now for a couple of years, and I hope to be able to demonstrate to you today that I think some of the rationale and some of the thinking behind putting the structure in place is really starting to pay off.

You can see that there's a couple of boxes combined at the top that we've had a couple of recent changes in Pfizer in the last few weeks. I've taken responsibility for Specialty Care as well as our Oncology business units. We operate these business units as separate business units, but they will both report in to me. Established products in emerging markets business units also have been consolidated under my colleague, David Simmons. David, myself and our head of Primary Care, Olivier Brandicourt, have also joined the executive leadership team, along with Ian Read, our CEO.

So, a couple of minor changes to the way that we're organized, but the rationale, the reason behind putting the business unit structure into place remains the same. We feel that having clear focus on business opportunities that are unique to these different business units, and the development of expertise and capabilities that enable us to optimize our business for each one of these business units, is essential to our commercial success.

And secondly, you'll notice the green in the middle of the chart where it shows business units are responsible for development, medical sales and marketing. This -- our expectation was that by developing these business units and taking this approach to the business, that we would bring the customer and commercial thinking closer to the development process for our new products working through our pipeline. And it's this partnership with the research units, and the accountability and responsibility that the business units now have for post-proof of concept decision-making that I think is starting to pay off. And I'll show you why I think that in just a few minutes.

But it doesn't happen just with structure. We've also developed a number of important tools to enable us to be more effective and rigorous in decision-making to support our pipeline. At the top of the page here you see this medical differentiation index. This is a tool that we apply to every compound coming through development to help us clearly understand and articulate



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points of differentiation for new compounds. And not only identify the point of differentiation, but quantify the degree of difference of our molecule relative to the standard of care.

By doing this, and documenting these points of differentiation, we ensure that we're all on the same page -- the commercial people, the research and development people, the regulatory people. And then we apply what we call our label-less driver tool, to ensure that those points of differentiation can actually make it into labeling and that would be supporting promotional claims.

You see on the right-hand side there's a box for HTA access readiness. We're also meeting with HTA authorities in countries around the world to discuss our development plans prior to completion of our Phase 3 protocols. And we've made amendments to some of our development plans on the basis of the feedback that we receive from HTAs. So it's a more rigorous process than it has been in the past.

So we take the right structure and the right tools, and then we apply that to a focus on specific disease areas, our Invest To Win areas. And we think we'll be more focused and more successful.

So we have five major disease areas that we call Invest To Win areas. In each one of these cases, I'm sure you'll recognize there's significant unmet need, whether it's Alzheimer's disease in neuroscience; rheumatoid arthritis; psoriasis; Lupus; irritable bowel disease, in the inflammation and pain area; infectious disease, where we both have preventative vaccines, as well as antibacterial and antifungal agents that we're developing; oncology and metabolic disorders that afflict tens of millions, if not hundreds of millions of people on a worldwide basis, and exert billions and billions of dollars worth of healthcare costs on society.

At the bottom of the page, you can see that we're able to apply three different platforms for development in addressing these unmet needs -- vaccines, small molecules, and biopharmaceuticals. With our expertise in both vaccines and biologics, we're able to bring forward compounds that we think may have a higher probability of success. We're advancing many of those products through late-stage development.

This is our pipeline as it stands today. As you see, there's 118 programs in our pipeline. We've advanced 25 programs from one phase to another in the past year. And importantly, in the middle of the page, you see 31 projects discontinued since our last update. That's not a bad thing.

There is some natural attrition that occurs in the pipeline along the way, but some of that attrition is a result of more rigorous decision-making on the part of our business units and research units. And we think that that enables us to move forward with only the most promising compounds and those likely to be successful from a clinical standpoint, a regulatory standpoint, and a value-generation standpoint for payers.

Now this is our late-stage pipeline. And you can see the page is broken into the top, which is compounds and registration, and the bottom, compounds in Phase 3 development. This is a pretty good picture for us. And let me talk about the registration -- in registration compounds first. There's 11 programs in this grouping. Actually, we just added a 12th recently, with Crizotinib, our new oncology product for non-small cell lung cancer, where we started the -- a rolling submission just last week. So we have 12 compounds in registration.

And you know, I would kind of think of these in three different buckets. There are those registration programs for successful major brands that we have, where we have opportunities to expand our business for Celebrex, Lyrica, and Pristiq, for example, and Sutent; we have an opportunity to add growth to already significant growth drivers within the Company.

There's a grouping of compounds that we've brought into the Company recently through successful business development activities. So, Xiapex and Tafamidis, and Taliglucerase are all compounds that we recently brought into the Company. And you can see we've been able to advance those programs and all three of those programs are in the registration stage.



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And then there are significant new programs that we're very excited about that came from within the Company -- Apixaban, which is done in collaboration with Bristol-Myers, and Prevnar 13 Adult, which you'll know we filed in the US and in Europe last year. Both of these programs represent, we think, substantial opportunities for us in the near-term.

So below this level in Phase 3 late-stage development, I'm really excited to be able to show you that our oncology portfolio is really starting to take shape. There's quite a number of programs here -- Axitinib, Bosutinib, Crizotinib, Neratinib, and a couple of other compounds on this page. It's a very robust, late-stage oncology pipeline. I'm going to talk specifically about a couple of these in just a few minutes.

And then among this group is CP-690550, which we call Tasocitinib, which is in development today in rheumatoid arthritis and psoriasis, in late-stage development. We presented some Phase 3 data on our RA program at ACR last November, and I'll talk a little bit more about that in just a moment as well.

So, 11 or 12 compounds in registration; 18 more in late-stage development. The portfolio is really taking shape. And I think this is the outcome of the business unit approach that we put in place a couple of years ago, starting to reveal itself.

Importantly, the new products that we're bringing along are going to fit nicely into areas of strength that we have from a commercial standpoint. So from the oncology perspective, we have the world's leading drug in renal cell carcinoma with Sutent; in inflammation, we have the world-leading product in Enbrel; and in the vaccines area, we already have a very substantial business in the infant end of the market with Prevnar. And we'll be adding to that, obviously, the adult indication in the near future.

So let me talk about these four programs that are particularly exciting. I chose these because, frankly, they are programs that I work with closely in Specialty Care and Oncology, and they represent a number of -- some of our more exciting programs, although there are more, as you saw on the previous slide.

So let me start out with Prevnar 13 adult. This is a huge opportunity for us. Pneumococcal disease is a highly prevalent disease, both in the infant end of the age spectrum as well as the adult -- late adult end of the age spectrum. IPD, or Invasive Pneumococcal Disease, incidents in patients and individuals over the age of 50 starts to approach the incidents that we see in young children, that supports the recommendation for vaccination of young children.

So there's ample rationale for vaccination of the adult patient population on the basis of invasive pneumococcal disease. But beyond the invasive disease, pneumococcal pneumonia is also a very serious problem, affecting over 0.5 million people in the United States every year and accounting for over 20,000 deaths in the US.

And when you look at World Health Organization numbers, these numbers grow by several orders of magnitude. So it's a very substantial burden of disease. Invasive pneumococcal disease, as well as pneumonia, are associated with significant mortality and morbidity. And the cost of caring for patients, managing through hospitalizations and secondary complications that occur in these patients, is extremely costly for healthcare systems around the world.

And we know today there's only really one intervention available for the adults, and it has some significant limitations in terms of its effectiveness in preventing community-acquired pneumonia in particular. We have an excellent profile with Prevnar with the conjugate vaccine, and we think we can build upon the foundation that we've established with the infant vaccine and bring a new solution to this significant healthcare problem going forward.

Importantly, we've made a significant investment in a major outcomes trial to clearly establish the effectiveness of this vaccine in the adult population, specifically with regard to its effectiveness in preventing community-acquired pneumonia in the adult population. It's the largest trial ever conducted in vaccines -- over 85,000 patients enrolled. And we will be seeing results within the next year or two, and be able to establish conclusively the efficacy of 13-valent in preventing community-acquired pneumonia. And that will be a substantial proof-point for payers and healthcare decision-makers alike.



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Now this slide may be a little bit hard to read, and that's the idea. This is about Tasocitinib, our JAK-3 inhibitor for rheumatoid arthritis. This is also a very substantial program. We have a Phase 3 program now being conducted in 35 countries and over 350 sites. And you can see on this slide there are six major Phase 3 trials underway.

Our goal here, coming into the RA market, which is becoming more and more congested, we want to be in a position to clearly describe the clinical profile of this drug in a variety of different patient subsets and clinical environments. So we're going to have data to show how this drug performs in patients who are DMARD failures; in patients who are TNF failures, in combination with Methotrexate and monotherapy.

Our goal is to ensure a appropriate and rapid uptake and adoption of this drug once it's available. And we've made the investment to ensure that we'll have adequate information to make the right benefit risk decisions as well as the right economic decisions for payers.

As I mentioned before, we presented our first Phase 3 data last November at ACR and it was extremely well-received. I think the world is anxious to see this new agent with a new mechanism of action add to the growing list of drugs in the management of rheumatoid arthritis.

What we've seen so far in Phase 3 is efficacy and safety that confirms what we saw in Phase 2 -- no surprises with the Phase 3 experience. We have biologic-like efficacy, manageable safety, and the convenience of an oral form. It seems to have a rapid onset of biologic activity and a sustained effect over time. So, we -- so far, so good, with Tasocitinib.

And beyond rheumatoid arthritis, we're exploring the utility of Tasocitinib in a variety of other inflammatory conditions. Listed here on this slide, you can see we have Phase 3 underway with RA and psoriasis, and Phase 2 trials underway for three or four additional indications. And clearly, these are indications that could add substantially to the size and impact of a product like Tasocitinib, should we find success within these trials. I think, cumulatively, if you add up the projected size of these markets, it exceeds \$30 billion. And we hope to have a real portfolio product here with Tasocitinib in the future.

Turning now to our oncology pipeline, I like this slide too. It just, visually, it looks nice. We have a number of important programs across each stage of clinical development; seven compounds in Phase 3 development; four different mechanisms of action; and again, a nice distribution of programs across Phase 1, Phase 2, and phase 3.

Somebody asked me earlier today if we're actively seeking more compounds to put into our oncology pipeline. And my answer really is that we're always looking for quality compounds to add to what we have. Our team at Pfizer has actually done more work paring away less-attractive compounds in the last year, so that we're really focused on the things that we think are going to add value and enjoy success in the clinic. We feel pretty comfortable with where we stand today -- although, again, we're always looking for high-quality assets to add to this list.

In oncology, one of the areas of focus for us now is in this area of precision medicine and personalized medicine. And this is just a slide to depict the advantages of focusing on precision medicine. Clearly, if we can identify patients who respond with a better treatment effect, we can design trials and conduct trials with smaller numbers of patients. We can conduct those trials more rapidly at lower cost. And for the patients, they are certainly more likely to respond and have a favorable reaction to the drug, and that should translate into a more successful therapy and a potentially longer duration of therapy in those patients who do respond.

Crizotinib, our lead drug in the non-small cell lung cancer, is a great example of applying personalized medicine, precision medicine, to the development of a new oncology drug. Now this is a chart from a study that was published in the New England Journal of Medicine last year, demonstrating the outstanding effectiveness of this drug in patients who are ALK- positive in -- with non-small cell lung cancer.



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Each line on this bar represents an individual patient. And you can see very consistent, very substantial response rates from these patients. So, we're pleased to see this development, and we're focused on trying to find solutions like this for other development candidates.

Crizotinib is also a very good example of -- in our business unit structure and organization and approach at work. Because of the seamless work from research through clinical development with Crizotinib, we were able to identify this compound and isolate a lead compound in 2005, identify the gene translocation in 2007, and have clinical data to file by late 2010/early 2011. So, all in a five-year period versus a typical 10-year period. And we think that this is attributable to the way that we're approaching development today.

My last compound that I'll just speak briefly about is Axitinib. This is a drug for metastatic renal cell carcinoma. And we recently published -- again, late last year, November, the results of this trial, where it met its primary endpoint demonstrating a significantly extended progression-free survival. And we're happy to be able to bring another modality forward in renal cell carcinoma.

We were obviously vested in RCC and been a leader in this area. We've watched this market develop from a very small market to a very substantial market. And we think with the addition of products like Axitinib and others, that this market has considerable room to continue to grow, as patients realize better outcomes and longer-term duration of therapy with well-tolerated, effective agents like Axitinib.

So, in summary, I really would like to impress upon you that we feel that our -- Pfizer's new structure does enhance our focus and expertise, running our diverse businesses that we've developed tools and processes for enhanced decision-making. We have the accountability in place for that decision-making, and as a result, our pipeline is developing nicely. We're in a strong position today with 12 products in registration and 18 more in late-stage development, and we're looking forward to bringing these products to patients and to the world.

Thank you very much.

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