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Foamix Pharmaceuticals Inc.

Phase 3 Data Call

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PRESENTATION

Operator:

Good day and welcome to the Foamix Pharmaceuticals Phase 3 Data Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Michael Wood of LifeSci Advisors. Please go ahead sir.

Michael Wood:

Thank you, Derek. Good morning everyone, thank you for joining us. Welcome to the Foamix conference call. Leading today's call will be Dave Domzalski, Chief Executive Officer of Foamix and Dr. Iain Stuart, Senior Vice President of R&D, and Ilan Hadar, Chief Financial Officer of the Company, will also be on the call and will be available to answer questions during the Q&A session.

After the market closed yesterday, Foamix issued a press release summarizing the top-line results from the recently completed confirmatory Phase 3 clinical trial of FMX101 for treatment of moderate to severe acne. If you did not yet receive the press release, it's available on the Investor Relations page of the Foamix website, foamix.com. There are also slides accompanying this call. They can be viewed by logging on to webcast. The link is on the Investor page of the corporate website under Upcoming Events. The link is also in the press release on Page 2. This call is being recorded and the replay will be available on the Company's website.

So, before we begin the formal remarks, I want to remind you that some of the information in the news release and on this conference call contain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words that express and reflect optimism, satisfaction with current progress, prospects or projections, as well as words such as believe, intend, expect, plan, anticipate and similar variations identify forward-looking statements but their absence does not necessarily mean that a statement is not forward-looking. As such forward-looking statements are not a guarantee of performance and the Company's actual results could differ materially from those contained in such statements.

Several factors that could cause or contribute to such differences are described in detail in the Foamix's filings with the SEC. These forward-looking statements speak only as of the date of the press release and today's conference call, and the Company undertakes no obligation to publicly update any forward-looking statements or supply new information regarding the circumstances after the date of this call.

So, with that I'd like to the CEO of Foamix. Dave, please go ahead.

David Domzalski:

Thank you, Michael and good morning everyone and thank you all for joining our call today as we share the exciting results from our FMX101 4% minocycline foam confirmatory Phase 3 clinical trial known as Study FX2017-22 or simply Study 22. This is a very exciting moment for all of us here at Foamix.

By now hopefully you have had a chance to read the press release we issued last night. I'm very pleased to report that Study 22 successfully met both its co-primary endpoints and that these results were achieved with a high magnitude of therapeutic effect and statistical significance. The safety profile of FMX101 continues to look excellent. Recall that this clinical trial was designed as a confirmatory Phase 3 study for FMX101 in moderate to severe acne. Following the completion of the prior Phase 3 studies with this drug candidate in 2017, which are Studies 04 and 05, we held a type B meeting with the FDA. We agreed with the agency at that time that statistically significant findings from a third study would constitute replication of the Study 05 results and would be sufficient for establishing an efficacy claim for FMX101. So, we now believe these data—these new data—we are announcing today meet this requirement and our goal is to move forward with an NDA filing to seek approval for FMX101 in the United States.

Let me begin with review of the study design. And this is outlined on Slide 4 of the slide presentation. Study 22 is a double-blind, randomized, vehicle controlled Phase 3 trial that enrolled 1,507 patients with moderate to severe acne at 89 sites across the United States. Patients were randomized 1:1 to receive either of them FMX101 minocycline foam at a 4% concentration or vehicle foam for 12-week period. Patients applied active drug or vehicle themselves once daily. The study was designed with two co-primary efficacy endpoints. First, the absolute change from baseline in the number of inflammatory lesions. Second, treatment success as measured by Investigator Global Assessment or IGA score, where success was defined as an IGA score of zero or one, which is clear or almost clear, and at least a two-grade improvement or decrease from baseline.

In order to be included in the study, patients were required to have between 20 and 50 inflammatory acne lesions and 25 to 100 non-inflammatory lesions. Patients enrolled had either moderate or severe disease, defined as a Grade 3 or 4 on the IGA six-point scale that we used. Because of quality issues identified at one center, 19 subjects were excluded from the intent to treat population. So, the ITT for the purposes of the efficacy analysis comprised of 1,488 patients and the decision to exclude these patients was made well before we received the top-line data.

The patient demographics and baseline characteristics are presented here—our next slide. For these data as well as the efficacy and safety data that I will discuss in the following slides, we are presenting it side by side with the results from Study 05 for comparison purposes.

In Study 22 the baseline mean inflammatory lesion counts were 30.7 and 30.8 for the FMX101 and vehicle treatment groups respectively. The baseline non-inflammatory lesion counts were 49.7 and 49.6 for active treatment and vehicle groups respectively as well. In the active treatment arm, 84% of patients had an IGA score of 3, which is considered moderate acne at baseline, and 16% had a score of 4 which is severe acne. This compares with 83.5% of patients in the vehicle group having a baseline score of 3 and 16.5% with a score of 4. The important thing to take away from this slide was that the patient demographics and baseline data were very similar between Study 22 and our previous Study 05 trial. The proportion of patients with severe disease appears slightly higher in both the active and vehicle treatment groups of Study 22 compared with the previous study.

The efficacy results on the first co-primary endpoint are shown here on the left-hand chart of Slide 6. Patients in the FMX101 active treatment group achieved a 16.93 mean absolute reduction in the number of inflammatory lesion count from baseline to Week 12. This compares with a 13.4 mean absolute reduction in the number of inflammatory lesion counts for the vehicle group. This result was highly statistically significant with a p-value of less than 0.0001. The efficacy results on this endpoint from the prior Phase 3 Study 05 are shown on the right. You can see the differences between aftertreatment and vehicle of approximately the same magnitude across both studies.

The data for the second co-primary endpoint treatment success based on IGA score are presented on Slide 7. You can see that in Study 22, 30.8% of patients in the FMX101 treatment arm achieve treatment success, compared to 19.6% of those in the vehicle arm. Once again, this result was highly statistically significant with the p-value less than 0.0001. For this endpoint, there appears to be a considerable difference to what was demonstrated in Study 05. You can see in the prior Phase 3 study the proportions of patients achieving treatment success were 14.7% and 7.9% for the active FMX101 and vehicle arms, respectively.

There are clear limitations in comparing data across our two studies being presented and would be speculative to suggest any definitive reasons for the different results, however as we've communicated many times over the past several quarters we have dedicated significant resources in clinical investigator training and operational management at the site level in partnership with our CRO. These efforts were led

by Dr. Iain Stuart, our Senior Vice President of Research and Development, and I want to personally recognize Iain and his entire team in the United States and Israel for their exceptional work.

The charts here on Slide 8 show the percentage change in inflammatory lesion counts at Weeks 3, 6, 9 and 12. This was a key secondary endpoint in both studies. At Week 12 there was a 56% reduction in inflammatory lesion counts for FMX101 compared to a 43% reduction for vehicle. You can also see that in Study 22, for all time points beginning at Week 3, there was a highly statistically significant percentage reduction in lesion counts for active FMX101 treatment compared with vehicle. Again, the p-value at all time points was less than 0.0001.

For capacity purposes, the results from Study 05 are presented on the right. The safety results from Studies 22 and 05 are summarized in Slides 9 and 10. Overall, FMX101 appeared to be generally safe and well tolerated and the safety data appear consistent with prior studies with this drug, including Study 05. Non-cutaneous treatment emergent adverse events that occurred at an incidence of at least 1% of patients in Study 22 and Study 05 are listed in the table on Slide 9. The most common systemic adverse event was upper respiratory tract infection. The overall incidence of this was 6.4% in Study 22 and 6.1% in Study 05.

No treatment related serious adverse events were reported in either study.

In Study 22, cutaneous treatment emergent adverse events in the FMX101 treatment group were few. Most were mild including pruritus, dermatitis, swelling, hyperpigmentation and discoloration. The actual number of events for each listed on this slide was only one per condition; that is it out of nearly 740 patients in the active group. In total nine subjects in Studies 22 and 05 discontinued treatment due to a treatment emergent adverse event, including five in the FMX101 treatment group and four in the vehicle treatment group.

We're going to Slide 11 to summarize. The data from Study 22 showed strong statistically significant disease improvement of FMX101 compare with vehicle for both co-primary endpoints of absolute reduction in inflammatory lesions and IGA treatment success at Week 12. These data are consistent with our prior Phase 3 study, Study 05. FMX101 appears to be well tolerated with an excellent safety profile. In both Studies 22 and 05, treatment emergent adverse events were few in type and frequency, thus mild in severity. No treatment related serious adverse events were reported.

Over the next several weeks we will receive additional data which we will submit for presentation at various medical conferences and for publication as well as update to our investor presentations on our website.

Finally, before we open the call for questions, on behalf of Foamix I'd like to thank the patients, clinical investigators and the support staff for participating in this clinical trial. I also want to thank all my fellow colleagues at Foamix for their tremendous work and dedication. A trial such as this requires enormous effort from all those involved and we are certainly very delighted with the outcome. With that I'd like to turn the call back to the Operator to open the line for Q&A. Operator?

Operator:

Thank you, sir. Ladies and gentlemen, if you'd like to ask a question over your phone at this time please signal by pressing star, one on your telephone keypad. If you are using a speakerphone please make sure your mute function is turned off to allow your signal to reach our equipment. Again, that is star, one to ask a question.

And we'll move to our first question from Ken Cacciatore of Cowen & Company. Please go ahead.

Ken Cacciatore:

Hey, congratulations guys on the data. Very happy for everyone.

Dave, since the development of FMX101 the markets shifted a little bit. So, I'm wondering if you could talk about some of the dynamics in the acne market in terms of pricing and managed care, and then maybe where this will fit into the paradigm and some thoughts about maybe an analog for us to compare it to so we could get some perspective around the market opportunity. Thanks.

David Domzalski:

Sure, thanks Ken. Of course, this market, not really unlike many markets in the pharmaceutical arena, is constantly changing. It's fluid. This market continues to be a large and sizable marketplace. Script volume, which is one that we really focus on, is around 5 million scripts. Just looking at branded therapies roughly a million—top—a million oral antibiotic branded prescriptions are written a year. About 4 million branded topical prescriptions. So, we continue to look at this as a large market, a multibillion-dollar category. Though of course there's been changes. There have been products that have recently been genericized but also, we have new products that hopefully will be entering the market, including ours if we are successful in an ultimate FDA approval down the line.

So, you know, we've done a lot of research in the States. There are significant unmet needs. We've talked about the continued opportunity of a product like ours. I think this data reflects the fact that we've shown strong efficacy. We have an excellent safety profile. We've repeatedly talked over the several quarters in the last few years about how this marketplace really is yearning for safe and efficacious new products for patients and we believe that we hopefully will have a product that will get approved and we'll be able to address that.

If you take a look at some of the leading therapies, whether it's the dapsone molecule, the combination adapalene-benzoyl peroxide product, these are our leading therapies in the category large prescription volumes, large revenue generated. And we know that the oral antibiotic space is just space we believe we can take market share from that with the product like ours that we've been able to demonstrate good efficacy and an excellent safety profile with—hopefully without a lot of the systemic side effects that are associated with those products. So yes, we've always said that FMX101 if approved has ability to compete both within

the oral antibiotic category, as well as, the topical category. I think the results that we saw from Study 22 just further strengthens our conviction around that.

So hopefully that provides some good color, Ken, for you.

Ken Cacciatore:

It does, thanks. Congrats again.

David Domzalski:

Thank you.

Operator:

Thank you. Our next think your next question comes from the Vamil Divan of Credit Suisse.

Vamil Divan:

Hi. Great, thanks for taking the question. So just a couple. One you mentioned there's one center where you had issues so you've excluding those patients. Can you just provide a little more detail on that and the decision to remove even though it was done, as you said before you saw any of the top-line data. And then maybe building off of Ken's question on the commercial side. I guess based on what you see with the data here, how do you envision sort of payer acceptance of the product? And would you envision, you know a certain number of generics that patients would need to go through before they can use this or maybe you can just kind of give us a sense of how you see the sort of treatment paradigm evolving, assuming this makes it to the market.

David Domzalski:

Hi Vamil, so I'll ask that Iain address the first question about the center. So, Iain.

Iain Stuart:

Hi, thanks for your questions, Vamil. In relation to the 19 subjects, how these were identified during our regular clinical site monitoring activities earlier this year, so well in advance of the top-line delivery communicated last night. I can't go—obviously because of the sensitivity of this issue—into specifics but it really revolves around data integrity and principal investigator oversight on the study. So, we identified this early and we took decisive action when we became aware of the issues. This was captured specifically in our statistical analytical plan prospectively and was handled way before we went anywhere near database lock and unblinding.

David Domzalski:

Thanks Iain. Vamil, to further comment on reimbursement, the reimbursement landscape in our product. So, a couple of thoughts as we've shared repeatedly. We've done a fair amount of market research. We've not obviously determined or have locked in on a potential price for our product and we won't do that for some time as you can appreciate. We'll continue to conduct the research but the research has been very positive from the payer category. We've always said that we believe that this is a product that would be at a significant discount to the brand of oral antibiotic therapies and in the range of the leading topical therapies. Our objective is to do what is necessary to make sure patients have access to our product if approved. That's obviously our goal. We will work with payers, we will work with patient-based organizations to do whatever is necessary to ensure that our product is accessible to patients. So, we continue to feel very good about that. We believe our product can address—if approved can address unmet needs for patients and for caregivers. We believe we have a very good value proposition for the payer base. And once again I think our results from Study 22 reinforced that position that we have.

Vamil Divan:

Okay. Thanks so much. Congrats on the news. Thanks.

David Domzalski:

Thanks, Vamil.

Operator:

Thank you, we'll next move to Ram Selvaraju of H.C. Wainwright. Please go ahead.

Julian Harrison:

Hi there, this is Julian on for Ram. Congrats on the data. My first question is, I was just curious if you're surprised by how low the discontinuation rate was for this trial, I guess particularly in light of trial size.

Iain Stuart:

No, I think it's completely consistent with our 04 and 05. We had approximately 13% discontinuation rate. So, we're satisfied with that.

Julian Harrison:

Okay, great. Thanks for that. Moving on. What—would you characterize the safety profile of 101 as comparable across all three pivotal studies? And if not, were there any I guess notable differences between those studies?

Iain Stuart:

No, I think broadly speaking they were comparable. As Dave outlined during the presentation of slides, the most frequent treatment emergent adverse event was upper respiratory tract or nasopharyngitis, commonly known as the common cold. So, I think that was consistent across 04, 05 and 22.

Julian Harrison:

Okay and my last question. Just looking forward, how long is it likely to assemble the materials necessary to file an NDA and what might commercial infrastructure around 101 look like and how long might that take to build?

David Domzalski:

I'll address those questions. Regarding the timing of an NDA filing, we completed the vast majority of the work to date. So, our goal is to file an NDA by the end of this year and we're working diligently to achieve that goal. As mentioned previously, we already had our pre-NDA meeting with the FDA earlier this year. So obviously a key component will be waiting till we get the final clinical study report from Study 22. As you can appreciate, it takes a little bit of time to get all of that. We've got other components of the filing, that's what we're working on. We've been doing this for some time. Again, our goal is to file an NDA by the end of a year. We'll keep everybody posted along the way.

Regarding the commercial infrastructure, (inaudible) for a couple of thoughts. One is we'll spend the next several months conducting a lot of work around healthcare provider education and awareness. That will include several components: publications, Congress and convention walkovers, presenting our data in posters, etc. And obviously continuing to work with the healthcare provider arena as well as with the payer base.

In terms of sales force size—I know this is a question that's come up often. We've always said that sales force size would probably be somewhere in the 50 to 100 colleague range. That does not change. There are roughly around 15,000 active dermatologists in the United States, of that about a third of them generate about 70% to 80% of the prescription volume to the majority of patients. So that gets you a commercial footprint in that 50 to 100 representative range and that's fairly consistent with what you see with other organizations in the category. Could that be a little bit higher? A little bit lower? It could. I'm thinking we'll determine that as we get closer to a launch.

Our focus in the near term, again, will be on healthcare provider education awareness. We've been doing a lot of work behind the scenes on our campaigns and now that we have data we'll continue to work on that with our various agency partners. We're excited about that but our focus will be mostly on education and awareness for the healthcare provider community. And then we'll focus on bringing our key strategic positions into the organization. We'll do that methodically. Then as we get closer to—hopefully an approval

and a launch, that's when we look at bringing in the sales organization. That's probably the last piece of the pie.

So, hopefully that provides you some good color in terms of what our next steps will be.

Julian Harrison:

Definitely. Thanks for that and congrats again.

David Domzalski:

Thank you.

Operator:

Thank you, we'll next go to Patrick Dolezal of LifeSci Capital.

Patrick Dolezal:

Congrats on the data and thanks for taking questions. So, the first one here, I was just curious what your current manufacturing capacity is and if this would need to be scaled up as you guys move towards commercialization.

David Domzalski:

Hi Patrick. Our main factory capacity is one ton. We've been at that level for some time. You know our registration batches were manufactured at that scale. We have considerable stability data that's been available for some time. So, you know, we are quite confident with being able to address the commercial needs of the marketplace at this current manufacturing scale capacity, but obviously as we continue to move on, as needed, we'll look to increase that where it warrants. But we have absolutely no concerns about our manufacturing scale capacity for a commercial launch.

Patrick Dolezal:

Great. Okay, that's helpful. And then obviously next is—well yesterday's data were in acne, but I'm kind of looking forward a little bit here. What's your view on the ongoing Phase 3 program for 103 and rosacea? Kind of in light of the positive data in acne, just curious if there's any potential read through here in terms of how the study is being conducted, mechanistic or otherwise.

David Domzalski:

Sure, sure. As we've communicated, we've completed enrollment. We announced a few weeks back a lot of patients enrolled in our two Phase 3 studies for FMX103, which is looking at our 1.5% concentration minocycline foam for the treatment of papulopustular rosacea. We remain on target to having a readout from those two Phase 3 studies sometime in the earlier part of the fourth quarter.

Regarding a read through, as I'm sure you can appreciate, Patrick and everyone on the call, were always very cautious about any kind of read through from one study to another. (Inaudible) at this moment focused on the results that we got from Study 22 and then obviously we will announce the results when the two Phase 3 studies for 103 when they come in. What I will say in terms of where there are connections if you will, it's the same CRO that is managing both programs. We've communicated paths. Our CRO is premier research. They're out of North Carolina. They've done an excellent job for us. They're managing both programs 101 and 103, these Phase 3 studies. You know, I'll just underscore again it's the same rigor and effort regarding training from our clinical operations team being executed for the 103 studies as we've done for 101. So those are the same. Beyond that, you know, we'll just wait for the results and we'll let you know as soon as they come in.

Patrick Dolezal:

Great. Super helpful. Looking forward to it. Thanks again.

David Domzalski:

Now the only other point I'll add to that is that is also a sizable, meaningful market. You know, it was the logical follow on place for us in doing clinical development work—rosacea after acne. As I've shared before, acne continues to be a large market with unmet needs, multibillion-dollar category with 5 million branded prescriptions a year. For the rosacea marketplace, it's about half the size, a billion to 1.5 billion, but unlike acne that has several players it's got just a few products that are out there. So again, we're looking at two categories. Both sides are both large with significant unmet needs. Our hope is that FMX103, like FMX101, will provide a meaningful solution and alternative to address those unmet needs.

Operator:

Thank you and we have no further questions in the queue at this time.

David Domzalski:

Operator, are there any other questions?

Operator:

No, sir, not at this time. I would like to turn the conference back over to Management for any closing or additional remarks.

David Domzalski:

Thank you, Operator and again thank you to everyone that's participating on this call. Appreciate you taking time out of your very busy schedules to join us. Once again, this is an exciting time for Foamix. This is a significant milestone in the history of the Company. I want to again recognize everyone that's been involved in getting us here to this point. We look forward to providing you with additional updates on the data releases for 101 as they become available as well as progress for 103 and the rest of our activities. So, thank you very much. Have a great day. We look forward to speaking with all of you soon. Take care.

Operator:

Thank you. Ladies and gentlemen once again that does conclude today's conference. We thank everyone for their participation. You may now disconnect.