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PRESENTATION

Operator

Greetings, and welcome to the Aurinia Pharmaceutical's dry eye results conference call. (Operator Instructions) As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Ms. Celia Economides, Vice President, Corporate and Public Affairs for Aurinia Pharmaceuticals. You may begin.

Celia Economides - *Aurinia Pharmaceuticals Inc. - VP of Corporate & Public Affairs*

Thank you, operator. Good morning, everyone, and welcome to Aurinia's presentation of our Phase II Dry Eye Syndrome results.

With me on the call today from Aurinia are Richard Glickman, Chairman and Chief Executive Officer; Dr. Neil Solomons, our Chief Medical Officer; and Michael Martin, our, Chief Operating Officer. Joining us for the Q&A portion of this call will be Dr. Joseph Tauber, principal investigator and head of the renowned Tauber Institute in Kansas City, Missouri.

Earlier today, we issued a press release announcing results of our Phase II head-to-head study of voclosporin ophthalmic solution versus RESTASIS for the treatment of Dry Eye Syndrome. The press release and financial statement package is available on our website at auriniapharma.com, and a 6-K was filed with the SEC as well.

I'd like to remind you that today's presentation is being webcast live on Aurinia's Investor Relations website, and a replay will also be available following today's call. The content of today's call is Aurinia's property. It cannot be reproduced or transcribed without our prior written consent.

During the course of this call, we may make forward-looking statements based on current expectations. These forward-looking statements are subject to a number of significant risks and uncertainties, and our actual results may differ materially. For a discussion of factors that could affect our future results and business, please refer to the disclosure in today's press release, our most recent filings with Canadian securities authorities and reports that we file on Form 6-K with the U.S. Securities and Exchange Commission.

All of our statements are made as of today, January 22, 2019, based on the information currently available to us. Except as required by law, we assume no obligation to update any such statements.

With that, let me turn the call over to Richard. Richard?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Thank you, Celia. And thank you all for being on the call this morning, and apologies to you folks living on the West Coast for this really early hour.

This morning, I am very excited to share the results of our exploratory Phase II head-to-head study of VOS versus RESTASIS in the treatment of Dry Eye Syndrome. I have a few comments to make, and then I will turn the call over to Dr. Neil Solomons to provide a detailed review of the data. First, a quick thanks to the team for the hard work in conducting the study and to the patients and physicians who participated.

Many of you recall that VOS is a product we had in our possession for quite some time. And we thought it would make some sense to spend a little money to see if we could generate some interesting data, and that's exactly what we've done here. Our exploratory study produced some very important results that will guide future development of VOS. This study is one of the only head-to-head studies conducted between a development agent and the current market leader, RESTASIS, for the treatment of Dry Eye Syndrome.

One of our goals was to assess potential differentiation of VOS and whether it could be a strong clinical and commercial contender in the dry eye market. We designed our trial to look at a number of endpoints, including the primary, which was a simple component to ocular tolerability called drop discomfort. It is a subjective endpoint that is measured after a patient receives 1 drop of the drug and scores his or her discomfort on a visual analog scale at minute 1 of the study. We also evaluated a number of challenging objective endpoints that have previously informed the basis of approval of the 3 currently FDA-approved dry eye therapies.

Our working hypothesis was that 100 patients would be enough to see a difference in drug installation discomfort at 1 minute, but it was unlikely that we would see statistical significance at the other more relevant and challenging efficacy endpoints given the sample size and short duration of the study. Clearly, we were wrong. In our study, both VOS and RESTASIS generated surprisingly low discomfort scores and both were very well tolerated. So it's definitely not the right choice as our primary endpoint in this exploratory study. However, we never imagined that the more challenging objective and subjective endpoints that encompass both signs and symptoms would yield such statistically significant and clinically relevant results. These results, which Neil will be presenting shortly, have given me tremendous confidence that Aurinia should aggressively pursue the clinical development of VOS and that should these efficacy data be supported, VOS has the potential to make a major contribution to the treatment of Dry Eye Syndrome.

I will speak more on this after Neil presents the detailed results. With that, I'll turn the call over to Neil who will walk you through these results.

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Thank you very much, Richard. So first, a very brief overview of Dry Eye Syndrome or DES. This is a chronic inflammatory disease characterized by irritation and reduced tear production. It affects more than 16 million people in the U.S., has an increase -- has been increasing in incidence for reasons not clear but are at least, in part, environmental.

DES is somewhat inadequately served by current therapies. Topical calcineurin inhibitors represent the mainstay of therapy for treatment of ocular surface disease. However, there is an unmet need for more effective drugs. And VOS is Aurinia's unique nanomicellar formulation that is being developed for the treatment of dry eye disease.

So there are currently only 3 FDA-approved therapies for the treatment of DES, and these are RESTASIS, Cequa and Xiidra. These products were approved based on the endpoints detailed in this slide. Both RESTASIS and Cequa have 10 millimeter increase in Schirmer score at 6 and 3 months; and more recently, Xiidra, corneal staining and eye dryness scores. And you will see that these outcome measures are important, as I present the efficacy data from this trial in the coming slides.

So here is an outline of what these tests are and how they are performed. Both are objective measures of efficacy performed by the ophthalmologist. The Schirmer test is when a doctor places filter paper inside the lower eyelid and assesses how far the tear has traveled, giving an objective measure of tear production. Improving dry eye will lead to increased tear production.

Corneal staining is where dye is introduced onto the surface of the eye. The dye stains problematic areas which appear green under blue light. Damage is assessed according to extent of the stain.

So here is a brief reminder of the study design. Subjects with DES were randomized to receive either VOS or RESTASIS. It's important to remind you at this point that this is an active control study comparing VOS with the approved standard of care. This double-masked exploratory study was powered, as Richard said, on expected drop discomfort scores. But as we will see in coming slides, hard objective measures of efficacy in dry eye symptoms such as SANDE were also assessed and reported.

So to summarize before we get into detail, VOS showed efficacy in multiple dimensions, consistently outperforming RESTASIS on important signs of dry eye syndrome, namely Schirmer test and corneal staining. Both VOS and RESTASIS patients also experienced significantly improved symptoms compared to baseline, too. And I'll take you through these exciting results on the next couple of slides.

The baseline characteristics are detailed on this slide, and it is important they are well-balanced between the arms and are representative of the dry eye population in the U.S. Most subjects were postmenopausal women, and I'll draw your attention to the baseline SANDE scores. These scores are consistent with the more active end of moderate disease with respect to dry eye symptoms.

So the primary outcome measure of drop discomfort was assessed 1 minute after the first installation of the drug by way of VAS, visual analog score. Discomfort was between 0 and 100 millimeters; with 0 being no discomfort, 100 being the worst possible discomfort. You can see here that there was actually very little overall discomfort in either group with minimal and nonsignificant difference between them. It is important to note that, initially, we expected 15- to 30-millimeter discomfort, but in reality, we observed less than 10 millimeters.

It is in the important efficacy endpoints that follow where things start to get interesting. When the Schirmer score was assessed, we found that VOS was statistically superior against the active comparator RESTASIS at nearly all time points. This chart details the mean change from baseline in Schirmer score for both eyes at week 2 and week 4. Statistical significance was seen at multiple time points, improving over time, 2 weeks to 4 weeks. Again, just to remind you, this is an active comparator study. We are not aware of any other product that has shown superior results to the current standard of care in this disease. And you can see an amplified treatment effect over time.

When we break down subjects by those who achieved a clinically meaningful improvement in Schirmer by greater or equal to 10 millimeters, and this, incidentally, is the threshold required by the FDA for the RESTASIS approval, things become more interesting. More than 40% of VOS versus 18% of RESTASIS patients achieved this impressive endpoint. And on the next slide, I'll show you how these response rates compared to those quoted in the package inserts for approved drugs in the class to give some context.

So it's helpful to look at this data in the context of potential commercial viability of VOS. Now while caution should always be used when we compare across studies, between 15% and 17% of subjects in the Cequa and RESTASIS studies achieved this 10-millimeter or breakthrough improvement in their Schirmer score at 3 to 6 months. This portion formed the basis of their approval.

On the right of your screen, you can see that, in this study, the RESTASIS group achieved a comparable 18% response with respect to the proportion of patients getting greater or equal to 10 millimeters of increase in their Schirmer score. This is dwarfed by the 43% VOS response after only 4 weeks of therapy.

The other critical objective in this disease is FCS or corneal staining. Now this is a well-accepted technique to show damage and scarring to cornea. Therefore, a reduction in the score represents a reduction in scarring. Again, when comparing against RESTASIS, we once again see that VOS was statistically superior, with dramatic declines in corneal staining, as you can see. And the improvement in this measure appears to increase the longer patients are on VOS.

This slide shows changes from baseline in corneal staining. Again, at most time points, starting as early as a week after the start of therapy, we can see the profound reduction in staining in the VOS group compared to modest reduction we've seen in the RESTASIS-treated patients. And by week 4, on the right of the chart, the difference is really quite pronounced. The SANDE score reduced significantly compared to baseline. Although no difference was observed between the groups, SANDE is a scoring system that assesses the severity and also the frequency of symptoms in Dry Eye Syndrome.

This slide summarizes the safety observed in the study. There were no serious adverse events. And adverse events tend to be mild and expected for the condition. Visual acuity was assessed as a safety measure with improvements from baseline on both groups. No meaningful changes from baseline were observed in either slit lamp assessments or ophthalmoscopic examination. So in summary, we were extremely impressed with VOS in this study in terms of the superior efficacy for signs of dry eye symptom -- Dry Eye Syndrome and improvements over baseline in these important but highly variable subjective symptom scores.

So now I'm going to hand it back to Richard for some additional comments. Richard?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Thank you, Neil. Before I open it up for Q&A, I have a few final remarks.

I believe this data indicate the significant potential for VOS in the treatment of dry eye. This study generated consistent statistically significant and clinically meaningful results for both signs and symptoms and demonstrated the statistical superiority of RESTASIS -- to RESTASIS on important efficacy parameters that have previously served as the basis of FDA approval for other dry eye treatments. Based on these positive data, we plan to aggressively advance VOS for the treatment of Dry Eye Syndrome.

We believe we could create considerable value for both patients and our shareholders. With its own IP protection until 2031, we believe that VOS has the potential to become the leader in the dry eye treatment market, which is currently valued at over $2 billion, where current treatments are marginal at best. Our pursuit of further development of VOS provides the company with an enhanced pipeline that can capitalize on the differentiating features of voclosporin and positions us for substantial growth. We've got a lot of valuable information from conducting this exploratory study, and we look forward to sharing future plans on VOS development over the next few months.

I'd like to -- before I actually move on to the Q&A, I'd like to ask Dr. Joseph Tauber, Head of the Tauber Eye Institute, to share his view on the data generated in this Phase II study. Dr. Tauber?

Joseph Tauber

I hope I'm audible. I was an investigator in this trial and have an over 25-year history of trial work in dry eye having been involved in each of the RESTASIS studies, each of the Cequa studies and quite a few other drugs that have not obtained approval.

This was an -- for me, this was an unusual study from the beginning in targeting post-installation discomfort. That's an endpoint that really has not been looked at in dry eye population, and I think in retrospect, I would describe that as an incorrect choice of parameter. The mainline parameters that we're all used to in dry eye are the ones that have already been discussed. And from my point of view, frankly, the results are extraordinary and in particular, in comparison with other studies that are out there for the drugs currently approved.

I'm just going to repeat some of the things already mentioned. The responder analysis, the improvement of 10 millimeters or more in Schirmer assessments is more than 2x higher than either drug that's on the market. That's never been reported before. An increase of 10 millimeters of Schirmer, speaking as a clinician, is an absolutely extraordinary degree of improvement, to the point where Dr. Chambers has said, "If you just show that, you've cured this patient, I don't need to see anything else." And that is the basis of approval for both calcineurin inhibitors on the market.

If you dig a little deeper into the fluorescein staining -- corneal staining scores on both RESTASIS and Xiidra, yes, they obtained a statistically significant change from baseline versus placebo but it was perhaps on the order of 0.25 of a unit. It didn't really reach the level of significance the FDA typically asks for, which is 1 unit. That's why language like the totality of evidence was used in some prior approvals.

The data in the Aurinia study, again, is extraordinary. It was greater than 1 unit change of improvement in corneal fluorescein staining at 1 week, more than 2 units at week 4, and the trend appears to be increasing. That's an extraordinary improvement.

The symptom endpoint on this study, again, I think was incorrectly chosen as SANDE, which has really never shown statistically significant separation between a drug and vehicle in prior studies. I don't believe the individual symptom data was shown to you, except for a summary table. But I have had the opportunity to see that, and there were significant changes in virtually all individual symptom scores for VOS versus, in this case, RESTASIS, not even versus vehicle.

So for me, what I've seen in this not gigantic study so far is quite powerful demonstration of improvement in both symptom and sign. And I would find this very exciting. I think the -- looking at it as this study did not meet its primarily endpoint is not the right way to look at it. I think looking at the data, I find them very powerful. And I'll stop there.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Thank you very much for taking the time to be with us today and actually share those comments. And hoping you could stick around a little bit for the Q&A session. I understand you have some patients waiting for you, but stay with us as long as you can.

Okay. We're going to open it up now for Q&A, and we'll start taking questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Ed Arce with H.C. Wainwright.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Congrats on the unprecedented data in dry eye. A few questions for you. I can really appreciate here from the data how quickly the onset of action is, as shown in both of the measures for signs. But as Dr. Tauber mentioned, the symptoms -- the measures for symptoms, SANDE and VAS, were not statistically significant. And I understand that there's a high degree of variability and perhaps some subjectability with that. Perhaps if you could help us understand better what you saw and what your impression is overall in terms of the symptoms with VOS.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Yes. No, I think that's actually a fairly straightforward answer. I'll turn it over to clinicians to answer in a moment, but I will say right off the bat that, in fact, your interpretation, I'm afraid, is actually incorrect. The SANDE scores as well as other sort of symptom scores were actually statistically significantly improved over baseline through the course of the study. What we said was that we weren't able to differentiate between improvements in RESTASIS versus improvements with VOS, but both provided very, very significant -- statistically significant improvements over baseline. So one of the things we find at highly variable symptomology-type endpoints is that there's a great deal of variability to them. And I believe that the longer you use the drug, the greater real data you'll generate and these early sort of 4-week type studies may not give you the full picture. Clearly, we're seeing tremendous improvements in -- but I also think that has to do with lubricating the eye as well. So I think they're useful in the longer term. I don't think the shorter-term studies are as effective as indicators, but I will repeat, both showed extremely significant reductions from baseline. Neil, any further comments?

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

No, nothing in particular. Thanks, Richard. But as Richard said, both showed a significant improvement in symptoms from baseline, but not significant between the 2. But I think what we can say in this study is that we showed an improvement in symptoms, albeit no different from RESTASIS, but also an improvement in signs, in contrast to what we've seen from the control on RESTASIS. So this is as good as we could possibly have done.

Joseph Tauber

This is Dr. Tauber. I just want to add a comment from the Cequa data. Cequa's studies also showed a 30% reduction on baseline symptoms from baseline and could not demonstrate separation from vehicle. This study is unique in comparing 2 actives without a vehicle. So if subsequent Phase III studies don't get the same magnitude placebo effect, this may prove significant. But it was equivalent to the prior work with Cequa.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay. A couple more follow-ups then, if I may. Again, the onset of action, clearly quite significantly better than RESTASIS. But wondering if this superior efficacy of VOS at 4 weeks could be at least in part a function of the short treatment duration versus RESTASIS. And then a last follow-up is -- I know that you had intended to look at a number of other potential differentiators. Were there any assessment done on the potential for qd dosing versus BID?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Okay. In terms of your first question in terms of onset of action, I think you could keep in mind that we're actually comparing apples to apples in terms of what are the recommended doses. We actually moved forward with our drug relative to RESTASIS. RESTASIS was given the way it's meant to be prescribed. And at 4 weeks, we assessed -- as we did at 2 weeks, then at 4 weeks, we assessed those scores. From an efficacy perspective, we clearly see that VOS far exceeded the performance of RESTASIS. And I think it's very, very meaningful, these reductions that we're seeing. And the reduction of RESTASIS was consistent with what we've seen historically in studies, yet ours was consistently and considerably better throughout the entire study. So I think it is very reflective of the difference. Now keep in mind why this may be occurring. When we deliver VOS, we're delivering 4x as much drug to the eye and we're delivering a drug that's probably about 4x more potent. So if you're looking at calcineurin inhibition, you're delivering almost 16x as much inhibition of calcineurin to the eye than you are with RESTASIS. So it's not surprising to us that this drug would work faster. And we expect that kind of trend to continue going forward.

But with respect to your second question, we have a partnership with Merck Animal Health. Merck Animal Health has actually allowed us to now begin to speak about some of the data they're generating. And one of the things they have shown clearly in their studies was both -- actually, becoming very important, which is if you actually look at their study in terms of their time line and how dogs react -- because, remember, that's where dry eye therapy started. It started with dogs and with Optimmune, their product, which is actually RESTASIS. So they compared the 2 directly. Their time line on response with dogs is almost identical to what the human response was like, which makes perfect sense. So we had an indication. We were scared to use it as a primary outcome measure because everyone thought it would be crazy. But we had an indication this drug is going to work quickly, and it sure did.

The other thing that we have done with them is that they actually overlaid their studies with just the once-a-day formulation strategy, basically the same product, just given once a day. And actually, almost virtually identical results. So I actually believe what we have here, at the worst-case scenario, is non-inferior in terms of drop discomfort. And we have much, much higher efficacy and faster onset and the potential for a drug that could be dosed once a day. And I think those are going to be important differentiators in moving this program forward. This was a guiding study. This is an exploratory study. This gave us great confidence on how to take the next step with this drug.

Operator

Our next question comes from the line of Joseph Schwartz with SVB Leerink.

Joseph Patrick Schwartz - *Leerink Partners LLC, Research Division - MD, Biotechnology*

Congrats on the positive data. So I was just wondering if you could just expand a little bit on the low drop discontinued -- discomfort rate and if there are any hypotheses, either from the company or perhaps Dr. Tauber has some thoughts on that. And how much of an issue is that in the marketplace, Dr. Tauber? And as you look at the emerging target product profile here, where do you think that a drug like this would fit in that seemingly has a lot more efficacy?

Joseph Tauber

I'm happy to answer from the patient perspective. I think there are 2 reasons that we don't have a higher success rate with RESTASIS. The first is it doesn't create a highly perceptible patient improvement. Xiidra, by comparison, my experience is about 20% of patients say, "Wow, this is a great drug. I don't really care what it costs, I'm going to keep using it." And no one says that about RESTASIS. I think it's more the slow onset of benefit that results in that patient evaluation compared to alternatives. So for me, the onset of improvement in staining at 1 week really holds some promise that we may see a very different patient perception. The issue about discomfort from the drop, while it is widely reported at 15%, I'll just speak as a clinician, that's not the reason very many patients stop using that drug, probably no more than 5%. Discomfort is a factor. Cost is a very significant factor. But in my experience, the time to onset of benefit and the limited perception of benefit are the bigger issues, and I think there is potential for this drug to get around that.

Joseph Patrick Schwartz - *Leerink Partners LLC, Research Division - MD, Biotechnology*

That's very helpful. And just for the company, if you could lay out for us what you expect the next steps to be in development of VOS.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Okay. And Joe, fair enough. Great. I think we're still assessing data, number one. The data has only been fresh in our hands for 2 days, and we wanted to make sure it was available to our shareholders as quickly as possible. So when we complete the assessment and analysis -- we've already actually presented to the company's Board of Directors. We already have an endorsement from the board to be aggressive on moving this program forward and to fully fund a program. Keeping in mind this study that we did is exploratory, we spent very little relative money to just see whether or not this drug actually deserved to be developed, and clearly, it deserves to be developed. So the next steps are developing the clinical program.

I think we have opportunities to even further optimize the drug, and I don't think it's actually going to take us that long. We have drug supply and we have various dosing available for the drug to move forward with. We've got the necessary tox data that we need in order to move forward with, with our next studies. So I don't want to put out a time line, right, yet today other than to say that we're actually well positioned to begin the next study fairly quickly. But that said, we really want to evaluate very carefully study design, take our learnings and actually enhance the resources that are available to us in developing this further.

Now I want to also make the point that we intend to take this further down the pipeline because we really do believe we can create significant value with this asset and it's probably better for us to take it another step than it would be, for instance, to partner it out immediately. We think that the development pathway is really clear. We know the regulatory pathway for the CNIs. It's actually fairly low risk for us. So we really believe this is an asset we can create like tremendous amount of additional value without actually being particularly expensive. And I could tell, compared to doing a lupus nephritis trial, the access to patients, the speed with which we can do these trials, it's actually kind of enjoyable relative to the trudge work and the tough work we faced in our LN program. So we're not letting this asset go too quickly. We really believe there's too much value here that's untapped.

Operator

Our next question comes from the line of David Martin with Bloom Burton & Co.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

So the first one is -- the formulation of VOS, your preclinical studies and the Phase I that you did previously would have suggested this would have been better tolerated given the known discomfort with RESTASIS. Why do you think you didn't see the difference in discomfort here?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

I think it really starts off the fact that we just didn't see the discomfort with the RESTASIS. And so I think -- let's think of this in a couple of ways. First of all, if cyclosporine in RESTASIS, which is 0.5% -- or like 0.05% is the reason why -- if it's the reason why there is discomfort when you apply it and we're actually applying a drug which is actually 4x as much drug actually being applied to the eye, if that's the case, then really in a worst-case scenario, we're actually applying 4x the amount of drug, getting the efficacy and having similar levels of acceptable tolerability. And that's the key here in understanding really what tolerability means for this drug. So I think that's partly the case.

But I also think that it's -- over a short period of time, it's really difficult in just 4 weeks to totally predict tolerability and comfort because I believe that, over time, as the eye begins to heal, that you will actually see changes in symptomology and changes in how that tolerability works. So I just don't think the study was designed well enough to be able to look at that longer term. And you have to keep in mind that both arms actually did really, really well. And it wasn't that patients were having a problem with both these drugs, they just didn't have a problem with either of these drugs in the study.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Okay. The other thing is RESTASIS actually perform -- like it didn't perform as well as VOS but it performed better at 4 weeks, and I think you would have expected the 18% getting the 10-millimeter improvement. Whereas, in Phase III, you saw 15% at 6 months. Like why do you think RESTASIS performed better than expected here?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

As we often say, it's difficult to compare a study to a study just sort of like -- and try to make them sort of identical with parameters. I do think that the 18% is kind of consistent with what you'd expect this drug to actually perform at as well. I also think that one of the issues is you just don't see a lot of data available at various time points to really go against. And so you are going a little bit blind, again, in terms of the time frame of response in terms of what's available in the public domain. But I think we're seeing a consistent response basically from RESTASIS. And I think that the increase -- the significant increase above that is actually a very real effect of actually having much greater calcineurin inhibition, much more greater, I think, inhibition to T cell activation in the eye, given you're treating a T cell-mediated disease.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Okay. And just last question is for Dr. Tauber. You mentioned that Xiidra, it was impossible to differentiate between vehicle and drug when it came to symptom score eye dryness. I'm wondering, is that going to be a necessary endpoint in the Phase III for VOS? Or have we moved beyond that and will be Schirmer and corneal staining?

Joseph Tauber

You may have misheard me. My comment about failing to show separation in symptom scoring between active and placebo is Cequa, not for Xiidra. Xiidra is a powerful demonstration of symptomatic improvement.

Yes, the FDA so far stands on 2 legs. You can demonstrate symptom and sign. Obviously, each can be an independent study, so it can be a package of 4 studies or this concept of return to normalcy, which Dr. Chambers has accepted on the basis of the Schirmer responder analysis, and is at least open to total corneal fluorescein clearing, which no one has ever demonstrated. So it is not necessary to be both symptom and sign. You got 2 drugs on the market that really didn't accomplish both at least in a very powerful way. That's one answer.

I want to come back to just one previous statement, the comment about why did we see -- the question about the RESTASIS responder analysis at 1 month, why is that so much better than what they had reported. Keep in mind the RESTASIS use of that parameter was a post-hoc analysis, and that -- and it's quite true they really were not permitted to comment about their data at anything other than the 6-month time point. So I think they really commented exactly right.

One last one about the drop installation discomfort, and it occurred to me as a clinical trial person. The way you ask a question really guides the answer. If I ask you how often have you had headache, you'd have a rather high incidence of saying, "Yes, I've had headaches." If we ask patients have anything negative happened since we've seen you, you get pretty spontaneous reporting. In this study, patients were asked, "Tell me how much discomfort you have." No one said 0. And I think that really was not the best constructive metric to look at what was intended to be looked at. And I'll stop there.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Thank you, David.

Operator

Our next question comes from the line of Doug Miehm with RBC Capital Markets.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Richard, when it comes to the timing of events, and -- I know you don't want to go into a lot of detail, but the next set of trials to support a final clinical program, would you expect those next set of trials to start and last as long as this first trial that you just did and had the great results in?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

No, I -- my anticipation really fundamentally is that we've learned a lot from this first trial and that the next step is to actually be more aggressive, larger trial size and actually duration -- and duration more consistent with what your approvable end points would be, sort of the 3-month duration. And so as we progress, you can expect a much more sort of standard program. I think you'll also see some dosing work being done on us -- done by us because we have different formulations and different dosing available to us and actually study it. We'll do it simultaneously. I think that maybe 16x the amount of calcineurin inhibition may be overkill. Maybe we only need 8. Maybe that leads to better tolerability. I think that while I focus on -- we didn't see a tolerability issue here, overall, in the real-world market, we do know that these people have sore eyes and what you put on their eyes tend to bother them. So we're going to do our best to see if we can even improve that further as we move forward. And so you'll see a fairly interesting, recently rapid determination of what our next steps are going to be. We will share those when we're ready to share those. But a lot of the pieces we need to do, all of those are actually already in place.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Okay. So would it be fair to say, based on the size of these trials, that perhaps the second half of 2020 is when you could start your final component, the Phase III component of this -- for this drug?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

I know you're trying to build -- to figure out the modeling on this, and I appreciate that, but we really just don't feel comfortable yet in setting sort of expectations until we really had a chance to take a look at what precisely the trial design needs to be and the time frame for it. I think you will find us to be very aggressive. I think you will find that we realize the value of time in driving this program forward. And so it won't be long, I will be able to answer that question openly. I just want to refrain until I think we really have done our homework.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Okay, that's fine. And a quick question for Dr. Tauber. Maybe as it more relates to Xiidra, how would you compare, on the face of these results, recognizing their shortcomings, et cetera, et cetera, versus what we saw come out of the Xiidra clinical results for ultimate positioning?

Joseph Tauber

There were certainly some surprises in what we saw in the Xiidra trials and the Xiidra real-world clinical experience. From the trials, we were all concerned about the dysgeusia, the so-called bad taste that patients reported in trial. It had never been reported in any eye drop study. In real-world, that's a nonissue. The complaints of discomfort from drop installation in this study did not seem to be significant. Real world, that seems to be the largest reason patients stop using it. It's not the taste, it's the fact that it stings, in some cases, rather prominently. People have described it as, "This isn't just burning when you put in the drop. This is broken-glass-in-your-eye kind of burning." So people who won't take it because of drop-related discomfort are totally opposed to them. They would think it's a horrible thing to ever do to a person. On the flip side, 20% say, "This is great. And what this provides me is worth any price whatsoever." So we've all learned not to take clinical trial experience as representative of what we'll see in the real world. The other perspective here, again, is the rapidity of onset of the benefit is striking, the strength of the response. And I'm, again, talking about both the size of the fluorescein stain reduction and the responder analysis are outstanding compared to anything reported in literature.

Douglas Miehm - *RBC Capital Markets, LLC, Research Division - Analyst*

Okay. And if the company were to take it down from 16x to 8x, would you see a commensurate decrease in efficacy in staining or anything like that? Or do you believe that enough drug is getting into the eye, where there is going to be negligible change as it relates to some of the outcomes that we saw here? I'll leave it there.

Joseph Tauber

I think the answer is, if we knew the answer, we wouldn't be doing research. I don't have any scientific basis to answer to that.

Operator

(Operator Instructions) Our next question is a follow-up from the line of Ed Arce with H.C. Wainwright.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Just a couple of quick ones. First, Richard, I just wanted to confirm or further clarify previous comments. Your intention is to continue to take this into at least a Phase IIb, sort of proof of concept yourselves before looking at potential partnering? Or do you think you could take this all the way

through to a registrational study? And then the second is along the registrational time point itself. Do you envision an ultimate pivotal study being either 3 or 6 months in duration?

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Yes. I think -- for your second question first. I think, classically, given the efficacy we're seeing and the time of -- and the rapidity of response, 3 months with a 9-month follow-up, from a safety perspective, is probably what the regulators are going to be looking for, but we'll confirm that with regulators as we go back. But we did present a potential clinical plan earlier to regulators. I think that wouldn't be inconsistent. But I think that we still need time to actually really confirm that.

With respect to your first question, which is around partnering versus -- I mean, any organization -- our job is actually, as you know and I truly respect shareholder capital, is to sort of respond. If someone is interested in owning this asset and is willing to pay the appropriate amount, of course, we have fiduciary responsibility to look at that. It's just that I think that by staying focused, putting our head down, investing in this product, we can create significant value. It's not particularly expensive. I don't see it as particularly risky. I don't see it as being -- taking particularly long. I think patient access is really easy with 16 million patients in the U.S. I mean, it's got all the hallmarks of things that we could do relatively quickly. Where the real issue comes down to is what kind of commercialization organization do you need. And I was joking the other day when I said that the kidneys are a long way from the eyeballs, and we really do focus on renal disease. So ultimately, having a commercial partner -- an ability to participate in the commercialization success of the drug really in my mind means taking it further along the line, creating more value and then being able to drive a better opportunity for our shareholders when we have the data to do so. So right now, it's put our heads down, let's do the right trial. If someone comes and knocks on our door, we'll answer the door to see what they have to say. But the reality is we're going to stay focused and actually create the value that I think is easily attained here.

Operator

Our next question comes from the line of Elemer Piros with Cantor Fitzgerald.

Elemer Piros - *Cantor Fitzgerald & Co., Research Division - Analyst*

Maybe a question for Dr. Tauber. Dr. Tauber, in what sense -- or in what measures do you believe that RESTASIS acted atypically, whether it is the discomfort measurement or the symptom, the onset of the improvement in the SANDE score, for example? What other aspects can you think of that we've seen RESTASIS digress from what you see in clinical practice?

Joseph Tauber

Digression is a hard word in part because the results with RESTASIS at these time points really haven't been reported before. The responder analysis results for RESTASIS seen at 1 month being equivalent to what we've seen at 6 months, that came as a surprise to me. You can also read into this comparing 2 different studies, which is always a challenge, but the percentage at 1 month being the same as what we've seen at 6 months. Let's contrast that with what we see with VOS, where the responder analysis percentage is -- and again, I don't think this data was shared with you, but the percentage increases from 1 week to 2 weeks to 4 weeks. So there's at least some reason to think that's continuing to trend upwards. That may represent some further promise here.

Apart from that, I'm just not surprised RESTASIS performed as I would have expected it would. I think perhaps there were fewer dropouts related to RESTASIS discomfort than in other studies. And that may in part be because of investigators that were also used to that. When patients complain about some stinging, we kind of try to talk people through it. Clinically, there are things like refrigerate the drop and other strategies. But certainly, on our side, it's no longer a surprise where our first instinct is to say, "Well, you can drop out of the study whenever you want." We try to talk people to get through to the end. Apart from that, I was not terribly surprised about what I saw.

Elemer Piros - *Cantor Fitzgerald & Co., Research Division - Analyst*

And on the symptom improvement front, the kinetics of the response of RESTASIS, was that surprising, how quickly it came on?

Joseph Tauber

Boy, I mean, you take me back to 2003. I'm not sure that I remember the kinetics of the symptom improvement with RESTASIS from back then. And of course, they were very different parameters. My recollection may be that OSDI is what was used in RESTASIS studies, and that essentially failed. I don't know for sure that they scored individual symptoms in those studies. If necessary, I can get back to you on that. I'm sure I have that data available, just not at the tip of my fingers.

Operator

Our next question comes from the line of David Martin with Bloom Burton & Co.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Yes. Two quick follow-ups. What were the discontinuations in both arms of the trial and discontinuations due to eye discomfort or drop discomfort in particular?

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Thanks, David. There were very, very few discontinuations and none directly due to drop discomfort at all in the study. But there were 3 discontinuations in total in the study due to dry eye symptoms.

David C. Martin - *Bloom Burton & Co., Research Division - MD & Head of Equity Research*

Okay. And last question, the Phase IIb, will it be placebo controlled or will it be versus RESTASIS again?

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

So we are -- I mean, our understanding from a regulatory perspective, from an FDA perspective is that we have to compare against vehicle in that study.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

At least one study.

Neil Solomons - *Aurinia Pharmaceuticals Inc. - Chief Medical Officer*

Yes, in at least one study. So -- but obviously, our thoughts on what we do in phase -- whether we stick with another study arm or not is still evolving.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

We actually think the data should be more profound.

Operator

That concludes our question-and-answer session. I'll turn the floor back to Mr. Glickman for any final comments.

Richard M. Glickman - *Aurinia Pharmaceuticals Inc. - Founder, Chairman, President & CEO*

Okay. Well, thank you all for listening. Thank you for your questions, and thank you, Dr. Tauber, for staying on line with us this morning.

I think you could see, based on the data that's been generated, just how excited we really are and why we're excited. I think that we learned a lot in this study. I think we have a real opportunity to take advantage of the -- of VOS and the differentiation we see of voclosporin in treating this disease. And so over the next several months, we will be working very, very quickly and be able to come back to you and share with you our plans in terms of the development of this drug and when we intend to initiate the next trial.

And once again, thank you all for attending this morning. Have a good day.

Operator

This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.