

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

PFE - Pfizer at Citi Global Healthcare Conference

EVENT DATE/TIME: FEBRUARY 26, 2013 / 9:35PM GMT



CORPORATE PARTICIPANTS

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

CONFERENCE CALL PARTICIPANTS

Andrew Baum *Citi Global - Analyst*

PRESENTATION

Andrew Baum - *Citi Global - Analyst*

I'm delighted to be joined by Geno Germano, who is President of Specialty and Oncology Medicines at Pfizer. Thank you for joining, Geno.

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

You're welcome, thanks.

Andrew Baum - *Citi Global - Analyst*

So before we get into it, why don't you just bring us up to speed in terms of the work that Pfizer has done, particularly with their innovative medicine part of the business.

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

Well, Pfizer has made a fair amount of progress, I think, in the last 18 to 24 months. We've made major changes to the way that we orchestrate our R&D organization. We've resized the R&D organization and challenged ourselves to operate within a more confined budgetary limit, which is part of the whole process of more robust decision-making and investing in the molecules that we have coming through the development pipeline. So we think that we've made some very good changes that have enhanced our ability to make tough decisions, identify drug candidates that we think have the highest value and the greatest return on investment for our shareholders. We've had some good success at the late-stage part of our pipeline. You probably all have seen, in 2012, we were the leading pharma company in terms of FDA approval with five approvals, which was a great accomplishment last year.

And we have some very exciting compounds in development now. I'm sure we'll talk about some of those. So from an R&D standpoint, I think we're feeling like we've got the engine moving in the right direction, and we're enhancing the productivity of our investment and our resources.

Andrew Baum - *Citi Global - Analyst*

So before we dig down into Pfizer, perhaps a few words about the reimbursements and access environments in the major territories given this conference is very much focused on what we call the value imperative. I guess if we take the US first and divide it into two buckets. Firstly, the risk to near-term pricing as part of sequester. Perhaps you could talk through the risk as you see it within Pfizer to anything that could result as negotiations to resolve the impasse that exists in the US in terms of pricing or dual eligibles being one key topic.

And then, secondly, the longer-term impact on moving away from fee-for-service towards capitation -- what that means and how you think about it inside Pfizer?



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

Okay, so, I mean, in terms of sequestration or managing the debt, clearly, there's potential for pricing challenges for our industry, and I think that dual eligibles are one of the more prominent targets. I think there are those in the administration that clearly see a big win there, and there will be some support for that.

Obviously, our view is that we've contributed pretty significantly to the Affordable Care Act, and we find that the Part D program is a very successful program; one that has cost less than was expected and one that seniors are very satisfied with. So it's certainly our view that the dual eligible should not be a source of solving the debt problem. But this is something that obviously will be hammered out in Capitol Hill over the course of probably the next several months, and we'll see where that leads.

So I think, short-term, within the next several months, I think that we're just going to have to watch what comes out of Washington and what revenue or cost impacts are on the industry and it will be a battle. I think, longer term, the whole shifting focus -- more capitation, more focus on paying for outcomes -- I think has caused us, obviously, to redouble our efforts to ensure that the compounds that we're investing in and developing are compounds that will bring value to the marketplace, and that we'll be able to demonstrate that value.

So as a result, we're working with health authorities, health technology assessment bodies, major payors in the United States, during and throughout the development process to understand how they view the compounds that we have and the development pathways that we're exploring to determine the best way to identify that value, extract the value from our compounds, and focus on the compounds that are most likely to be able to support a value argument so that the health care system will recognize where those value drivers are, whether it's specific patient populations that we exploit in our development programs, or specific health cost avoidance opportunities with the use of our therapeutics. This is something that we're focused on now.

Beyond that, we're developing stronger capabilities as an organization to tap into real-world evidence, real-world data, building our capabilities in a data analytics standpoint so, again, that we have a better idea of the patterns of usage of our medicines and competitor medicines and health care costs within health care systems. It's causing us to have to play a broader role other than being a manufacturer, discoverer, developer, manufacturer and seller of medicines, we are now needing to become more focused on ensuring that the medicines that we discover or develop, register, and manufacture actually bring value to the payor, to the patient. And so that causes us to have to behave differently.

Andrew Baum - Citi Global - Analyst

And you touched on outside the US. So there's one further op in the US, but just given you mentioned Europe, obviously, IQWiG recently rejected your arguments for Xalkori in terms of reimbursement. How should we view this? Is this a major impact that is likely to be unresolvable? Or are you optimistic that in a fairly short timeframe you're going to be able to come back with the existing data you've got and present arguments that's going to secure reimbursement and what does it mean more broadly in terms of getting the right price for what your innovative drugs in that market?

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

Yes, well, I mean, there are a number of challenges with the different health technology assessment bodies and pricing and reimbursement bodies in different countries around the world. They have algorithms that they use, processes that they follow, rules that they've established. And sometimes and especially for a drug like Xalkori, where this is a drug that was developed very rapidly with a very small patient population on the basis of the availability of a clear biomarker and a profound impact on the health of patients that need the drug.

So you have a drug like Xalkori developed in an accelerated way because of the potential impact on the health of patients, you're not necessarily going to meet the needs and the desires of each and every one of the health authorities and the algorithms that they use to evaluate a medicine.

So I think that's what happened in Germany with Xalkori. We obviously have continued to invest in the development of Xalkori, and we feel fairly confident that we can bring a convincing argument forward for the adoption of Xalkori in Germany and other health care systems. But, as you

know, there's different assessment processes that are used, and that does present some hurdles particularly for really novel new medicines, new mechanisms, and where they're developed in an accelerated fashion.

Andrew Baum - Citi Global - Analyst

So moving on to the individual product lines within the business -- oncology has been a notable success story of late for Pfizer. We were just talking outside, you've had three recent approvals -- Axitinib, your Bosulif, and I'm missing one, which one am I missing?

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

Crizotinib.

Andrew Baum - Citi Global - Analyst

Crizotinib, exactly, there we go. And that's for a company, which historically one did not think as an oncology company, which with disappointments such as tremelimumab and now there is a step change. So I guess the first question is, is that possible to ascribe any particular factors for the ability to commercialize these products and develop these products?

And then, second, and perhaps more interestingly, you have a very, very high potential innovative asset called PD-991, the first-in-class cell cycle inhibitor, different from the other three assets we spoke about, it is not a next-in-class. It's a first-in-class and therefore there is no template for developing it. You are going to have to write the rule book on your own. Do you think Pfizer has that level of competence internally or through its network, was this an area you think you are actually looking to augment through external collaborations and so on and so forth?

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

Well, that's a lot of question there.

Andrew Baum - Citi Global - Analyst

You can start with the last one -- forget the first one.

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

I actually would prefer to take a moment and just say that I think -- several years ago, I think Pfizer decided that oncology was an area that was important to its future and made the investment to identify and to track some very capable oncology talent from the marketplace. And Garry Nicholson came from Lilly where he spent a couple of decades in oncology. Mace Rothenberg came from Vanderbilt and came into the organization, and they've augmented the oncology team over the course of the last several years both in terms of talent and in terms of paring down the pipeline to identify molecules that they believe are the most appropriate ones to take into development.

And they have a very disciplined approach to ensuring that before we invest in advance molecules that there's strong rationale, scientific rationale, for going forward and there's data that supports that scientific rationale.

So I think it's a much more effective and clear and disciplined approach. I think when they both got there, we were doing a lot of work with a lot of molecules kind of hoping with a shots on goal kind of mentality, that we would be successful.



So -- I think it is a different environment today, and axitinib and bosutinib and crizotinib approvals in the last 12 months not only in the United States but in Europe and Japan and many other countries around the world now I think shows that the organization is effective.

To your point, these are mechanisms that had been preexisting to some extent, although I do think that there's some creativity to some of the development programs that they've put in place. And following those three there's dacomitinib for lung cancer and inotuzumab, the antibody drug conjugate for CML. So there's a strong late-stage portfolio.

We were very pleasantly surprised last year when -- I'm not sure surprised is the right word -- but it was a pleasant day when we saw the outcome of the palbociclib trial, the Phase 2 trials in breast cancer. And the data are very promising, very exciting. The external community is very excited about the compound, and I think with the combination of the talent that we have, and the network that we have in the marketplace, advisors throughout the oncology community that we're well positioned to bring this molecule forward.

Andrew Baum - Citi Global - Analyst

And there's been some speculation, at least in the financial world, for that molecule, for the cell cycle inhibitor -- how quickly you can bring it to the market. Now, I guess my personal sticking point is the Phase 2 trial you've got is a hodge-podge of patients of many first line, second line, third line. So even though the data is very compelling, given the outcomes and (inaudible) at PFS, it would seem a very high hurdle to expect a regulator to approve it, because it's not really clear what potentially they're approving it for. Is that an overly cautious view of the world, or you're more optimistic that you could carve out a population or a pathway through which the FDA could bring it faster than waiting for a Phase 3 outcome trial?

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

Well, I think the answer is it's probably a little bit early to tell. I think that there's a tremendous amount of enthusiasm for the drug and enthusiasm for the results that were achieved in Phase 2. But, to your point, it's not a typical Phase 3 program by any means, and it would be atypical of the agencies to approve on the basis of the data that we have today.

Now, the data, even the Phase 2 data, continue to mature. We've completed what we call Part 1 of the Phase 2 trial, and the results were very strong, and that was kind of an all comers population. There's a second stage or a second part to the trial that was a selected population, and that is ongoing. It will complete -- we expect that to complete by around the middle of this year.

I think that the combination of those two data sets will give us a little bit more clear picture of the profile of the drug in this patient population and even subsets of patients across the two populations. And we'll meet with regulators, so we'll talk to them about the data. We were encouraged to initiate a Phase 3 right away. We're in the process of initiating that Phase 3 trial. We have agreement among the major regulators on the design of that trial, and we're off and running. So we expect to report initiation of that study imminently.

So we're preparing ourselves for a best-case scenario, but I think it's hard to handicap the likelihood of an accelerated review.

Andrew Baum - Citi Global - Analyst

Just so I'm clear -- the cohorts are actually going to see any data from patients that we have not seen presented, to date. So my impression is that all the patients we have, what we're seeing now is extended follow-up and then sub-groups of, is that right, or -- ?

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

No. What we've seen now is at San Antonio last year we presented the results of -- it was like a combination of Part 1 of the trial and an interim read at Part 2 of the trial. So when we complete Part 2, there will be a release of new data.



Andrew Baum - Citi Global - Analyst

But there's no new patients?

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

No, there won't be more patients.

Andrew Baum - Citi Global - Analyst

Yes, okay, it's fine. Before we move off PD-991, just as we think about the development plan, is the focus very much breast? Let's figure out how we develop this thing in breast? Or are you starting to think about high-level developments in non-breast indications?

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

Yes. So our first priority was to get the Phase 3 trial ER positive, HER2 negative, postmenopausal patients ongoing. The next step will be expansion of the breast patient population. There are several patient populations for trials that we're evaluating and discussing with regulators now. So that would be kind of our next step. And then there are exploratory trials underway right now in a number of other tumor types, and we're looking at beyond additional tumor types, potential additional combinations of PD-991 with other mechanisms in a variety of different tumor types. So we're looking very broadly at the molecule to explore its application across a fairly wide range of tumors and in treatment regimens.

Andrew Baum - Citi Global - Analyst

Within breast cancer, does that include HER2 positive cancers?

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

It may.

Andrew Baum - Citi Global - Analyst

Okay. Secondly, on Xalkori, there are a bunch of ALK inhibitors from your competitors working their way down the pipe including one, which seems to have efficacy in patients who have become refractory to your drug. What's your confidence in -- how should we think about the ability for Xalkori to preserve that the random events and given, one imagines, the regulatory rate is going to be fairly fast especially for a drug, which is active in refractory patients?

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

Yes, well, I mean, our primary goal right now is to get -- to establish the pattern of molecular testing, identification of appropriate patients for Xalkori, get more experience with Xalkori and to see -- we're seeing now as we've had more time on the market that patients are being identified. Those that are identified earlier in the course of their therapy, of course, generally tend to have a longer duration of treatment and longer duration of response.

So we're going to need to understand that pattern and, again, we're looking at combinations of Xalkori and other mechanisms to extend the treatment using Xalkori as the foundation therapy. We don't know yet whether the best thing to do is to go from one ALK inhibitor to another ALK



inhibitor or to take an ALK inhibitor to the point where it's experienced resistance and then to manage that patient with another drug with another mechanism that avoids that resistance mechanism.

So I think that this is an area that we're going to continue to develop the science, understand the patients and the course of therapy. And we have a number of approaches to try to manage that patient who does achieve resistance on Xalkori.

Andrew Baum - Citi Global - Analyst

And in terms of penetration -- well, let me back up a second -- so what percent of your patients have a test for an ALK mutation in both the US and Europe? And then what penetration do you think you've got of the drug in eligible patients?

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

So what was the first part of the question?

Andrew Baum - Citi Global - Analyst

So patients who actually get -- patients with non-small cell who actually get a test for an ALK mutation?

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

Okay. So in the United States it's at about 60% now. At the end of last year, it was about 60%. Maybe it's a drop higher than that now. And our penetration -- we think about 25% of the patients that we believe, given the prevalence numbers that we're using, are actually getting -- ultimately being put on crizotinib. So there's a significant opportunity for improvement there.

Andrew Baum - Citi Global - Analyst

And the reason why it's 60% and not 100% is what the difficulty is in getting in biopsy samples or -- ?

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

That's a portion of it. I mean, it's molecular testing for this mutation is not -- it's only been one year that there's been a reason to test for an ALK mutation, and there was about 11% testing about a year ago. So we've gone from 11% to 60%.

Molecular testing process in the United States at least, is a kind of very fragmented process, and some hospitals or some cancer centers, diagnostic testing is driven by the oncologist. In others, it's driven by a pathologist or a radiologist. Some centers send out samples to be tested, some do it with in-house, some have very rapid turnaround time, some have longer turnaround times. They have different mechanisms and techniques and success rates for biopsy and capture of tissue.

So there's a wide range of different elements that are playing into the diagnostic testing rate. When you talk to oncologists unanimously want their patients to be tested and, again, we're seeing a nice progression. I think this year we're going to see more pathology association guidelines come out that will support appropriate diagnostic testing for ALK. So we think that the testing process is going to continue to improve.

Andrew Baum - Citi Global - Analyst

In Europe I imagine it's much, much lower level. Is that a fair assumption?



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

In Europe it is?

Andrew Baum - Citi Global - Analyst

Yes.

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

It is today. It's more -- it's less mature than in the United States.

Andrew Baum - Citi Global - Analyst

And on inotuzumab, which I think you mentioned earlier, which is a CD19 -- ?

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

22.

Andrew Baum - Citi Global - Analyst

CD22. This is clearly a less -- it looks to be less toxic than Mylotarg. But still there's a fair degree of systemic toxicity attached to it. I think, hepatic, from memory. Roche has presented data against the same target with their drug, which seems to have a better tolerated profile. How are you thinking about your ability to maintain market share in a market when there is a competitor somewhere closely behind?

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

Well, we're just going to have to see all the data to know. I don't know -- I'm not intimate with the data, so I can't really comment very fully on that. But I think that -- we do think we'll be out ahead of Roche, and we'll have to see how the data plays out.

Andrew Baum - Citi Global - Analyst

So moving gears and going towards Prevnar 13 in the CAPITA trial. I know there's been a very severe flu season in the US this year.

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

Yes.

Andrew Baum - Citi Global - Analyst

I tried to work out through Google Trends -- take the flu season in Holland, but the data is not great. It doesn't look like it. Again, I think the robustness is questionable. On a serious note, when should we expect, given you have access to a number of events, are you still on track for getting a read by the end of this year? I think that was the guidance?



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

Yes, we believe we are.

Andrew Baum - Citi Global - Analyst

Okay, and then just to outline the primary endpoints in what patient population, could you remind us of that?

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

Well, the primary endpoints are vaccine type pneumonia, non-bacteremic pneumonia and vaccine-type invasive pneumococcal disease.

Andrew Baum - Citi Global - Analyst

And when we think -- if this trial is positive, which we have to think it's likely to be, what's it going to take for the European payors to make this mandatory, and how fast will it happen, and one might imagine in Europe they're not going to suddenly reimburse it for all over 50. They're probably going to try and segment out on that risk group. So how are you thinking about how this pans out both in the time and the magnitude of impact?

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

Well, I mean, in addition to collecting the data from the CAPITA trial, we are also, obviously, using surveillance and prospective studies, population-based studies, to bring more clarity to the disease burden in the adult population.

As you know, that there's some -- especially in invasive pneumococcal disease, there is a herd effect from vaccinating the children, so there's a decrease in invasive disease when a country has an effective pediatric immunization program in place. We don't know what the herd effect is for community-acquired or non-bacteremic pneumonia. We know that the incidence rates of non-bacteremic pneumonia are very, very high, especially relative to invasive disease. And hospitalization costs and mortality associated with the disease are, therefore, on a prevalence basis, a fairly substantial number.

So what I'm getting around to saying is that the -- we think that the combination of the effectiveness of the vaccine in CAPITA and the demonstration of the disease burden within the country are going to be the two pieces of information that are going to lead to the adoption or the lack of adoption of the vaccine as a recommended vaccine, mandatory vaccine, or just available vaccine. And that will determine whether or not we're out there with a typical salesforce driving demand for the vaccine or we get some help from the guidelines from the individual countries and for reimbursement from individual countries.

So there's a range of different, I guess, situations for vaccines. In some countries, the recommending bodies make a recommendation, and it's up to the physician to prescribe and administer. In other cases the country will actually purchase and distribute in an NIP-type fashion. Not as much at the adult end of the population as in pediatrics.

But I think the story is pretty similar everywhere. It's that combination of showing efficacy and showing disease burden, but the way it plays out can vary from country to country.

Andrew Baum - Citi Global - Analyst

And then within the US, I think your penetration rate is 65%, something like that.



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

For -- ?

Andrew Baum - Citi Global - Analyst

For Prevnar 13. (multiple speakers).

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

No, no. In the United States, Prevnar 13 for elderly -- for the adult population is very, very small.

(cross talk)

You're thinking of the polysaccharide, yes.

Andrew Baum - Citi Global - Analyst

So given we -- assuming CAPITA is positive, one would imagine that the outlook for Pneumovax is pretty limited given the robustness of your data set compared to what they have? So that should be an opportunity, which you should capture and be able to reprice fairly significantly in a fast period of time? Is that a fair -- ?

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

Well, that would be our strategy.

Andrew Baum - Citi Global - Analyst

So then the second question is -- if you manage to do that, that would be capturing 65% of the market and repricing. Looking at the way that health care is moving in the US and the move towards preventative care in the economic consensus provided, do you see upside to that?

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

Yes, I mean, personally, I would like to believe that if you're over 50 years of age, and you have the ability to vaccinate with a single shot that takes mere moments to administer, that it's almost hard to think of a reason that you wouldn't do that, especially when you think about what people do and how much energy and time and effort they put into other things that they think are preventing negative health consequences down the road.

I think there's likely to be good reimbursement in the United States, so there's not even a cost burden for adults. So I do think that with a vaccine like Prevnar Adult, under the right set of circumstances with, again, a positive outcome on CAPITA, a good demonstration of disease burden, strong recommendations from ACIP, our ability to promote, that there is an opportunity to expand the market in the United States.

Andrew Baum - Citi Global - Analyst

So moving on to Xeljanz for the last 10 minutes or so -- could you give us an update on the launch, where the drug is being used, the extent to which your sampling and outlook in other indications. Just a few questions.

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

Yes, sure. So -- well, first of all, we're even more excited about Xeljanz than we are about PD-991 at the moment because it's real, it's out there in the marketplace, we've got a great label. We were very excited to get the second-line indication and, frankly, with the feedback we're getting from rheumatologists is they are very pleased with that as well. They see it as a natural place to use Xeljanz. The patient has been on methotrexate. They are failing, or they can't tolerate it, which is a fairly common occurrence, and they go to another oral before going to -- now, while they say that to us, their initial experience is oftentimes, in a more difficult patient who has failed more TNF inhibitors or biologics. So it's kind of an interesting dialog when you discuss this with rheumatologists.

We do think that there are some rheumatologists that are using it in the post-methotrexate patient population, but I would think that more are likely to have their first few experiences in the post-TNF patient population. But the two things that we're hearing back from rheumatologists are they're really excited about the second-line indication, and they are very intrigued by the idea of being able to use this drug without the need for methotrexate because, as you know, the TNF inhibitors require the methotrexate for their effectiveness.

And they're, again, I think, at first, intellectually stimulated by the idea, and I think it will take them a little bit of time to adopt the usage of Xeljanz without methotrexate except in those patients who just really can't tolerate or won't tolerate methotrexate side effects.

So we think the opportunity is really good, and the feedback has been good. We know from the six large Phase 3 trials that we did with Xeljanz that it's likely that physicians are going to get a good response regardless of whether they use it pre- or post-TNF inhibitors.

And, importantly, one thing that was not talked about a lot was Xeljanz's -- the quality of life or patient-reported outcomes data was very favorable with -- in the clinical trial. So we're expecting that when physicians try a few patients, see those patients back, that's going to help reinforce their adoption of this drug.

We didn't get a lot of labeling with the patient-reported outcomes, so we're not able to make a lot of noise about that, although we are filing a supplement to get that labeling into the label and looking forward to that.

So that's kind of where we are right now. I mean, we did put out -- there's two sampling programs. One, we gave a select number of doctors experience kits where they could give their patients 30-day supply. That's a limited number of doctors, but we wanted to give them -- these are physicians that were eager to try the drug, and we didn't want them to cause anything to stand in the way of initiating a patient. And some of those have obviously used some of those samples.

And then through the reimbursement process, we have a 14-day supply for patients as they're going through the process of getting their reimbursement in place. And so we've been distributing those since we started. Again, the theory right now is to get everybody who wants to try the drug, remove all barriers and give them an opportunity to try it.

And so that's happening. We're seeing a nice, consistent week-by-week uptick in the number of prescriptions, the number of physicians who are administering the drug, the number of physicians who are administering a second and a third time, and it's just a nice steady growth of experience. And right now, I think, we're still in the early stages of the launch. I feel like all systems are go. It's going to be a building process, and we think we're on track.

Andrew Baum - Citi Global - Analyst

And your formulary position within those Medicare and commercial books? What kind of positioning -- ?



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

We're getting good reimbursement across the board and, you know, basically, what's happening is most plans are just paying for it and putting the claims through. And then they are -- over the course of the next, say, six months or so, we'll go through a formal formulary review process and determine whether or not they're going to -- you know, where they're going to position it in the formularies, what -- and how they're going to manage the drug.

But initially we found fairly widespread processing of claims across both commercial and government payors. So -- so far so good there as well.

Andrew Baum - Citi Global - Analyst

And the FDA only gave you approval for the 5 mg?

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

Right.

Andrew Baum - Citi Global - Analyst

What's the plan for the 10 mg. Are you going to still try to get that approved or -- ?

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

Yes, we still believe that there's a patient population there that will benefit from the 10 mgs. I think the FDA saw the 5 milligrams as being quite effective. In our trials, the way our trials were designed, we had patient cohorts on 5 mg BID and other patient cohorts on 10 BID. We didn't have dose escalation in our trial. So the FDA was concerned that we don't know which patient, per se, will benefit going from 5 mg to 10 mg, and, frankly, they were impressed with the efficacy of the 5 mg, and being a new -- I think being a new mechanism of action, they thought that the best course was to approve the 5 mg and get it out there, and we will be generating additional -- we are, as we speak, generating more long-term data on the 10 mg.

We'll be doing post-marketing studies that will include the 5 mg and the 10 mg to evaluate the relative efficacy and safety. And we're in discussions with the FDA right now over what will be required to actually register a 10 mg dose in RA.

At the same time, we've got Phase 3 trials underway that will read out this year in psoriasis with 5 mg and 10 mg. We have ulcerative colitis Phase 3 with 5 mg and 10 mg. We are initiating Phase 2 trials in ankylosing spondylitis and Crohn's disease this year. We have a topical psoriasis formulation that we're advancing in development, and so we're going to continue to develop a robust data set over time.

Andrew Baum - Citi Global - Analyst

This isn't a feature yet for Xeljanz, but Orencia and, I think, Humira have been caught up in Humana's attempts to refuse to accept co-pay vouchers for their commercial patients. Just stepping back from Xeljanz, I'm thinking about the outlook. Do you think that's a threat that the industry needs to think about? Or is there going to be a pushback from patients, which is going to make it unworkable?



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

Yes, that's a good question. I'm really not sure. I know the payors don't like the co-pay cards, and we don't like the high co-pay, so it's not a great situation. You'd rather be aligned with your other stakeholders in the system. I would prefer if we could find a way to kind of co-exist in a manner that serves both of our needs. But I'm not sure how that will play out. I really can't predict.

Andrew Baum - Citi Global - Analyst

And if anyone has any questions, by the way, in the last few minutes, please raise a hand. I'll -- so just -- I guess ending up with your hemophilia franchise. There is -- it's obviously not a huge driver for you, but there is a considerable momentum of long-acting versions coming to the market.

As you think about the stickiness to the existing products among patients, is that going to be more important than the less-frequent dosing? How quickly are those drugs going to erode?

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

Well, I think that it has been a category where stickiness has been a factor. I mean, patients tend to want to stay on the drug that they believe is working best for them, or the factor that they believe is working best for them. They're not anxious to switch in most countries. In some cases, there are examples where there is kind of a fourth switch with some tender activity, but in the majority of countries, developed countries, you know, the physician and the patient tend to choose the factor. And there tends to be a fair amount of patient affinity for the brand that they are using that they are satisfied with.

So I do think that that's a factor in this marketplace. I think that with the longer-acting products there's an opportunity for some market expansion. I think it will make it easier for more prophylaxis use and maybe earlier in the management of patients. So I think there's an opportunity for the extended half-life agents to come on and help expand the market.

In the meantime, I mean, for us, we've introduced a number of kind of patient benefit-type features to our products over the course of the last several years that have helped endear our patients to our products. We are also working on ways for patients to administer a factor in more convenient ways, more convenient forms and different dosage regimens.

So we feel like we have a strategy. We don't have an extended half-life agent in development, but we think that the market will sustain both the existing products as well as the extended half-life products.

Andrew Baum - Citi Global - Analyst

And then, I guess, finally, in the last couple of minutes -- business development. Which areas within specialty and oncology are you particularly focused? I mean, if I was to look at your oncology business, you haven't got an immunomodulator. You've got one conjugated monoclonal. Those things, which there are active opportunities out there to either partner or to relicense or, indeed, are there other targets that you would be interested in?

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

Yes, look, I think that we would love to find some really attractive molecules out there that we could acquire and bring into the house and own them and develop them. What we've found is that all the really attractive stuff is really attractive and is very expensive, and it's very difficult to pay it back.

So while we never stop looking, I think that we're doing more work with other companies with some of these mechanisms that we don't have to team up and do co-development projects with them. We have also had some success with partnering with third parties to have them actually run

development programs for specific patient populations. We've done a couple of Asian deals where we've got programs underway kind of outside of our own shop where we either buy back in at the end of the clinical trial, or we take a milestone and just realize royalties over time.

So what we're finding we're having more success with -- and then we're even outlicensing and selling some of our assets that don't fit into kind of our definition of what's best for us, and Neratinib is a good example of that with Puma. So we have a fair amount of business development activity going on, but it tends to be in that realm as opposed to major acquisitions.

Andrew Baum - Citi Global - Analyst

Would you like to say a few words about -- I think it's -- the oncology's (inaudible) recently?

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

(inaudible)?

Andrew Baum - Citi Global - Analyst

It's an Italian company that you purchased a monoclonal from. It doesn't matter. It was very early, very small.

So, look, we're at the hour. I'd like to thank Geno for his time and many thanks for attending, everyone.

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

Thank you.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2013, Thomson Reuters. All Rights Reserved.