

FINAL TRANSCRIPT

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CORPORATE PARTICIPANTS

Chuck Triano

Pfizer, Inc. - IR

Geno Germano

Pfizer, Inc. - President & General Manager - Specialty Care & Oncology

Yvonne Greenstreet

Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

Mark White

Pfizer, Inc. - Commercial Development Lead - Inflammation

Saeed Fatenejad

Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Tamas Koncz

Pfizer, Inc. - Medical Lead - Tofacitinib

CONFERENCE CALL PARTICIPANTS

Dave Risinger

Morgan Stanley - Analyst

Chris Schott

JPMorgan - Analyst

Alison Yang

Barclays Capital - Analyst

Jami Rubin

Goldman Sachs - Analyst

Gregg Gilbert

Bank of America Merrill Lynch - Analyst

Kyle Rasbach

Cowen & Co. - Analyst

Seamus Fernandez

Leerink Swann - Analyst

Jon LeCroy

MKM - Analyst

Alex To

Cross Current Research - Analyst

Alan Sebulsky

Apothecary Capital - Analyst

Ben Weintraub

inThought - Analyst

PRESENTATION

Chuck Triano - *Pfizer, Inc. - IR*

Good evening, everybody, and thanks for joining our team here today to discuss and review the clinical programs for tofacitinib. I'll introduce the Pfizer team here. We're very happy to have with us Geno Germano, who most of you probably know. He's a

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member of our executive leadership team as well as the President of the Specialty Care and Oncology business unit.

To Geno's right is Yvonne Greenstreet, who is Head of Medicines Development for our Specialty Care business; Saeed Fatenejad, who leads our Inflammation Group; to his right, Tamas Koncz, who is the Medical Lead for tofacitinib; and at the end is Mark White, who is our Commercial Lead for Inflammation.

Certainly, in this discussion this evening we will have forward-looking statements and, of course, actual results may differ.

We'll move now to prepared remarks. Geno and Yvonne will give prepared remarks, probably about 25 minutes or so, and then after that we'll move to take all of your questions with the team here.

So with that, I'm happy to turn it over to Geno Germano.

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

Okay, thanks, Chuck, and welcome, everyone. It's a pleasure to be here, both at ACR where we're presenting a fair amount of data this week and, of course, here this evening with all of you.

I'm very excited about tofacitinib, about the progress that we've made with this program, and about sharing some of the findings with you tonight and taking some of your questions. I'm going to really kind of buzz through a few slides and give some high level comments and Yvonne will go into a little bit more detail on the data before we get to the questions.

But first and foremost, obviously, we're excited about the opportunity that tofacitinib presents. As first indication, we expect to be rheumatoid arthritis, which is a very large and still very rapidly growing market, a market that we at Pfizer know very, very well after about a decade now in the Enbrel business and with experience with Celebrex and other drugs in the rheumatoid arthritis arena. We're looking forward to bringing another advance to this marketplace.

And some statistics here, you can see that there are some projections that the market will increase by 50% in the 2010 to 2015 timeframe. As more patients advance to more modern therapies, as the population continues to age, and as patients stay on therapy for longer periods of time, we can see this expansion continue for the foreseeable future.

Importantly, as you can see on the bottom of the slide, despite the availability of some newer and contemporary agents, about a third of patients today remain uncontrolled on therapies that are available, so we think there's an opportunity.

And we're excited about having tofacitinib as an entirely new and novel mechanism in this marketplace and we think that it may help solve some of that inadequate responder problem in patients that have tried other agents. We also think that it could present a very competitive profile relative to existing agents on the market today.

Importantly, tofacitinib was discovered by Pfizer scientists in our Groton, Connecticut facility and represents a novel mechanism of action. And unlike the existing TNF inhibitors and other biologics that work extracellularly, this is the first agent that -- or most advanced agent that works on intracellular signaling. So it's clearly a distinctive approach to the management of this condition.

The program has been an extensive program, one of, if not the most, extensive development programs in the field with close to 5,000 RA patients, 5,700 patient years of exposure. And importantly, the program was able to give us a good look at the profile of this drug from a safety and efficacy standpoint because of the extent of investigation.

You can see it's a very global program and we were able to test the agent in patients that are in various stages of management of their disease and on a number of different concomitant therapies. It's been given as monotherapy; it's been given concomitantly

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with Methotrexate and other DMARDs, in patients that are DMARD-inadequate responders as well as TNF-inadequate responders. So we feel that we have a pretty good sense of what the profile really is with this program.

There were five major Phase III trials that will make up the registration dossiers that we're filing now. You may be familiar with these trials. The first, ORAL Solo, tested tofacitinib as monotherapy in patients who were inadequate responders to DMARDs. The ORAL Sync was tofacitinib on top of DMARDs in inadequate responders.

The ORAL Scan gave us radiographic data to show structural progression. The ORAL Standard is a trial where we had an active comparator, adalimumab, in the trial. And then, of course, ORAL Step is the trial demonstrating tofacitinib's safety and efficacy in patients who were inadequate responders to TNF inhibitors. And you'll see some of the results in a minute as Yvonne goes through her slides.

Importantly, we have one additional large Phase III trial still underway, the ORAL Start up trial, which is a trial in Methotrexate-naive patients where we're comparing tofacitinib head-to-head with Methotrexate in this patient population, and we look forward to those data hopefully next year.

And then, our ongoing long-term extension studies to enable us to continue to accumulate long-term safety and efficacy data and adding to the overall understanding of the clinical profile of this drug.

So, from an efficacy standpoint, again, I think what's really impressive about tofacitinib in these differential trials and these different patients and these different comparator groups is no matter which study we've done we've seen a very consistent efficacy profile and very consistent efficacy performance across all endpoints -- of signs and symptoms, functionality, structure, remission, and in patient-reported outcomes. So it's been a very, very consistent picture through Phase II and into Phase III and across each of the Phase III trials, and I think that gives us a great deal of confidence going forward.

And I will say, frankly, from a safety standpoint it's a very similar story. What we've seen is a very consistent safety profile. And I'm not going to go into each of the individual elements, because Yvonne will do that, but the point that I would make on the safety profile is, again, because of the large size of this program, we feel that we've uncovered a very clear understanding of what the safety profile is, number one; and number two, we've seen nothing in the safety results that would be foreign or unusual to the prescribers who treat these patients with the medicines that are available today and with a drug like tofacitinib when it becomes available. So again, that enhances our confidence going forward.

So why are we excited? I think it's, again, robust efficacy and consistent and understandable safety profile that will be familiar to, again, physicians who treat rheumatoid arthritis patients with moderate to severe RA. And we believe that tofacitinib will add to the armamentarium for these physicians and hopefully help additional patient populations in need of new options.

So finally, just to close out this section, Pfizer believes that we've created a clear understanding of the risk-benefit profile. We believe that we've demonstrated a positive risk-benefit profile for both the 5 milligram and 10 milligram BID doses. And we are looking forward to the acceptance of filings in the US and Europe this year and also a filing in Japan before the end of the year.

So with that, I'm going to turn the stage over to Yvonne to go into a little bit more depth on the data. Thank you very much.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

I think Geno provides a good overview of our Phase III program for tofacitinib in patients with rheumatoid arthritis, so I want to reiterate our very extensive database for this medicine, which is actually quite unusual for a medicine at this stage of development.

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We've assessed the efficacy of tofacitinib in a variety of situations in patients with RA -- patients who don't respond to DMARDs or Methotrexate, TNF failures, in monotherapy, in combination. And across all the important endpoints -- sign and symptoms, disease activity, structure, physical functioning. So I think we really have a very good package of information for tofacitinib.

We've actually presented two of our five key Phase III studies already. We presented ORAL Solo, the monotherapy study, at EULAR last year -- at ACR last year, I'm sorry, and Sync earlier on at EULAR this year. And at this meeting, we're going to be featuring the remaining three of our key Phase III studies -- Standard, Scan, and Step -- as well as the three-year update to our ongoing open-label long-term extension safety study, Sequel. And these are the studies that I'm going to be focusing on presenting to you today.

So, first is ORAL Standard. And I think the important aspect of this study is that it's the first study which has a tofacitinib arm alongside an active comparator, a TNF inhibitor, adalimumab. And I think it's important to note that whilst this study was not designed as a head-to-head study, analyzing non-inferiority or superiority between tofacitinib and adalimumab, it does provide us really useful context of the profile of tofacitinib alongside an anti-TNF.

And you can see here in this slide that all three active arms -- adalimumab arm and both tofacitinib arms, 5 milligrams BID and 10 milligrams BID -- were significantly superior to placebo, the primary endpoint of ACR20 at month six. And you can see there the response rates -- 28.3% for placebo; 51.5% for the tofacitinib 5 milligrams BID arm; 52.6% for the tofacitinib 10 milligrams BID arm; and 47.2% for the adalimumab arm.

The next study I'd like to present is ORAL Scan. And the important aspect of this study is that it's the first study in which we're assessing the impact of tofacitinib on structural progression, using the endpoint for modified Total Sharp Score and measuring changes, mean changes, from baseline.

And what you can see here is that both the 5 milligrams and 10 milligrams BID of tofacitinib have less disease progression when compared to placebo. Now, this reached statistical significance for the 10 milligram BID arm and narrowly failed statistical significance for the 5 milligrams BID.

Importantly, there was a pre-specified secondary endpoint in this study, looking at the proportion of non-progressors. The patients are classified as being non-progressors if they have less than an 0.5 unit change in the modified Total Sharp Score. And this actually is a very clinically relevant endpoint because it assesses, if you like, radiographic remission, so it's an important piece of information.

Here, you can see in this study that both doses of tofacitinib, the 5 milligrams BID and the 10 milligrams BID, demonstrated significantly superior benefits when compared to placebo at six months as well as 12 months. So I think when you look at the package of information that we have for tofacitinib with respect to structural progression, I think we have a very good picture demonstrating the impact of both doses of tofacitinib on structural progression.

And then ORAL Step. This study is important because it assesses tofacitinib in patients who have failed treatments with anti-TNF. And as you can imagine, this is a very important patient population -- they're refractory; they're difficult to treat; and many of the patients in this study cycle through not just one but two and sometimes three rounds of anti-TNF therapy.

And importantly, both doses of tofacitinib, 5 milligrams BID and 10 milligrams BID, demonstrated a significantly superior benefit compared to placebo. And if you look at the ACR20 at month three, you can see that data displayed.

We also showed that tofacitinib demonstrated a benefit in even more stringent assessments of response -- the ACR50, 70, as well as clinical remission. You can see the ACR50s and 70s on this slide, and I really want to make two points about the time course that we can see here.



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The first is that you can see that tofacitinib has a very rapid onset of action; you can start to see benefits of treatment within the first two weeks. And if you look at the placebo arm -- if you remember, placebo patients were advanced to tofacitinib at month three in this study. You can see that these patients then begin to respond.

So I think overall we have very good efficacy for tofacitinib. And in these three studies we've shown efficacy alongside adalimumab; we've shown efficacy with respect to structural progression; and we've shown efficacy in a difficult to treat patient population, those that have failed TNF.

I'd like to turn to safety. And I think it's important to reiterate again, whenever we talk about safety, that we have approximately 5,700 patient years of exposure and a large and global program. And if you look at exposures in Phase III, you can see the differences between tofacitinib, placebo, and adalimumab. We have about 2,000 patient years of exposure for tofacitinib compared to about 200 patient years of exposure for placebo.

This is primarily because of the unequal randomization schedule in the study, but also because patients who were given placebo were progressed to active treatment for ethical reasons. And with adalimumab, we have about 179 patient years of exposure, remembering that, of course, we have five Phase III studies for tofacitinib, but only one Phase III study that included an adalimumab arm. We have, if we include the long-term extension studies as well, therefore, a 30-fold greater patient exposure with tofacitinib compared to placebo and adalimumab.

Now, the majority of adverse events that we saw in the program were mild or moderate, and they resolved. The most frequently reported were infections, mainly nasopharyngitis, upper respiratory tract infection, and urinary tract infection. These adverse events and discontinuations were infrequent and the low numbers of serious adverse events that we saw in our program mean that it's actually quite difficult to compare serious adverse events between studies, but also between different time points within the same study.

But given that we've studied tofacitinib so extensively, we need to look at the safety data in its entirety, and I think the best way of thinking about the safety -- looking at the safety of tofacitinib is to consider both the overall Phase III results as well as the long-term extension safety experience.

Let's start with mortality, and this slide has an excerpt, actually, from one of our posters and it looks at mortality across two different dimensions. You can see up at the top all-cause mortality including events that occurred more than 30 days after the last dose; and below that, all-cause mortality up to 30 days after the last dose; compares the different doses of tofacitinib to placebo and adalimumab in our Phase III program as well as data from our long-term extension study.

The first point to make is that if you at Phase III all tofacitinib doses, you can see an incidence rate of 0.57 for all tofacitinib doses compared to 0.49 for placebo. So really, very similar rates between tofacitinib and placebo in the Phase III. Remember, there are no placebo in the long-term extension study, so we can't actually make a placebo comparison there.

When we compare all tofacitinib doses in Phase III to all tofacitinib doses in the long-term extension, the 0.57 compared to 0.64. And if we look at the incidence rates between the different doses of tofacitinib, 0.78 for tofacitinib 5 milligrams BID and 0.44 for tofacitinib 10 milligrams BID. And importantly, there were no patterns of death that we saw. The deaths were exactly what you would expect for RA patients being treated.

There were two deaths in the tofacitinib arm and one in the adalimumab arm which were attributed to cardiac events by our cardiovascular safety endpoint adjudication committee. We set up a committee that was independent and blinded to assess cardiovascular adverse events as well as mortality.

And the rates in Phase III and the long-term extension studies are consistent with the rates that we've seen reported in the literature for patients with RA. As a summary of mortality, serious infections, there's no apparent increase in rates of infections

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or serious infections with longer treatment duration. You can see that when you compare the rates in all tofacitinib doses, 2.91, with the rates that we see in all tofacitinib doses in the long-term extension study of 3.

There was a higher incidence rate of infections with the 10 milligram BID dose versus the 5 milligrams BID dose in the long-term extension studies, but no difference between doses in Phase III.

And I think it's important to note that the duration of exposure for our 10 milligram BID is much less. After Phase II, patients were advanced to a 5 milligram twice daily regimen in our long-term extension studies, so it's not surprising that we have more exposure to the 5 milligram dose than the 10 milligram dose. And again, the rates of serious infection are consistent with the rates that we see in the literature for patients with RA who are treated with both non-biologic and biologic DMARDs.

Herpes zoster. What was interesting here is that when we looked at the development program as a whole, rates of herpes zoster were higher across the program for tofacitinib, for placebo, and for adalimumab. Quite interesting.

And there's some recent work that's been done by the Mayo Clinic which has shown that there's been an increase in reported rates of herpes zoster over the last few years. So it's likely that the rates that we see reported in the literature are probably an underrepresentation of the true reported rates.

The rates of herpes zoster was similar in both those groups and did not increase with longer treatment duration. And importantly, there were very few cases of serious herpes zoster. In fact, there was only one case of disseminated zoster, still restricted to skin manifestations, but crossing more than one dermatome -- two dermatomes.

Now, to laboratory changes. We know that we see changes in laboratory parameters for tofacitinib 5 milligrams and 10 milligrams, and they're consistent across studies. We see dose-dependent decreases in mean neutrophil counts; dose-dependent increases in mean LDL, HDL and total cholesterol; small increases in mean serum creatinine; and small increases in liver function tests, and increases that are potentially important that go above three times the upper limits of normal were uncommonly observed. The mean overall values for our laboratory parameters stabilized over time with longer treatment duration in both tofacitinib groups.

So here's the neutrophil picture taken from the long-term extension studies. You can see that the decrease in neutrophils is predictable; it starts to occur early in treatment; it's dose-related and it's non-progressive; and importantly, is not associated with an increased risk of infection. We see a similar magnitude of decrease in the adalimumab arm in the ORAL Standard study. No patients experienced a confirmed potential life threatening neutropenia is less than 500 cells per millimeter cubed across the development program.

Hemoglobin. Mean hemoglobin levels increased from baseline for the 5 milligram BID arm and with very minimal changes from baseline for the 10 milligram BID arm of tofacitinib and placebo, and Hb levels remained largely within the normal reference range throughout the duration of treatment. Most cases of anemia were mild to moderate in severity and occurred with similar frequency across tofacitinib and placebo-treated patients.

Cholesterol. And I think you're probably all familiar with the lipid changes that we observed with tofacitinib, a dose-dependent increase in serum LDL, HDL and total cholesterol, which we see within the first three months, remained stable after that, and with no change in the LDL/HDL ratio. And we presented data that shows that Atorvastatin is effective in reducing tofacitinib-associated increases in LDL.

Now, we know that RA is associated with an increased risk of CV events, but the real mechanism behind these lipid changes isn't clear to us. But what's important is that to date we have not observed any increased risk in ischemic cardiovascular events. Events have been rare and the rates that we have seen are consistent with those that we see reported in the literature with other DMARDs used for rheumatoid arthritis.

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Serum creatinine. We've seen small increases in mean serum creatinine, but these largely remain within the normal reference range. They plateau over three months and remain stable thereafter. They're reversible and renal failure has occurred infrequently. And when it has, it's been in combination concurrently with an illness like infection. We did a healthy volunteer study and this study showed no changes in renal function, renal plasma flow, or creatinine clearance.

Liver function tests. I think I've said already that tofacitinib causes modest and not clinically meaningful mean elevations in ALT and AST. And the important point here, of course, is that important increases, those that are greater than three times the upper limits of normal, are uncommonly observed, and actually they occurred more frequently in patients who are on background DMARD therapy than those who earlier received tofacitinib as monotherapy. And the risk of drug-induced liver injury appears to be low.

So, in summary, I think with our work to date with tofacitinib I think we've demonstrated what I believe is a very robust efficacy profile. I think the extensive safety database that we have has given us a really good insight into the performance of this medicine from a safety perspective. And I think both the efficacy and safety data really drive, to my mind, an attractive risk/benefit profile for tofacitinib.

I'm looking forward to tofacitinib being available as a new medicine for patients with RA in the future. Thank you very much for your attention.

QUESTIONS AND ANSWERS

Chuck Triano - Pfizer, Inc. - IR

Okay. Thank you, Yvonne. We'll now move to Q&A. And a couple of points, just for the benefit of those who are listening via webcast, if you can wait for the microphone and when you're recognized if you can just indicate your name and your affiliation. But feel free, we've got the panelists here ready to go.

Dave Risinger, down in front, just wave at Suzanne and you can have the mic here.

Dave Risinger - Morgan Stanley - Analyst

Thanks very much. Dave Risinger from Morgan Stanley. I was hoping that you could provide a little bit more detail on serum creatinine. In the abstract for 407, it discussed creatinine increases greater than 33% in 12% of patients, but then in the poster it only discussed the percentage that experienced more than a 50% increase.

So I don't know if you have any more color on the greater than 33% figure so that maybe we could understand how to compare that 12% to what the percentage would have been in patients on background DMARDs. And any other color you can provide on creatinine outliers that would help to frame that as an issue or a non-issue for the FDA. Thank you.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

Thank you. I'll start off by just making a couple of points. I think really what's important here is that the increases that we saw were really very, very minimal. And we're talking of between a 0.04 to 0.06 change here and not associated with any other renal risk markers.

I think we obviously don't fully understand the mechanism behind these modest changes and we'll continue to evaluate what we see with serum creatinine going forward, but it really doesn't seem to be clinically meaningful. I don't know if you want to add anything to that.



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Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Well, besides what Yvonne said, the serum creatinine really is important as far as in some regards indicating renal function. We indeed have done a study of renal function which specifically looks at that question. And that study was the one that Yvonne mentioned in healthy volunteers, and there was no effect on renal function.

So exactly what the clinical significance of this very small creatinine increase is unknown. The reason that the 33% is mentioned, that was really what was mandated by the protocol that if you have an increase of 33% you would get a repeat creatinine, and that reflects that number that was there.

As you could imagine, if someone comes in with very low creatinine, it's much easier to get 33% above, which is basically what we've seen. We have not seen any differences between patients who are on DMARDs versus none as far as an effect on creatinine. And also, the discontinuations as a result of any of these laboratory findings have been very, very infrequent.

Dave Risinger - Morgan Stanley - Analyst

Thank you.

Chuck Triano - Pfizer, Inc. - IR

Chris?

Chris Schott - JPMorgan - Analyst

Great. Thanks. Chris Schott, JPMorgan. Just two questions. First, what role do you see for the 5 milligram versus the 10 milligram, maybe especially considering the failed ORAL Scan study at the 5 milligram? How do you think about that data also in context of approval for 5 mgs versus 10? And maybe, just talk a little bit about those two doses, how you're positioning them relative to one another.

And the second, just a broader question from a commercial standpoint. Given how entrenched the TNFs are, can you talk a little bit about the commercial approach you're going to take here? Should we think about this, that initially you'll be going after more of a second-line market? Will you immediately go after a front-line biologic? Can you just talk a little bit about how you see the commercial kind of landscape playing out, especially given your kind of role in the TNF market as well?

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

Maybe I could start off by taking the third quarter then ask Mark or Geno to take the commercial question. I think actually we've got a compelling risk/benefit profile for both the 5 milligrams and 10 milligrams BID.

As I tried to present with the x-ray data from Scan, once we narrowly missed the primary endpoint for the modified Total Sharp Score, when you look at important clinical assessments of structural progression, both doses provide significant -- statistically significant benefit.

And I think the 5 milligram and 10 milligram doses have slightly different characteristics. You've got slightly better numerical efficacy for the 10 milligram BID dose across some domains, likely different safety parameters. And so I think when you look at both doses, I feel very confident that the risk/benefit of both the 5 milligrams and 10 milligrams are there.

Mark, I don't know if you want to take the commercial question?



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Mark White - Pfizer, Inc. - Commercial Development Lead - Inflammation

With Enbrel, we still think it will be one of the cornerstones of RA treatment for years to come, as will other biologics. And, as you know and as you saw, tofacitinib has been studied in a lot of different patient populations. So those TNF failures it's been studied in; it's been studied before TNFs, in combination with oral DMARDs, and as monotherapy.

So we think there are a lot of different places it could be used and we think, in the end, the marketplace will start to decide where that should be used based on the need of the patients and where the physicians feel comfortable.

The other thing we do have to remember, though, is we still have the wait for the FDA and other regulatory agencies to give us a label, and it depends somewhat what kind of label we get from that standpoint as well.

Chuck Triano - Pfizer, Inc. - IR

And then, just on the same point, a question from the webcast, which is, "How will the current Enbrel team work with tofacitinib? Will you be using the current sales force or enlarging?"

Mark White - Pfizer, Inc. - Commercial Development Lead - Inflammation

Yes, at this point that's still really up in the air. It's a little early for us to be making those decisions, but I can say we're actually working on that. We actually had a meeting this morning on that and there's a lot of discussion going on, but those decisions won't be made until we get closer to launch.

Alison Yang - Barclays Capital - Analyst

Hi. This is Alison Yang from Barclays Capital. This question is for Yvonne or Saeed, looking at slide 26. At the poster presentation, we noticed that if any patient reached the hemoglobin sufficiently low, 8 milligrams per deciliter -- or liter, they're taken out of the trial.

I was just wondering, can you comment on what is the effect of taking people who have severe laboratory aberrations -- that's this graph and there's the fact of the graph getting better because those people who have really bad labs get out of the trial? Maybe you can comment on that effect on neutrophils as well, that'd be great. Thank you.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I think what you said is absolutely true; would be true if we actually had large number of patients who qualified for that. The fact of the matter, this was very, very -- very few patients actually were discontinued because of that. So we don't think that that actually affected the outcomes of what we see.

Also, remember the graphs that we shared with you are the means, and means really are not generally swayed by a few patients going out. And the fact that we see a slight increase, actually, in hemoglobin from the 5 milligram and that the 10 stays level for a long period of time indicates that it's something that could certainly be managed.

Chuck Triano - Pfizer, Inc. - IR

Jami? There's a mic right there.

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Jami Rubin - Goldman Sachs - Analyst

Thank you. Just a few questions. In the ORAL Step study, in the patients who failed three or more TNFs, it wasn't clear to me if the tofacitinib arm showed statistical significance for those patients.

And also, if you can discuss herpes zoster, because it does seem clear that the rate of herpes zoster is higher than with the anti-TNFs and why you think that's happening. And just my other, last question is related to the label. The fact that you have long-term studies out to 36 months, will that be a limitation at all in terms of the scope of the indication you think you can get? Thanks.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

So maybe I'll answer -- I'll start with your first question, which was related to ORAL Step. Remember that once we get to patients who had failed three or more, there were very few patients. So we actually see a pretty good difference. But you're right, it's always very difficult to show statistical significance when you have only six, seven patients that do qualify. We think that's probably what it is.

The magnitude of effect is indeed very similar and you certainly see that also with individuals who failed one or two. So I think that shows there's not like a trend as you lose it, so that's probably the explanation. The --

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

I think I ought to say a few words about herpes zoster. And I think what's interesting about zoster is even though the rates of all cases of zoster seems to be higher in the study across all the arms, as I said already, compared to what we've seen historically, when you look at [serious] zoster, you're actually looking at what's important clinically. You're actually looking at very, very small numbers.

Chuck Triano - Pfizer, Inc. - IR

We'll go to our question now from Tim Anderson. Two questions. First question is --

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

There's a third one. We're not --

Chuck Triano - Pfizer, Inc. - IR

Oh, I'm sorry. Sorry, Jami.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

-- about the label, yes. You confused us by asking three in a row, you see. We can only cope with one at a time. The labeling? Could you repeat the question on labeling?

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Jami Rubin - Goldman Sachs - Analyst

(inaudible question - microphone inaccessible) compared to the anti-TNF it's not a lot, and how much do you think that will limit the scope of the indication initially?

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

The indications are based on some guidelines. You saw, actually, ICH guidelines, that basically suggest that you need certain amounts of safety information at the time of your launch. Those are based on overall exposure primarily and then exposure of six months and one year, and we have more than enough to qualify for that. So we think that package is enough to get approval, yes.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Saeed. Tim Anderson's two questions. First one, "In your 36-month open-label extension, you appeared to call out hypertension for the first time as an adverse event. Can you characterize this further?" That's question one.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I think it's an adverse event because when you have a large clinical program you can imagine you will see all kinds of adverse events reported, including, for instance, hypertension. We do not see a signal related to hypertension.

And you know, there was so much data we could present at ACR. We are actually looking forward to presenting our full cardiovascular information hopefully at the upcoming scientific meeting, but we have not seen a signal of increased high blood pressure with tofacitinib.

Chuck Triano - Pfizer, Inc. - IR

And the second question, "At approval, do you expect a broad label that would have first, second, third-line indications?"

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

I don't think we can really comment on what we're going to get at approval. I think we believe that we have conducted a really extensive program. We've looked at tofacitinib in all sorts of situations and I think we have a compelling package of information to present directly, because at the end of the day, they're going to decide how this medicine ought to be labeled.

Chuck Triano - Pfizer, Inc. - IR

In front, Gregg Gilbert.

Gregg Gilbert - Bank of America Merrill Lynch - Analyst

Thank you. First, maybe a more general question. How do you think the FDA approvability bar for this indication has changed since the biologics were approved? And I don't know if you have specific data or specific changes or just more of a qualitative feel for that.



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And secondly, specifically when next year will the ORAL Start data be available, and will that be relevant in the FDA's review, in your opinion?

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I actually can't remember exactly the dates of -- and I don't know if we've announced that. We could certainly look and see. It's a two-year study. That study is in patients who are Methotrexate naive, and we don't -- it's a two-year study, so we're not planning to include that in the submission.

Of course, you're right. If we see something that's completely out there and that potentially could be seen by the FDA, but we don't anticipate that because it's in a completely different population. That has really -- everything we've done so far has been in individuals who have been DMARD naive.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

And again, I don't think we can really comment on exactly how the FDA is going to look at a specific situation. I do think that if we were developing this medicine absent any other treatments for rheumatoid arthritis, clearly then the bar is likely to be lower.

But I think the data are actually quite compelling that we have for this medicine. All the information that we have to date, I think, demonstrates very robust efficacy. It's a very consistent, well understood, predictable safety profile. And I think we've done what we need to do here to demonstrate a good risk/benefit profile for tofacitinib.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I can just add that as far as what's changed over years, you may or may not know, but the original anti-TNF agents that were submitted, they were submitted, some of them, with less than 1,000 patients. So what is happening is that yes, that you are, we understand since that there are available drugs out there that we would need to provide a more robust data set, but we believe that this really qualifies for that.

Chuck Triano - Pfizer, Inc. - IR

In the second row?

Kyle Rasbach - Cowen & Co. - Analyst

Hi. Kyle Rasbach from Cowen. If I could just follow-up on the blood pressure question. You may not have this information, but do you have it broken down by the number of patients who were started on a blood pressure medication, perhaps, within each of the groups?

And secondly, I noticed that there appeared to be an increased incidence of infections across the Phase III trials and long-term extension in men compared to women. Is there a biologically plausible reason for this or can it be explained by concomitant medications or something else?



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Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I can tell that, first of all, on the hypertension question, again, our policy has always been to present scientific data in scientific settings, and we are looking forward to actually presenting that. We have looked at the data and including outliers, of course, and we are very confident that we don't see an issue of tofacitinib related to hypertension.

As far as the men and women, that's a great question -- a good question. We don't really know. There are differences. In general, we had fewer men in the study, as you probably know. As you get to older ages, you all know the comorbidities and mortalities of men are higher than women, so we don't know if that's -- essentially, the cardiovascular of men in general is more than women.

So whether this is all linked to that or -- we are not 100% sure. But this, we don't think, is unique to tofacitinib. You also see an increase in serious infections in patients who more than 65 years, and that also is not unique to tofacitinib. That's seen across all of treatments for rheumatoid arthritis.

Chuck Triano - Pfizer, Inc. - IR

Seamus?

Seamus Fernandez - Leerink Swann - Analyst

Thanks. Seamus Fernandez from Leerink Swann. So, forgive me, I'm going to warn you to write these down. I have four. I'm hiding over here. I actually have four questions that are actually pretty brief and quick, though.

So, just talk about the completely non-overlapping confidence intervals for infections as it relates to the 5 milligrams and 10 milligrams. Can you give us a little bit more color on what you think the impact is there and what really is driving that differential?

Second, and I'll stay on the clinical, therapeutic window, again, as we kind of think about the how the FDA thinks about therapeutic window and the differential of actually having a completely different control point from the point of the FDA.

So the FDA, from the view of, okay, physician manages IV, physician can't manage sub-Q. Actemra is IV, different questions there versus an oral drug where, again, the patient could double the dose or triple the dose if they feel pain. How do you manage that? How do you attack that from a REMS perspective?

Fourth quarter, again -- or the third question, is once a day a possibility with this drug? One of the physicians at your poster actually specifically talked about the prospect of the pharmacodynamic abilities of this drug being very different from the PK potential.

And then lastly -- this is for Geno -- pricing. As we think about pricing, the 5 milligrams versus the 10 milligrams, people think about pill-splitting, all kinds of crazy things from a commercial potential. How do we think about that as analysts? Thanks a lot, and sorry for so many questions.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

I'll start answering a couple and then the others will join in.

In fact, I think once a day is a possibility and it's something that we would be interested in evaluating. I think -- you raised an interesting question, actually, around the fact that this is a tablet and other medications, other than the additional DMARDs that are either IV or sub-Q.

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We're going to think quite carefully, actually, about the REMS program that we put out for this, because we're actually committed to making sure that this medicine is used in the right kind of way and we were doing that for the thinking at the moment.

And then there was a question, I think, for you, Geno?

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

I also agree that the once daily is something that's interesting that we are attracted to and are evaluating.

With regard to the pricing question, I think it's unfortunately a fairly standard answer that we'll price to optimize the value of the asset at the time that we introduce the product. So we're well aware of the dynamic that you mentioned, Seamus, with potential for pill-splitting, and we'll take that into consideration in our kind of final decisions.

Seamus Fernandez - Leerink Swann - Analyst

(inaudible question -- microphone inaccessible) let us know, is it a capsule or a tablet that it's been developed as?

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

It's a tablet.

Seamus Fernandez - Leerink Swann - Analyst

Since a capsule is hard to split.

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

It's a tablet.

Chuck Triano - Pfizer, Inc. - IR

A question about --. Yes, there was an infection question over there.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

Can you repeat the infection question, so we're just clear and we know what we're answering?

Seamus Fernandez - Leerink Swann - Analyst

Just to give us a little bit more color on the completely non-overlapping confidence intervals, but somehow differential timeframes, obviously, that we might be looking at?

Tamas Koncz - Pfizer, Inc. - Medical Lead - Tofacitinib

What we saw in the Phase III, the 5 milligrams and the 10 milligrams BID, they both have similar rates. And what you see in the Phase III long-term extension is that there is a slightly higher rate of the 10 milligram BID.

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Now, what is important, these rates, including the long-term extension rates, are within the rates of what is expected with these treatments. And also, there is no increase over time -- it's actually presented in the poster as well. And the difference that you're referring to maybe actually driven by the fact that there was up to 36 months of experience with the 5 milligram whereas the 10 milligram experience was out to 18 months so far.

Seamus Fernandez - *Leerink Swann - Analyst*

Got it. Got you.

Jon LeCroy - *MKM - Analyst*

Hi, thanks. I just had a couple. It's Jon LeCroy from MKM. First, on the liver, were there any cases of Hy's law seen in any of the trials?

Unidentified Company Representative

No.

Jon LeCroy - *MKM - Analyst*

No? Okay. And then second, due to the LDL signal, can you talk a little bit about your exposure in high risk cardiovascular patients? And then also, do you expect a post-marketing requirement in high risk cardiovascular patients?

And then finally, on the cancer cases, it looked like there were a couple of cases of lung cancer. Can you talk about any groupings there of specific types that might come up at an FDA panel?

Yvonne Greenstreet - *Pfizer, Inc. - Head - Medicines Development Group, Specialty Care*

As far as marketing, again, I think it's one of those areas where I don't think we can speculate what the agency is going to require. We certainly feel going into a submission that we have all the information that's required for an approval. We'll have to wait and see.

Your other question was around exposure in the higher risk cardiovascular patients. Saeed, you want to take that one?

Saeed Fatenejad - *Pfizer, Inc. - Head - Inflammation, Medicines Development Group*

Yes. I'm not sure what you mean by exposure, but -- you mean like number of patients?

Yvonne Greenstreet - *Pfizer, Inc. - Head - Medicines Development Group, Specialty Care*

(inaudible -- microphone inaccessible)

Jon LeCroy - *MKM - Analyst*

(inaudible question - microphone inaccessible). In a post Vioxx world, with a product that raises LDL coming to the FDA, are you prepared for a panel saying --

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Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Yes.

Jon LeCroy - MKM - Analyst

-- we need a lot of exposure here?

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Correct. So, as a result of our consensus, actually, that was the reason that an external adjudication committee was established before Phase III programs started. And this is a program, as Yvonne mentioned, that was -- that the members of them, which are independent of Pfizer, are blinded to therapy. So they don't know if a person is on adalimumab or different doses of tofacitinib or placebo.

So that panel is looking at all of the cardiovascular events and mortality, so that's one group that's watching it. We have another group, which is an independent DSMB, which again was actually established around the same time, and that's a separate group and that group looks at all of the unblinded data. We provide it to them and they review them, and the group, as is customary, meets on a regular basis. And so far they have told us that they're happy with the program; we can continue.

So this is really as far as I can tell you, which is very reassuring. When we said that we don't see a signal of cardiovascular event, that includes, really, looking at patients who have been high risk.

Remember, our program included a very broad population. We indeed did not have an upper age limit. We have fairly substantial number of patients who are more than 65 and more than 75. So I think we've really addressed a relatively high risk group and we haven't so far seen any signal.

Unidentified Audience Member

(inaudible).

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

On the cancers --

Tamas Koncz - Pfizer, Inc. - Medical Lead - Tofacitinib

With regards to the malignancies, sorry -- events that we have observed so far were within the range of what's expected in the treatments and there were no also patterns with regards to any specific cause for malignancy.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Tamas. We'll take one more from the webcast from Catherine Arnold. "Just to be clear, is your filing seeking approval at multiple stages of therapy such as post Methotrexate-DMARD failure, anti-TNF naive, and post anti-TNF failure?"

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Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

That's the filing -- it's based on that data, which addresses all of the --

Chuck Triano - Pfizer, Inc. - IR

Are we seeking the indication? That's the question.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Yes, of course.

Chuck Triano - Pfizer, Inc. - IR

Yes, okay. Thanks, Saeed. Just making sure it's clear. Then another one from the webcast. Two questions from John Boris. "Have you filed the sequel three-year safety data in the US and EU regulatory filings? If not, is there a chance the FDA or EMA need to see that data before it makes a decision on your regulatory filing?"

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

The question, whether the filing includes the long-term studies? If that's the case, yes, it is included. So everything you saw on the overall poster, which included the 5,000 patients and the 5,700, is included in the submission.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Saeed. And then John's second question on commercialization, asking, "When we present the tofacitinib product concept to rheumatologists and managed care specialists in market research studies, what are the most important features in rank order of preference, and how are the responses you are getting in your market research shaping how you are thinking about pricing?"

Mark White - Pfizer, Inc. - Commercial Development Lead - Inflammation

I don't think that I can necessarily quote the market research in sequential order from most important to least, but I can say that there are a lot of features about tofacitinib that payors as well as physicians are excited about. They're excited about a product that has a different mechanism of action from everything else out there.

As Geno mentioned, somewhere between 20% and 40% of the patients today are not getting the response they need. And the ACR and EULAR guidelines are specifically calling out that these patients need to be treated to either low disease activity or remission, so there's much more discussion around treating these patients. So, a new mechanism that actually works in TNF failures is something that they're very excited about.

Obviously, the fact that it's an oral medication is something that they're excited about as well. What we've heard from our market research is that the total package -- it's not just one thing, but a total package of having robust efficacy, a very manageable safety profile, and oral medication that's a new mechanism of action is something that they're very excited about.

Again, back to what Geno said about pricing, it's very early and we're not ready yet to start talking about where tofa will be priced and we really haven't made those decisions yet.



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Chuck Triano - Pfizer, Inc. - IR

Thanks, Mark. And then one more from the webcast from Tony Butler. "Can you comment on uses in other indications such as colitis, et cetera.?"

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Yes, we have programs.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

We've got an extensive program ongoing in a range of different indications, actually -- ulcerative colitis, psoriasis. We think this is a medicine that's going to have broad applicability, actually, in a number of disease types where immuno-inflammation is the key feature.

Chuck Triano - Pfizer, Inc. - IR

Jami, a follow-up?

Jami Rubin - Goldman Sachs - Analyst

I know it's early for some compounds, but maybe if you could comment on the differences that you've seen in safety and efficacy of your JAK inhibitor versus some of the others such as Incyte, Vertex, etc.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

Really, the first time we've seen data coming from a controlled study is what's going to be presented, I think, on Tuesday. So we have seen the abstract and that's what it is. Remember, there's just that one Phase II study, and one has to really look out. First, we haven't really seen the data, as well as we need to look at all of the package once all of that is done. It is difficult to --.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

We're at very different stages of development. We've delivered an extensive program. Many of the other drugs are much earlier in development, and so I think trying to kind of draw conclusions at this preliminary stage is probably not appropriate. Thanks for the question.

Chuck Triano - Pfizer, Inc. - IR

Yes. Right there, Suzanne.

Alex To - Cross Current Research - Analyst

Alex To at Cross Current Research. Just how current, the session on kinase inhibitors? The speakers all brought up the observation that monotherapy seems to work better than the combination with Methotrexate. Do you have a program that explored that? And, if so, what kind of commercial implication would that be?

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Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

We have heard those comments from some of the experts. We certainly are not making those comments because it is very difficult to go from one study to another study. If you look at the overall, we have indeed looked at that and looked at all of our programs working together. We see essentially the same levels of efficacy in both of those indications.

However, in both of those patient populations, because remember we have only one study that's monotherapy and we have in this package four studies that are on top of the Methotrexate. So the comparison is not only different studies, you also have much less experience with monotherapy compared to the other ones.

We think that in both settings -- actually, we know that in both settings the drug has efficacy. A study of exact comparison of that has not been done, and that's one of the things we are thinking about. But so far, we see them working in both of those cases.

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

And I would say from a commercial standpoint that I think that if -- I think there is an interest from the clinical community to explore the use of medicines without Methotrexate. Key opinion leaders will tell you that sometimes the lack of efficacy in TNF inhibitor patients is due to the fact that they discontinued the TNF themselves because of the adverse events and side effects associated with TNF. And so to have a therapy that would be effective without the Methotrexate would be attractive -- would be an attractive offering.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Geno. Gregg? Follow-up?

Gregg Gilbert - Bank of America Merrill Lynch - Analyst

Sorry if you already said this, but when and where will you be presenting that cardiovascular information?

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

What I said was that we are hoping that we will be able to actually submit it. We don't have a plan. I'm hoping that -- our programs, the abstracts are written by authors who are investigators, so we are hoping certainly to present that at an upcoming meeting.

Chuck Triano - Pfizer, Inc. - IR

Dave?

Dave Risinger - Morgan Stanley - Analyst

Yes. Dave Risinger from Morgan Stanley again. With respect to the various side effects of tofacitinib, how much of an advantage can you position tofacitinib's oral dosing as offering, meaning with many of the other therapies, they're not reversible or stopped as quickly because they're infused or they're dosed once monthly. But being dosed twice a day, a patient can stop therapy pretty quickly to address a side effect concern.

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So, with respect to the various side effect issues, which the FDA is going to be evaluating, how much of an advantage is that relative to the existing therapies that are on the market?

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

I believe in principle it is an advantage, not one that we're focused on at the moment. I think really where we focus is trying to understand what we have in our hands as far as safety profile is concerned. But I think it is an interesting feature, the oral administration of the drug, that if you do run into safety issues you can stop the drug.

Saeed, I don't know if you want to add anything?

Chuck Triano - Pfizer, Inc. - IR

Second row, I saw a hand?

Unidentified Audience Member

Thank you. Good evening. A question on renal function. Do you have hard data in healthy volunteers? I'm just wondering if we're going to see that in RA patients with tofa.

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

[Perfect time], as you can imagine, we've got a lot of data at the moment and we're making our best efforts to bring it all into the public domain, so expect to see a lot of information presented on tofacitinib over the next few years.

Unidentified Audience Member

(inaudible question - microphone inaccessible) so far in RA tofa patients?

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

We do have plans for -- I think it was you were saying -- for a measured GFR study. We are considering all of those, including a study of measured GFR in patients with rheumatoid arthritis, yes.

Tamas Koncz - Pfizer, Inc. - Medical Lead - Tofacitinib

If you actually want to look up the healthy volunteer data that Yvonne presented, that was published in 2009 already in the Journal of Clinical Pharmacology.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Tamas. A question from the webcast from Tim Anderson again. The question -- two questions. "First, it didn't appear from the Oral Standard trial that the onset of action for tofa was any better than . Is this a fair way to look at it?"

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Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

I think we're trying to emphasize with the Standard study that it wasn't designed to actually do head-to-head comparisons between tofacitinib and adalimumab. I think what we can say if you at the data is that the onset of the action for the tofacitinib and adalimumab is rapid.

Chuck Triano - Pfizer, Inc. - IR

And then his second question, "Your PsA program was recently posted on ClinicalTrial.gov and then pulled. What was the issue and when is it scheduled to start?"

Yvonne Greenstreet - Pfizer, Inc. - Head - Medicines Development Group, Specialty Care

We're currently evaluating the best study design, actually, for tofacitinib in this patient population and we're making plans to investigate the medicine over the next year or so.

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I just want to say on that, that was not related to any safety issues or anything. We are discussing the different approaches for different programs with different regulatory agencies, technical discussions. And we were in the process of starting that study; however, we decided that we needed to look at the program again, and hopefully we can go ahead with the psoriatic arthritis soon.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Saeed. Alan Sebulsky?

Alan Sebulsky - Apothecary Capital - Analyst

(inaudible question - microphone inaccessible). Just to go back to creatinine issue. I realize the change is not very significant, but can you just discuss it all, either the -- any outlier factors in terms of either dropout rates or other data that would suggest there's no issue with a smaller group of outliers, and particularly maybe in the elderly?

And I think I just wanted to clarify that you did say earlier that the renal events you have seen have not been correlated with a reduction in creatinine? Is that correct -- did I hear that correctly?

Tamas Koncz - Pfizer, Inc. - Medical Lead - Tofacitinib

I think the right way of putting it is that the -- because there was reference to this 33% increase and I think what we said and what Yvonne said was that the vast majority of these patients that have this level of increase did not have an adverse event and did not have renal failure.

We have seen cases of renal failure. Of course, when you have renal failure your creatinine goes up, just to clarify; however, those cases had other reasons beside a person being on tofacitinib. So, for example, we mentioned serious infection. So if you are septic and have multi-organ failure or anything else, you would have renal failure, of course. So that's basically the way it is.



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We have looked at outliers, of course. And so far we are confident that we don't really see any indication that there is deleterious effect on renal function. That's basically our conclusion at this stage.

I just wanted to add that we -- for those patients who didn't have an elevation in creatinine, we didn't see markers of renal injury like proteinuria.

Chuck Triano - Pfizer, Inc. - IR

Thanks, Tamas. There we go.

Ben Weintraub - inThought - Analyst

Thanks. Ben Weintraub from inThought. Let me ask two questions, a scientific question first. It seems when you use a TNF inhibitor that if you make it through the first few months that the risk of infection goes down and rheumatologists are fairly comfortable. I'm not sure that you saw that, or you have enough data to see that, in the tofa studies yet, but how do you think rheumatologists will think about that safety over time kind of question?

Saeed Fatenejad - Pfizer, Inc. - Head - Inflammation, Medicines Development Group

I think the data that Yvonne shared with you, and we have actually presented from Oral Sequel, shows that the rate of serious infections indeed do not go up with tofacitinib over time.

Ben Weintraub - inThought - Analyst

But do they go down?

Tamas Koncz - Pfizer, Inc. - Medical Lead - Tofacitinib

We actually have this in the poster. What we are saying is that we are in the range of what is expected. So it's actually the figure, too, in the poster; you can take a look.

Ben Weintraub - inThought - Analyst

And the second question is just a commercial question. We've heard Pfizer talk a lot about emerging markets and a lot about tofacitinib, so I was wondering if you could put them together. And we know that in the emerging markets, perhaps the TNF inhibitors aren't as established and there might be an opportunity for an oral drug to be used there much more rapidly than in places where TNF inhibitors are well established.

Mark White - Pfizer, Inc. - Commercial Development Lead - Inflammation

I guess it's somewhat dependent on the emerging markets, but we feel like Enbrel actually has done very well in the emerging markets. I think maybe the difference that we've thought about, although we haven't explored a lot, there are some emerging markets that have difficulty with cold chain storage and transports. And having an oral drug may allow for use in some countries where they have a difficult time with some of the biologics that have to be refrigerated.



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Chuck Triano - Pfizer, Inc. - IR

Thanks, Mark. Seamus, did you have a follow-up?

Seamus Fernandez - Leerink Swann - Analyst

Actually, this question is for Geno. So, Geno, can you just kind of quantify for us --? It's almost impossible for us to actually put a good number around this as analysts. Second line, third line, fourth line TNF, if you were to kind of carve up the non sort of TNF first line market and go beyond that, 20% to 40% is a nice number for not managed well right now.

But let's just say, for example, FDA says, "Okay, let's give them a second line label, but this is the first oral drug. And if physicians are going to jump from a TNF straight to tofa, let's imagine that as a possible scenario." What is that market for Enbrel plus Humira right now as we think about that sort of second -- that true second line next to market?

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

Yes. You're referring to the after TNF market or prior to TNF?

Seamus Fernandez - Leerink Swann - Analyst

Well, it's kind of inclusive of the second TNF, right? Because right now our understanding is that the way that patients are treated -- give a TNF, give a second TNF, then go to Orenicia or --.

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

Right.

Seamus Fernandez - Leerink Swann - Analyst

-- the next line. So, it kind of feels like what's the size of that --?

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

I think that --.

Seamus Fernandez - Leerink Swann - Analyst

-- immediately, that second line TNF market?

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

Yes, that's a good question. I'm not sure I have a number that I can give you. I will give that some more thought, but I think that the numbers that I did share, the 20% to 40% range, that's generally patients that have exhausted the TNFs, tried at least two and sometimes even three. So the number for a single TNF failure would be -- I would expect it to be a considerably higher number.

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I think we know with our Enbrel experience -- and, Saeed, maybe you can comment as well -- that 30% plus, particularly over time, you see some loss of efficacy over time; you see some non-responders and complete responders. And it's like any therapy, you stay with what's working as long as you can until there's something better to do. If there's nothing better to do, an incomplete response is better than no response.

So how much faster will the transition be from a TNF to a new agent, particularly one with a novel mechanism of action, there may be a bigger appetite to make that transition more quickly.

Chuck Triano - Pfizer, Inc. - IR

Okay. I think that exhausts our questions. I'd like to thank our team here and thank all of you for your attention tonight. This ends the webcast. Thank you.

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