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PFE - Pfizer at Cowen Group Health Care Conference

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PRESENTATION

Steve Scala - *Cowan - Analyst*

Well, good morning. I'd like to welcome Pfizer to the Cowan Conference. Representing the company is Geno Germano, who is President and General Manager of Specialty Care and Oncology. He's joined by two other members of management.

I'd also like to remind you that we are recommending Pfizer stock at Cowan for three or four reasons. First, we think the post-Lipitor pressure growth recovery is impressive. We think the upcoming new products are exciting and have big potential. We like the fact that the dividend is on the rise, and Pfizer clearly has the cash flows to support the dividend. And we think the valuation is compelling. So, for those reasons, we like Pfizer stock. And I'll turn it over to Geno.

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

Okay, thanks, Steve, and good morning, everyone. I'm going to spend just a couple minutes talking a little bit about one of the reasons that Cowan is recommending Pfizer's stock, and that is the new product story. In Specialty Care and Oncology, we've been a bit flush with new product development and filings and introductions. So, I just want to comment a little bit on that, and then I will open it up for your questions.

I'm joined here today with -- with me is Mark Swindell, who's President of our Vaccines Division. So, to the extent that we -- you have some questions about the vaccines business, we have the expert here.

So, just to comment a little bit on the pipeline and on the productivity that we've seen recently, you may know, since Ian Read became CEO a little over a year ago, he's made fixing the innovative core his number one imperative. And frankly, I think we've made a lot of progress. In Specialty Care, in the last 12 to 18 months, we've launched Xiapex in Europe for Dupuytren's Contracture. We've launched -- filed, approved and launched Vyndaqel, which is the drug that we acquired from FoldRx a little over a year ago. It's a drug for a rare disease, an amyloid poly neuropathy. And we're now launching in several European countries. We filed Tafamidis also in the US, and we're working with the FDA on an accelerated review of that product here.

And then, most importantly, last year, filed Tofacitinib, our JAK inhibitor for rheumatoid arthritis in the US and Europe and Japan. And that review is ongoing. We have completed five phase three trials, approximately 5,000 patients. And we're excited to be able to bring this new mechanism, a new opportunity for the rheumatoid arthritis patients who are inadequately controlled with current therapies to the marketplace.

In the oncology area, again, a lot of activity over the last 12 months. We filed three drugs in most markets around the world. First and foremost was Xalkori or Crizotinib for ALK-positive non-small cell lung cancer patients. You know that we filed and within five months had approval in the US. We launched the product in the fourth quarter of last year, and we're seeing a continuous uptake in the US now. We're expecting approvals in Japan in the near term and in Europe, as well, this year.

We filed and had approval for Inlyta or Axitinib for advanced renal cell carcinoma second line therapy. The approval occurred early this year in the US, and we're advancing the registration process in Europe and Japan, as well.



And then, Bosutinib for CML has also been filed in both the US and Europe, and we're working with regulators on approval of that product, as well. So, we had a lot of activity in the oncology area.

And then, of course, with vaccines, we're very excited to have new approvals for Prevnar 13 in the adult population in over 40 countries, including the European Union and most recently approval in December in the United States. And we think the opportunity for Prevnar 13 in the adult population is extremely exciting. The disease burden is substantial. The cost of care is substantial. And the number of, frankly, just the number of potential recipients of that vaccine is extraordinary when you consider the number of adults now over the age of 50 in the developed world, and frankly, the emerging markets and the developing world, as well. So, we're very excited to have those approvals and to make continued progress with bringing Prevnar 13 to the adult population.

Beyond these very late stage products, we have a very active late stage pipeline in the, kind of the phase two area. So, for Specialty Care, Tofacitinib - our phase three program is underway and advancing nicely for psoriasis. We're about ready to start a phase three program for ulcerative colitis.

We have programs in place for the use of Tofacitinib in Crohn's disease and ankylose and spondylitis and psoriatic arthritis and transplant. We even have a topical psoriasis program underway for Tofacitinib. So, we see the molecule potentially becoming an entire franchise for the company over the long term.

And beyond Tofacitinib, our inflammation team has been extremely busy with a number of other molecules, an ILC6 inhibitor, a MAdCAM antibody for indications such as lupus, irritable bowel disease and rheumatoid arthritis. So, there's a strong pipeline in the inflammation area with a lot of activity in the phase two, 2A and 2B range.

In oncology, the next wave of compounds includes Dacomitinib for non-small cell lung cancer and Inotuzumab for advanced non-Hodgkin's lymphoma and additional expansion opportunity for Xalkori - so, a lot of activity there and then a number of other compounds further back in the pipeline.

And then, in the vaccines area, we're excited to continue to make progress with our mening B vaccine. We're working with FDA to finalize trial design for our phase three program. We have registration trials underway, concomitant use trials with other adolescent vaccines. And we see the progress in that program occurring imminently.

We have a staph aureus vaccine that's in phase one that's advancing, [Quadrivan] staph aureus vaccine. So, we -- and then, there's a C Difficile vaccine behind that. So, we have a good pipeline of new vaccines coming along.

Last year, we did a business development deal with a company called Glycomimetics for a pan selected inhibitor for patients with vaso-occlusive sickle cell disease. And we're expecting a proof of concept readout in the near term and hope to be able to advance that compound, as well.

So, these are just the compounds within the specialty care and vaccines and our oncology arena. I won't comment much on the other areas. We are focused now -- we've kind of resized and refocused our research and development organization. We're focused on five key areas - immunology and inflammation, as I've already commented on, neuroscience, cardiovascular metabolic diseases, oncology and vaccines. We also have programs ongoing in pain management and rare and orphan diseases. We have a rare and orphan disease research unit focused on filling significant unmet needs in that area.

So, we think we've kind of right-sized, right-focused our research and development organization. We're making good decisions. We're working effectively with regulators. We're advancing the pipeline. And we look forward to continuing this work to develop the portfolio for Pfizer of the future.

So, with that, I'll stop and welcome the questions that you might have. Yeah, Steve?



QUESTIONS AND ANSWERS

Unidentified Audience Member

Three questions on Tofacitinib -- first, investors generally believe an FDA advisory panel will absolutely be held to review what happens. Would you like to alter that expectation in any way?

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

That's our expectation, as well. I mean, it's a new mechanism of action, and that's our expectation that we'll have an advisory committee.

Unidentified Audience Member

Second, where do you see the drug initially being used? Is the battleground mono -- or new patients, is it prior to a biologic? And could you speak to this in your label, your proposed label?

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

Yes. So, I mean, I think our expectation -- I mentioned that we did five phase three clinical trials. So, we have -- we've evaluated Tofacitinib in a fairly wide range of potential patients. The majority of the trials, four out of five, were done in DMARD or Methotrexate inadequate responders, so prior to TNF use.

And of course, the results have been at least partially publicized. So, we have very strong evidence of efficacy across frankly all of the primary and secondary endpoints in those trials. And then, we did a post-TNF trial and showed effectiveness in that setting, as well.

So, we have -- we believe that the evidence suggests that the drug can be used both in DMARD inadequate responders and TNF inadequate responders. And that's what we addressed in our labeling, the labeling that we submitted.

In speaking with rheumatologists and key opinion leaders, like most new mechanisms, drugs with new mechanisms, in a severe patient medical condition, it's most likely that initial use will occur in the post-TNF setting. So, there -- a rheumatologist's first try with the drug will likely be in that setting, and that's our expectation. We think we've got the data and the evidence, and we hope to have labeling that makes it easy for physicians to migrate to pre-TNF use. And frankly, we have a trial underway today. It's been underway for over a year now in a -- as a monotherapy evaluating the effectiveness of Tofacitinib relative to Methotrexate in patients who were pre-Methotrexate patients.

So, eventually, we may actually be able to migrate ahead of Methotrexate. But, it'll be an evolution, and it'll start with the post-TNF patient population and move back over time.

Unidentified Audience Member

My third question is, in the list of possible additional uses for Tofacitinib, I thought I heard you say transplant rejection. I know you said transplant rejection.

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

Yes.



Unidentified Audience Member

And maybe I'm confusing this with a different drug, but didn't this drug start its life out as a transplant drug and it was dropped? So, are you revisiting it and why?

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

Yes, it -- actually, I think the initial -- some of the earliest work was in the transplant area. I'm not sure if that was the very beginning, but it was -- there was some early work done in transplant. And frankly, the results were compelling.

So, what happened over time was we initiated the RA program, and the RA program advanced more rapidly than the transplant program. But, we have evidence of effectiveness in the transplant setting. We have the ability to continue in that direction. And so, it's one of the potential additional applications beyond RA and psoriasis that we are evaluating.

Okay. Got another one.

Unidentified Audience Member

A question on Prevnar 13.

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

Yes.

Unidentified Audience Member

So, I thought that what the company had last said is that you were going to await the ACIP prior to the launch. And so, now that you've had the ACIP, are you launching?

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

So, the ACIP meeting occurred in -- a couple of weeks ago, and the committee decided not to make a recommendation at this particular meeting. They alluded to the potential for a recommendation in the June meeting. So, we are -- we have a commercial plan in place, and we expect to communicate with physicians and providers about the use of Prevnar. It's an approved product. It can be used in the adult population today. It will be a much slower uptake without the ACIP formal recommendation, but we will be interacting and communicating with customers.

Unidentified Audience Member

And the second question is we have vaccines experts who think that you'll get an indication or an ACIP recommendation for the immunocompromised patient population only initially. So, if that's the case, how can we get that population? Is it 1% of the addressable over 50s or is it 35%?

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

Yes. So, the ACIP Committee did allude to the potential for a, an immunocompromised patient recommendation on the basis that this is a patient population that has not realized protection from the polysaccharide vaccine. Despite the availability of the polysaccharide vaccine, there's a considerable amount of pneumococcal disease in this patient population. So, there's nothing available for them.

So, the ACIP had commented that they were considering a recommendation for that population in the June meeting, and that's why that speculation exists. So, if that occurs, we think the patient population in the United States, depending upon how they define the patients that fall into that category, could be in the neighborhood of 10 million patients, in that range. And, again, it'll depend on which patients they include in the ultimate recommendation.

We frankly think that there are other patients who fit the description of not receiving protection from the polysaccharide vaccine today who could benefit from the conjugate vaccine, and we plan to discuss those patient populations with ACIP. But, I really can't speculate on the receptivity of the ACIP to those suggestions.

Yes?

Unidentified Audience Member

(Inaudible question - microphone inaccessible.)

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

So -- yes, I'm not real intimate with Eliquis. I think what we've said is that there's a three month delay as a result of the submission of additional information to the file. There's nothing unusual about that. It happens frankly all the time. And I don't think we anticipate any further delay beyond that. In terms of the Advisory Committee, we're not currently scheduled to go to an advisory committee. And that's all I know really at this point.

Yes, Steve?

Unidentified Audience Member

Could you compare and contrast your meningitis B program with that of Novartis?

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

Yes, now, here's one I might ask my colleague Mark to help me out with. They are different -- they're certainly different vaccines. They have different spectrum of coverage. And they are being tested in different patient populations. They're being tested using different endpoints that may be more receptive in a US setting versus a European setting.

So, Mark, maybe -- can I ask you to come up and add any commentary to that?

Mark Swindell - Pfizer - President, Vaccines Division

If you can hear me okay -- yes, the Novartis vaccine and the Pfizer vaccine both operate primarily on the basis of factor H binding protein. The Pfizer vaccine has evidence of effectiveness against strains from both the primary sub-families of the factor H binding protein, sub-family A and sub-family B. The Novartis vaccine, on the other hand, only appears to work on sub-family B.

The evidence that's been presented up to now for the Pfizer vaccine is evidenced against heterologous strains of the meningococcal B disease, which gives us the confidence that the vaccine will have effectiveness against the broad range of different strains. There are some 1,200 strains of disease.



In contrast, the Novartis vaccine has been tested only against [homodular] strains of the disease. And you would expect that vaccine to work against [homodular] strains. So, that's kind of what we know today. As Gino already alluded, the Novartis vaccine is currently pending European regulatory review for an infant's indication. Pfizer's vaccine is in development (inaudible).

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

And I think the importance of that difference is that, with the -- with meningococcal B disease, we believe that the adolescents are the carriers of the pathogen. So, if you can eliminate the pathogen in the adolescents, you can actually potentially have a herd effect and prevent disease in the infants, and the opposite would not be true. So, there would be a number of differences.

Unidentified Audience Member

One issue that Novartis has had is that they've had fever in their trials. Have you seen fever, and that's just something you can't get around? And how problematic is that?

Mark Swindell - Pfizer - President, Vaccines Division

In the phase two studies that we did in adolescents, there was, we know, a significant evidence of fever. You're right that in the infant trials that Novartis have conducted that there were -- I forget the precise numbers, but it was a substantial number of fevers that were reported. (Inaudible.)

Unidentified Audience Member

And how problematic do you think fever is in this population?

Mark Swindell - Pfizer - President, Vaccines Division

In very young infants, it's a big problem.

I think we have one here. Yes.

Unidentified Audience Member

(Inaudible) and this is an early question, and I'm not asking you to tell me the price, but given some of the small molecules coming into a biologic pricing market, do you think Pfizer has a real advantage here (inaudible)? And one of the issues that came up, and this came up more than once (inaudible) prior auth issues of these drugs (inaudible) for RA. And I was just wondering, does Pfizer have some type of secret way to get yourselves better positioning in terms of prior authorization? Like, do you think Pfizer has an advantage there, maybe sort of products or just giving higher discounts to managed care, so that might be an advantage for you versus your competitors? You have the same efficacy, so I'm just trying to see where maybe you can get a greater market share (inaudible).

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

Yes. So, I don't -- there's no secret weapon. It'd be nice to have something like that, but there's nothing that Pfizer really can do that others in the industry can't do. But--.



Unidentified Audience Member

--But, it is a small molecule, and so you have better gross margins.

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

We do -- that's true. So, we can price the product -- we have pricing flexibility. And we are evaluating the, kind of the best combination of price, access, prior authorization rules so that we can make the drug accessible and achieve an optimal return on our investment.

So, it's kind of a difficult way of saying that we're going to evaluate all of the factors that you commented on and we'll determine what's the best path for us to take. And there'll be a balance of what's best short term versus what's best long term. If we can avoid prior authorizations in settings where TNF inhibitors have prior authorizations, obviously, that would be a big advantage. And it's yet to be seen what's required to kind of achieve that level of access. But, we're working through those items now.

It's important for us to understand what labeling we're ultimately going to have, and there's a time element. We don't want to do -- we're not going to do anything at the initial launch that's going to prohibit our options in the future. So, it's -- there's a lot of considerations to evaluate.

Unidentified Audience Member

Once you set a price, just say that you set a price similar to the current biologics, can you separately (inaudible) at a later time and say (inaudible) much greater dividend for better access? Is that a (inaudible)?

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

Sure.

Unidentified Audience Member

Okay. Thank you.

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

Yes.

Steve?

Unidentified Audience Member

Investors generally believe that Bosutinib will be a third line [PML] agent. Would you like that to be more optimistic than third line PML?

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

I think in the US, that's what we're -- that's what we filed for.

Unidentified Audience Member

What about outside of the US?

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

Outside of the US, there's actually potential for other regimens. Actually, it's a first line file in Europe.

Yes?

Unidentified Audience Member

(Inaudible question - microphone inaccessible.)

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

Yes. I mean, Xiaflex -- am I happy with it? I think that it's been a slower uptake than we expected. I think the reimbursement challenges were more significant than we had initially anticipated. We got national reimbursement recommendations in place and then learned that, in many cases, there are local funding requirements for a product that administered the way Xiaflex is administered.

So, it's been -- it's required a lot more effort to get the local reimbursement and funding in place even though there's -- there are positive national recommendations in place. The good news with Xiaflex is the -- once the physicians and patients have experience with it, the feedback is very positive. It's not going to be a monster product for us, but it can be -- we think it can be a nice contributor to our overall portfolio over time.

Yes?

Unidentified Audience Member

I think at least 10 other companies have tried and failed to get a staph aureus vaccine. So, why does Pfizer have a better mousetrap? And secondly, I think Merck had tried, found a quick to market strategy in CABG patients. Is that what you'll do or will you try some different strategies?

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

Yes. Maybe, Mark, can I ask you to help me out here?

Mark Swindell - Pfizer - President, Vaccines Division

Yes. I don't know the specifics of the Merck compound and other compounds that have gone before Pfizer's investigational approach to our staph vaccine. The vaccine that we have in phase one, phase two today is a four component vaccine. It's a vaccine that shows incredibly high immune responses in healthy adults in a previous phase one.

So -- and we've got, I think, a high level of confidence that that immune response will translate into the potential prevention of staph disease. But, that will only, of course, be proven as we go into phase three, which if we're successful in proof of concept, would occur some time in the next 18 months or so.

The second part of your question about which approach will we take, we're evaluating all of the options right now, and we'll determine our phase three approach at the conclusion of phase two.



Unidentified Audience Member

(Inaudible.)

Unidentified Audience Member

(Inaudible question - microphone inaccessible.)

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

Well, I think that that's really one of the benefits of the, kind of the business unit structure that we have in place now at Pfizer. And we operate with people who have enough focus to keep things like the orphan rare disease business going.

It's actually a pretty decent business for us. We have the hemophilia business, which is a \$1 billion business. We have growth hormone. We have Revatio for pulmonary arterial hypertension. We have now Tafamidis that's recently been approved for amyloid poly neuropathy. We have the sickle cell disease drug in phase two.

Within specialty care, I like to think of it almost as business units within a business unit. So, I -- we have different business models and different commercial approaches within the business unit itself. So, one end of the spectrum is the kind of rare and orphan disease area where there's generally highly specialized practitioners, generally a small number of them, significant amount of customer intimacy there, not only with the providers, but in many cases, with the patients themselves.

And we have a group of people within the business unit who are focused on and dedicated to running that business, understanding those customer needs and executing a commercial model that works for those kind of rare and orphan diseases. And we have a research unit here in Cambridge that is dedicated to development in the rare and orphan disease space.

Then, we have what I kind of term more mainstream specialty care, which is the -- in inflammation as a good example where you have rheumatologists or you have a psychiatry medicine or something for ophthalmology where it's not kind of at the rare disease end of the spectrum, still specialty care. And we have a go to market approach for those businesses.

And then, we have an institutional business with our hospital based infectious disease portfolio. And then, we have the vaccines business where we sell product directly to a physician, take payment from that physician, manage inventories and things like that. So, even within specialty care, we have four different business models. And I think that that's how we make things like rare diseases a -- something that doesn't kind of get lost. The people that are dedicated and focused on it, they kind of live and die by the success that they have. And it's working pretty well.

Steve Scala - Cowan - Analyst

We're actually--.

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

We're out of time?

Steve Scala - Cowan - Analyst

Yes?

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

Okay. Thanks very much, everybody.

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