Sun Pharma Advanced Research Company Ltd
Transcript of Management Presentation
4.00 pm, March 25, 2013

## Participants:

Mr. Dilip Shanghvi – Chairman & Managing Director

Dr. T. Rajamannar – Executive Director

Dr. Nitin Dharmadhikari – Solid oral innovative delivery systems

Dr. Subhas Bhowmick – Injectables and other liquid innovative delivery systems

Dr. Yashoraj Zala – Solid oral innovative delivery systems

Mr. Kirti Ganorkar – Business Development

Mr. Narendra Lakkad – Business Development

Dr. Ajay Khopade – Injectables and other liquid innovative delivery systems

Dr. C. T. Rao – New Chemical Entity Development

Dr Shravanti Bhowmick – Clinical Pharmacology

Dr. Atul Raut – Clinical Pharmacology

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**Moderator : -** Ladies and gentlemen, good day and welcome to the SPARC Investor Update Call on R&D Pipeline. As a reminder, for the duration of this conference, all participants' lines will be in a listen-only mode. There will be an opportunity for you to ask questions at the end of today's presentation. Should you need assistance during this conference, please signal an operator by pressing '*' and then '0' on your touchtone telephone. Please note that this conference is being recorded. At this time I would like to hand the conference over to Mr. Nimish Desai. Thank you and over to you sir.

**Nimish Desai :-** Good afternoon and a warm welcome on the SPARC update on Novel Drug Delivery Systems (NDDS) and New Chemical Entity (NCE) projects. We hope you received the presentation that we sent out sometime back. This is also available on our web site for downloading. The call transcript will also be put on SPARC's web site soon. It would be appropriate to mention that the discussion today may include certain forward-looking statements and this must be viewed in conjunction with the risks that SPARC business entails. During today's call, we will make an effort to answer all your questions, but if time does not permit, I request all of you to please send in your questions to the IR team.

We have the entire SPARC team with us on the call today. Let me briefly introduce the team to you. We of course have Mr. Dilip Shanghvi – Chairman and Managing Director with us; Dr. Rajamannar – Head of R&D and is the Executive Director of SPARC; Dr. Nitin Dharmadhikari and Dr. Yashoraj Zala handle the Solid Oral Innovative Delivery Systems; Dr. Subhas Bhowmick and Dr. Ajay Khopade handle the injectables and other liquid innovative delivery systems. We have from the business development team Mr. Kirti Ganorkar and Mr. Narendra Lakkad. We also have Dr. C.T. Rao who handles the New Chemical Entity Development and we have Dr. Shravanti Bhowmik and Dr. Atul Raut who handle the clinical pharmacology.

We are starting with Slide #3, which indicates the Lead NDDS program which SPARC is engaged in. Now, I hand over the call to Dr. Ajay Khopade to give you the details. Over to you, Dr. Ajay.

**Dr. Ajay Khopade :-**Thank you, Nimish I am Ajay Khopade working with the formulation development department in SPARC. Today, I will be updating on some of the products based on the technologies that have been discussed with you in the past. The first product is Latanoprost BKC-free ophthalmic product based on our SMM technology.

Firstly, just to recall, this technology has two distinct advantages. One, it is free from toxic preservatives like BAK and could be useful for chronic indications like glaucoma, especially for the glaucoma patients who have developed dry eyes. And second, this product can be stored at room temperature and will not be a cold chain product.

Coming to the update of this product progress. In the past we have shared that we are conducting two Phase-III trials in the US and I am pleased to share with all the investors today that we have successfully completed the required Phase-III clinical program for this product in the US with encouraging results. The IOP reduction was comparable to Xalatan as you can see in this figure on the slide.

We have shared this data with USFDA in a pre-NDA meeting in February this year and we shall be filing this product in Q2FY2014. We also plan to file this product in various emerging markets.

The second product which I am sharing is Latanoprost and Timolol OD Ophthalmic Solution. There are many glaucoma patients whose IOP is not controlled with the monotherapy and needs to be treated with a combination therapy. We have developed a combination product of Latanoprost and Timolol using the elements of our two ophthalmic platforms which have been shared in previous calls. The first is Gel Free Reservoir element which, due to its natural tear-like characteristics imparts once-a-day property to the Timolol present in this product. And second, the BAK-free and room temperature stability elements of SMM technology for an enhanced safety and non-cold chain transport.

I am pleased to share that we have completed a 4-arm Phase-III study for this product. The 4-arms consisted of SPARC fixed dose combination arm, Xalatan with Timolol concomitant arm and Xalatan alone arm, Timolol alone arm. The responder rate analysis results of this study are shown in this figure in the slide. It shows that SPARC's FDC was statistically superior to Xalatan alone arm as well as Timolol alone arm. At the same time it was comparable to Xalatan and Timolol concomitant administration. And it is to be noted that Timolol was given twice a day in Timolol alone arm as well as the Xalatan and Timolol concomitant arm.

Based on this Phase-III study we have filed a product in India and we are trying to understand what is required to file this product in EU. For which we have planned a scientific advice in Q2FY14. We also plan to file this product in emerging markets.

Now, with this update on ophthalmic programs I will request my colleague Dr. Shravanti Bhowmik to give an update on the PICN program. Thank you.

**Dr. Shravanti Bhowmik :-** Thank you, Ajay. I am Shravanti Bhowmik from Clinical Research. We have in the past shared information with you on the Novel Paclitaxel formulation developed by SPARC using the nano technology. As you are aware this is a Cremophor and Albumin free formulation with the added advantage of a very simple infusion preparation method. A considerable amount of clinical trial data has been generated. We have conducted Phase-I clinical trials in India and USA and a Phase-II/III trial in India. Approximately 1,000 treatment cycles have been completed in 200 patients, majority with breast cancer and a few with other types of cancer. We saw that premedication was not required in these patients. There were no significant hypersensitivity reactions. Also, the adverse events were as expected with Paclitaxel. This data therefore validates our technology and product.

With this slide on efficacy, I share the final results of the completed Phase-II/III study in India in patients with breast cancer. A centralized assessment and analysis of imaging data from 130 patients was performed. As seen, the response in patients stated as objective response rate was similar in the PICN and Abraxane groups. The response in the 295 dose of PICN appears numerically better than the 260 dose of PICN and Abraxane. The percentage patients with stable disease and with disease progression are similar between the group.

Slide 13 shows you the adverse event profile. We all know that Paclitaxel is known to lead to severe Grade-3 and Grade-4 side effects. These side effects are the major reasons for patients not completing the recommended treatment. Improving treatment adherence may lead to better outcome. The most common side-effects are reduction in blood counts and effects on the nervous system such as peripheral neuropathy. The nano dispersion formulation is expected to improve the adverse event profile. The safety results from the Phase-II/III study show comparable side effect profile to Abraxane. Also, a low percentage of subjects developed side-effects with 260 PICN as compared with Abraxane. For the next step we intend to take the development process forward by sharing the efficacy and safety data with the US FDA and obtaining guidance on the clinical program required for registration. In India, we intend to seek an approval after submitting the data accrued till date. We also intend to expand the use of PICN in other indications and treatment regime. We are currently conducting Phase-I studies in combination with

Carboplatin. In another Phase-I trial we are administering PICN in a weekly dosing regimen. These Phase-I trials are currently ongoing in India and in the US.

With this I would like to hand over to Dr. Yash. Thank you.

**Dr. Yashoraj Zala :-** Thank you, Dr. Shravanti. My name is Yashoraj Zala and I will be sharing with you the update on SPARC's oral products and pipeline. Important products which I include in the update are Levetiracetam, Venlafaxine and Baclofen. I am on Slide #16. It describes Levetiracetam ER based on the Wrap Matrix. Since Levetiracetam is a drug which has very high solubility and has a very large dose, it is used in epilepsy and it has thus become an ideal candidate to be formulated using the SPARC oral control relief system Wrap Matrix. An acceptable size control release tablet of 1500 mg and 1000 mg was possible based on the Wrap Matrix technology. An NDA filing for Levetiracetam ER tablet for once a day administration was completed in Q1FY13. This product is protected by one granted and two allowable patents in the US.

We move over to Venlafaxine ER on Slide #17, which is another product under development. As we all know Venlafaxine is an antidepressant drug and it is available in control release dosage form in strength ranging from 37.5, 75, 150 and 225 mg. However, about 10% of the total prescriptions for Venlafaxine in the US are written for 300 mg. Thus, there existed a need to develop 300 mg Venlafaxine ER tablet which was achieved using the Wrap Matrix platform. An NDA for Venlafaxine ER 300 mg has thus been filed through the 505(b) (2) route and has been submitted to the USFDA.

As shared previously, we already have marketing approval for the lower strengths both in the US as well as in Europe. A few other products based on Wrap Matrix are in pipeline. One of them is a skeletal muscle relaxant with a very short half life and high water solubility. Thus this molecule too could be formulated easily using the once a day Wrap Matrix system. A possible advantage by using this system is that it has to be taken only once-a-day over the immediate relief dosage form which needs to be taken three times a day. An additional benefit which could be achieved would be the reduction of side effects. Currently, the pharmacokinetics studies are ongoing for this program and clinical studies have been planned.

Another product belonging to the CNS category is under development for a new indication. Proof-of-concept studies have been completed and further work is on.

On Slide#19, I move on to the next GRID technology and the product which is based on it, the Baclofen GRS. As you are aware, GRID is a gastric retention system of SPARC. Substantial progress has been made on Baclofen GRS which has been developed in six strengths. Strong patent protection is obtained through a number of patents. Three patents covering formulations, once-a-day therapy, indication of spasticity and reduced side-effects have been granted. This patent portfolio will help in protecting the product from generic competition when approved.

On the clinical front, Phase-III clinical trial in the US has been initiated. Currently, 20 sites have been activated and are actively recruiting patients. We are planning to increase the number of sites to speed up steady completion. Two additional clinical trials will be required for which work is ongoing. An additional interesting indication for Baclofen GRS, is the treatment for alcohol-dependents, has also been proposed. Treatment of alcohol-dependents is particularly challenging when the patient has to take medicines a number of times during the day because such patients are non-cooperative and need motivation to complete the treatment. Being a once-a-day product Baclofen GRS will be able to address this limitation. A clinical study has been completed in India and results are expected shortly. Further Phase-II studies are planned in Europe.

With this update i hand over now to Dr. C.T. Rao who will take you through the next part of the SPARC update. Thank you.

**Dr. C.T. Rao :-** Thank you Dr. Yash. I am Dr. C.T. Rao from medicinal chemistry and I have the pleasure in updating you on the status of our leading steroid NCE namely, SUN-597. Also, I will be discussing our new NCE in the respiratory therapy, namely SUN-L731 which is an LTD4-antagonist, which we are discussing for the first time. And I will also discuss our NCE in leukemia, namely SUN-736.

I refer to Slide #23. In our last meet with you we had disclosed that in Phase-I single dose escalating clinical study on SUN-597 there were no safety issues whatsoever even up to a single dose of 3200 micrograms. We have also completed the Phase-I multiple dose escalating study and we are happy to inform that SUN-597 was found to be safe and very well tolerated even up to the highest dose tested that is of 3200 micrograms per day for 14 days.

I now refer to Slide #24. With the encouraging data from Phase-I study randomized placebo controlled Phase-II clinical study was conducted to assess the efficacy and safety of SUN-597 in patients suffering

from Rhinitis. We are very delighted to share with you that SUN-597 demonstrated an encouraging efficacy in relieving nasal symptoms in all subjects at all dose levels in the study. In terms of safety, there were no concerns and there were no significant differences between SUN-597 and placebo. The efficacy of SUN-597 was good and was comparable to the reported clinical data for the marketed nasal steroids Fluticasone and Mometasone.

I now refer to Slide #25. If you take the clinical studies further on SUN-597 nasal a pre-IND meeting is planned with USFDA with a proposal for Phase-IIb study for identification of optimum dosage and dosing regimen. We intend to initiate the Phase-IIb study in Q3FY14.

I refer to Slide #30. Besides Rhinitis in preclinical studies on SUN-597 in diseased animal model, we have also studied its efficacy for Asthma indication. Lung Eosinophilia is one of the hallmarks of Asthma. In our studies in animal model involving Lung Eosinophil infiltration, pulmonary administration of SUN-597 reduces Lung Eosinophilia in a dose dependent manner. The effect being comparable to the marketed steroid Fluticasone. The study indicates the potential for SUN-597 inhalation for Asthma treatment also.

I refer to Slide #27. By the pulmonary route of administration we find that SUN-597 has good efficacy as we have seen earlier in the lung inflammation model. We have assessed the safety versus efficacy profile in the lung inflammation model and we find that SUN-597 has an excellent side-effect to efficacy profile. In fact, the safety index in this model for SUN-597 is about 22 times when compared to Fluticasone.

I am referring to Slide #28. Although the current inhale steroids are safer than oral steroids the concern for safety still exists when these drugs are used chronically in diseases like Asthma. This is because a portion of the inhaled drug is swallowed and is likely to be systemically absorbed through the GI tract. Besides, the inhaled portion of the drug may also be absorbed through the pulmonary route. The drug thus entering circulation could lead to both immunological and metabolic steroid side-effects. Our preclinical studies, both by the oral route and the pulmonary route of administration, indicate that SUN-597 has a much wider margin of safety with respect to undesired systemic side-effects and has an optimal efficacy in Asthma models when compared with the current marketed topical steroids for Asthma. The preclinical finding strongly encourages us to clinically develop SUN-597 inhalation for Asthma therapy.

I am now referring to Slide #29. We propose to conduct Phase-I clinical trials for SUN-597 inhalation which would include Phase-Ia, that is single dose escalating studies in healthy volunteers and Phase-Ib, that is multiple dose studies in mild Asthmatics to assess efficacy trend. The clinical trial application in this regard is planned in Q2FY14.

I refer to Slide #30. In line with our focus on treatments for respiratory disorders we have initiated a new program in developing new chemical entities that has cysteinyl Leukotriene antagonists or LTD4 antagonists which is an effective complementary therapy for mild Asthma and Rhinitis. In Asthma, cysteinly leukotrienes are implicated in airway edema, smooth muscle contraction and alteration in cellular activity associated with the inflammatory process. Besides, this mediator relieves from nasal mucosa after allergen exposure are associated with the symptoms of allergic Rhinitis. Cysteinyl Leukotriene receptor antagonists also known as LTD4 receptor antagonists are primarily used in alleviating the symptoms of Asthma and allergic Rhinitis. Montelukast of Merck is the leading drug in this class.

I refer to Slide #31. The desired attributes of a novel NCE in this class of drug are good potency in selectivity for the cysteinyl Leukotriene receptor, quick onset of action and lasting oral efficacy.

I am referring to Slide #32. Our candidate molecule being developed as a selective LTD4 antagonist, is SUN-L731 whose brief preclinical profile in both in-vitro and in-vivo is summarized in this slide. Besides, in animal models we find that SUN-L731 has desired attributes such as quick onset and long duration of action and a very good oral bioavailability.

I am on Slide #33. In animal model of LTD4 end use lung resistant SUNL731 was demonstrated to be superior in potency by about ten-fold when compared to the leading marketed drug Montelukast 24 hours post treatment, indicating potential for once a day dosing.

I am referring to Slide #34. Eosinophil infiltration into the lungs as we have said earlier is the hallmark of Asthma and our studies in animal models involving Eosinophil infiltration show that the oral administration of SUNL731 is quite efficacious in reducing Eosinophilia when compared to Montelukast.

I refer to Slide #35. We plan to file IND in India by Q1FY15 after completing the regulatory safety pharmacology and toxicology study for this molecule.

I am on Slide #36. In the last meet we had disclosed our molecule SUN-K706, a Bcr-Abl Tyrosine kinase inhibitor for the treatment of Chronic Myelogenous Leukemia (CML) which is a form of blood cancer and especially we were keen on targeting patients who are resistant to the currently available therapies. We had disclosed that in in-vitro assays SUN-K706 significantly inhibited not only the Abl kinase but also its important mutants, including the key mutant, namely the T315I mutant. Also, SUN-K706 displayed an excellent potency in cell-based assays. Currently, we have assessed the oral efficacy of SUN-K706 in mice leukemia tumor xenograft model. As we can see in this slide, SUN-K706 demonstrated superior efficacy and anti-tumor activity when compared with the approved second generation drugs namely Nilotinib and Dasatinib and also the third generation drug Ponatinib.

Please refer to Slide #37. Cardiac safety is one of the major concerns for drugs in this class. In this regard we have assessed SUN-K706 in-vitro for its binding to hERG potassium channel which is implicating cardiac safety. Its insignificant binding to this channel suggest that there is lack of potential for cardiac safety in SUN-K706. Besides, SUN-K706 did not inhibit any of the major cytochromes in-vitro indicating its lack of potential for drug-drug interactions.

I am on Slide #38. Further, we have assessed SUN-K706 for cardiovascular safety in Telemetered Beagle Dogs. Our animal study indicates that SUN-K706, even at a very high dose, did not show any significant effect on cardiovascular parameters such as heart rate, blood pressure and QT intervals.

I am referring to Slide #39. Dasatinib is one of the second generation therapy for CML has the issue of thrombocytopenia, that is decrease in platelet count. This can cause bruising and bleeding problems. We have assessed SUN-K706 for the side-effect in animals and we find that unlike Dasatinib, SUN-K706 has low potential for such side-effects.

I am on Slide #40. We also are currently studying SUN-K706 in animal models of leukemia including the T315I mutation. We are happy to inform that the initial results are very encouraging and we are seeing efficacy similar to Ponatinib. We shall update you of the results once the studies are completed.

Currently, we are in the process of optimizing the oral formulation for SUN-K706 and our plan is to file IND for clinical trials in India by Q3FY14.

Thank you. And with this I hand over to Dr. Bhowmik for discussing our NDDS projects.

**Dr. Subhas Bhowmik :-** Thank you Dr. Rao. I am pleased to update you on the three important products - Combitide Starhaler, Docetaxel injection DICN and Octreotide depo one-month injection.

I am referring to Slide #42. SPARC developed an innovative device for the delivery of dry powder into the lungs. Last time we briefed you about the various salient features of this device. Combined with this innovative powder formulation technology the device delivers a higher amount of the drug to the lungs and that reduces the dose to a level of 50% which could be a great advantage of steroid fairing and also long-term safety. Patients get an audible feedback like a whistle blowing. It is not a simple blowing. It actually indicates that the patients are able to activate the device and the drug depositions will be completed by another second.

I refer to Slide #43. The product was launched in India in Q3FY12. There were some functional issues that were addressed and field trials were conducted in more than 400 patients and based on these positive field trials we are happy to inform you that the product has been re-launch in March'13.

For US, this product will be filed through the 505(b)(2) route and we have completed the pre-IND meeting in Q4FY11 and we plan to file IND in Q4FY14. The EU scientific meeting for this product is scheduled for Q4FY14.

The next product we want to update is the docetaxel nano injection (DICN). I am referring to Slide #45. DICN is an extension of our platform nano technology. We avoid the use of any toxic excipients and nano particles are formed spontaneously upon dilution only. Higher exposure to tumor is observed in the preclinical animal model.

Slide#46 indicates that, in the Phase-I study we could inject 150 mg/$m^2$ dose which is 50% higher than docetaxel conventional injections. In this study we had not given any premedication like steroids and antihistamines which is otherwise required in any docetaxel conventional injection. Also, we did not observe any hypersensitivity in any patients in the study. So, based on the safety profiles of the product a clinical study is initiated in lung cancer patients as second line therapy.

I am referring to Slide#47. We plan to have a pre-IND meeting with FDA for lung cancer patients.

I now refer to Slide#48, which gives an update on Octreotide depot one month injection. SPARC has an expertise on Microsphere Technology. Based on the particle size and porosity, the drug will release uniformly throughout the month after injection. We have done one clinical study in acromegaly patient. And based on the study the product was launched in India. Currently, we are developing 3-months depot injection.

I am referring to Slide#49. We are planning to file the IND for this product in FY15.

With this I request my colleague Mr. Kirti to update further.

**Kirti Ganorkar :-** My name is Kirti Ganorkar. As informed to you by my colleague, we have made a significant progress in the development of NCEs and NDDS program. But as we go further we also need to do the commercial reassessment of some of these clinical programs due to the changing reimbursement environment. I am referring to Slide #51. As all of us know that the reimbursement environment in the US and Europe is changing. For the success of NCE and NDDS business, there are two key issues. One is we need to generate the IPs around the program and second is we need to have a right reimbursement strategy. For some of our NCE and NDDS programs we have been successful in generating the IPs. Now, we need to look at the reimbursement strategies. Some programs like SUN-1334H oral as well as ophthalmic have completed Phase-II studies. The pro-drug, B09, has completed Phase-I and G44 is into preclinical studies. Now, we are looking at this commercial reassessment based upon the changing reimbursement environment. What does this mean? This means that we will talk to the payers in the US and Europe and try to understand their mindset when such programs come to the market, what kind of price we will get. Secondly, we will also talk to the key open leader from the respective therapy areas to understand their views about this program. To all the investors, we will keep you updated as and when we complete the commercial assessment. And these programs for commercial assessments are listed on the Slide #51.

Slides #52 and #53 is basically summary of all SPARC NCE and NDDS programs. This we have already discussed with you. These two slides give you summary at a glance. Now, I request Mr. Dilip Shanghvi to take over the remaining part of the presentation

**Dilip Shanghvi :-** Thank you Kirti. My colleagues have briefed you about the progress that we have made with various projects that SPARC has worked over between last presentation and today's

presentation. And if I reflect and look back I have reasons to be happy and I have reasons where I feel that we could have done better or should have done better. As I have consistently shared with you, innovation is an iterative process and also for us it is a learning process. But if I summarize my overall feeling about what we have achieved in last 7-8 years that SPARC has been in business, I am very happy with the progress that we have made and let me share with you which key program and performances have met and cleared certain critical milestones.

We look at bringing to the US, two solid oral delivery system-based products based on SPARC technology, Levetiracetam and Venlafaxine. These products will have potential niche opportunity in a market in which the parent molecules have been genericized. However, our assessment is that there is a market which will justify developing these two products further. If I look at the progress that we have made with Latanoprost BAK-free product, this is a product which has an interesting opportunity in the US. More than 10% of the patients suffer from dry eyes who are also suffering from glaucoma. And even if we are able to address that subset of patient population, we see an important opportunity for our product. Baclofen GRS both for spasticity and alcohol de-addiction are important medical progresses and we should meet unmet patient needs even in a changing reimbursement environment. Paclitaxel nano dispersion has come out with a profile which is in line with what we were expecting and that program is progressing in-line with what my colleagues have shared with you. SUN-597 is an interesting product, in a market in which all other existing steroids have significant systemic side effects. It is safer product for both Rhinitis as well as for Asthma as an important place in the overall treatment.

Slide #55 is a summarization of the value proposition as I see in terms of SPARC and the various projects that are close to market, we have two products for which we have filed a NDA or are likely to be filed in first quarter of next year. Two products will go into proof of clinical efficacy, both SUN-597 as well as PICN. For the BAK-free ophthalmic solution, once we complete the Phase-III study and submit to FDA and await its approval. In the same way Baclofen GRS both for alcohol de-addiction as well as spasticity, as the trial progresses we will keep you updated. While all of these programs will involve a significant cost, in addition to getting the royalty for the other activities that SPARC has been doing in the past we see royalty also of Liposomal Doxorubicin, Levetiracetam and Venlafaxine in a way helping towards reducing the overall burn rate or potentially closing the gap between the burn rate and the cost of operation. We have completed the fund raising program where we have raised close to Rs. 200 crores and this money should hopefully help us in continuing to fund our investment for various studies going

through. So in a business which is very cost intensive and involves long-term projects, I think as a company we have progressed up to now with relatively low burn rates, have a significant basket of products to show as a result of our efforts. And if we look at a slightly longer term then SUN-706 with the kind of profile that we have seen in the preclinical studies, if we get validation of that in human studies then it can be a very interesting product once it comes to market. In the same way if we are able to see the same levels of safety index for our soft steroid project, it can be a significant improvement over current treatment. So this can be a significant upside but they can be seen as coming to market 3-4-5 years down the line. So they do not have any short-term cash flow possibility. But like in Sun Pharma, we have always focused on investing in short-term, medium-term and long-term businesses. Using the same philosophy I think we are constructing a product basket for SPARC which, while will continue in short-term and medium-term revenue, will create very large opportunity when some of the long-term projects come to market. So with this we finish our presentation to you and we are happy to respond to your questions. Thank you.

**Moderator :-** Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. The first question is from Manish Jain of Axis Holdings. Please go ahead.

**Manish Jain : -** My question is on Dry Powder Inhaler. Should Glaxo's Fluticasone plus Vilanterol combo come through; will it reduce the potential market opportunity for your dry powder inhaler combo of Fluticasone plus Salmeterol?

**Dilip Shanghvi : -** I think till we see the exact clinical data of the new Glaxo product it would be difficult to respond on what kind of label that product gets.

**Dr. Atul Raut :-** Basically, Glaxo product is being discussed by FDA and they had one public assessment meeting but that meeting has been rescheduled. That combination is of course Fluticasone Furoate and Vilanterol. So if we look as a therapeutic molecule or compound towards Fluticasone Furoate versus Fluticasone Propionate we have different data in different therapy areas. So right now it would be really difficult to predict or project what could be the market dynamics once that product comes to the market.

**Dilip Shanghvi :-** Manish, I think the other important issue for us to keep in mind is that even though Advair is approved for twice a day dosing, both prescription analysis as well as our interaction with specialists indicated that it is used quite extensively as a once a day product.

**Kirti Ganorkar :-** Once the patient is stabilized then it is also used as a once a day product. And another very important thing is there is a good experience with Advair with a large number of patients. So whenever we are interacting with the physicians they are very comfortable using Advair. So unless Vilanterol comes to the market and proves itself better than Advair, it is difficult to predict what kind of market share it will get.

**Dilip Shanghvi :-** And also if you see the other marker is that Fluticasone Furoate is already available as a nasal spray and Fluticasone Propionate has more than 65% market share compared to less than 5% market share for Fluticasone Furoate.

**Dr. Atul Raut** :- So overall when we compare Fluticasone Furoate with Propionate there is more familiarity in the patients as well as in doctors for the compound propionate.

**Manish Jain :-** And my second question is on Octreotide. Is there a threat from either oral Octreotide or Lanreotide?

**Dilip Shanghvi :-** I think we do not have a detailed analysis on preference of physicians. However, many indications if you see in specially the CNS area, the once a month product coming after once-a-day oral products have done quite well. So I think there would be a room for both, oral as well as once-a-month or once-a-three month injectable product. If it is a choice between once-a-day oral product and once-a-day injectable product then clearly once a day oral product will get a very large market share. But once-a-month I think there is a trade-off between compliance and convenience.

**Manish Jain :-** Just on Octreotide are you planning to develop it for cancer diagnostic purposes by combining with the radio-labeled indium by any chance?

**Dilip Shanghvi :-** No, that is not the plan.

**Moderator: -** Thank you. The next question is from Girish Bakhru of HSBC. Please go ahead.

**Girish Bakhru :-** First one is on the BAK-free Latanoprost, given that in the market we have seen some of the BAK-free formulations already coming. Allergan has something on Brimonidine platform and Alcon on some other platform. Any color on how those products have been seen by doctors and what are the markets there and where do you see your product fitting in, in terms of market size and market share?

**Dr. Atul Raut** :- The acceptance to BAK-free ophthalmic preparations is being widely increasing in the US and the Europe also. And if you see Alphagan B product, the original Alphagan 0.2% it was with BAK and all other subsequent products are BAK-free and they are using Duride. If you see the market share of Duride versus BAK containing products it has taken all over the market from the BAK. So as I mentioned the acceptance is widening worldwide.

**Kirti Ganorkar :-** And also there are a lot of publications against use of BKC in a chronic use. So that should also help us in getting a good market share for our product.

**Dr. Atul Raut :-** Because BAK in the literature it has reported that it has deleterious effects on corneal apical. So we anticipate that BAK-free product will be more beneficial for patients with dry eyes.

**Girish Bakhru :-** If you can also just give an idea of how is the Duride-based product different from yours, is there any particular superior advantage coming in that product?

**Dr. Ajay Khopade :-** Duride-based products contain oxidation kind of preservatives. As soon as they are put in the eye and any kind of bacterial ingress takes place it immediately kills the bacteria and therefore they preserve the whole ophthalmic formulation. At the same time, our formulation is a non-oxidating and an ionic kind of preservative which is quite safe, it kills the bacteria by fluidizing the bacterial membrane and it does not have the toxic effect on the corneal surface like any of the positive charged preservative.

**Girish Bakhru :-** Just moving to Baclofen, there are some companies with similar compound in pipeline like Intec Pharma and all. Any color on where they are vis-à-vis our product?

**Kirti Ganorkar :-** You are talking of XenoPort compound?

**Girish Bakhru :-** Intec Pharma has R Baclofen.

**Dr. Nitin Dharmadhikari :-** We believe is our program is much more ahead of all the programs.

**Girish Bakhru :-** Just lastly on the programs which have been put on commercial evaluation. If you can share how much money would you have spent in those programs? And if it is correct to assess would they be on complete hold from till you get some feedback from the key experts?

**Kirti Ganorkar :-** I do not have a number on how much money we have spent on each of these programs but what I try to say is that these are the programs which had achieved some clinical milestones, like SUN-1334H oral also was effective, even eye drop was also effective at stage. But in today's environment where the reimbursement and the pricing strategies are changing we are relooking whether we need to develop this program and whether they will give us some differentiating point from the commercially available products. That is the key. And we are not stopping this program at this moment. But the commercial assessment is continuing in parallel to the development of the program. And once the commercial assessment is completed once again we will update you on what is the next action plan.

**Moderator:-**Thank you. The next question is from Sameer Baisiwala from Morgan Stanley. Please go ahead.

**Sameer Baisiwala :-** First question is on Levetiracetam XL, you filed this NDA first quarter of fiscal '13. How has been a dialogue going on with the FDA and when do you expect the approval to come through?

**Management:-** Dialogue is quite positive and in the next few months we expect the approval.

**Sameer Baisiwala :-** And both for this product as well as for Venlafexine ER 300 mg, what could be the marketing efforts that would be required and would this need a specific detailing to the doctors or can you do it otherwise?

**Dilip Shanghvi :-** Both these program, Levetiracetam ER and Venlafexine ER, will need to be promoted to doctors under a trademark or a brand name because these are not a generic substitute of existing products. So SPARC is looking at various options and identifying a partner with whom they were for commercialization of this program. And that activity is already going on. And we will need some time to tell you like which partner SPARC has selected for which program.

**Sameer Baisiwala :-** Just one more question on Levetiracetam, if I am not wrong the pricing between the brand and a generic which is available, there is a huge gap or a huge premium attached to it. If I have got my numbers right, I think on a per month therapy basis assuming 2000 mg dosing per day it probably works out to about $50 maybe less for a generic product and about $500-600 if one is using

the innovator product. Are these numbers correct? And if yes, what could be SPARC's pricing strategy for this product?

**Kirti Ganorkar :-** When you are comparing yourself with R&D and generic this number would be correct because I do not have an exact number in front of me but what you are saying it would be in the range of 500 to 50. What SPARC is trying to work with the partner who will work out on a commercial strategy. So whether our product can be priced closer to 500 or closer to 50 is what the commercial strategy will decide depending on what market share we want to get. But what we are offering is a convenience benefit. And for convenience we cannot get a very high price but at the same time we will get a price better than the generic.

**Dilip Shanghvi :-** If you look at Venlafexine ER, then UCB marketed a 225 mg Venlafaxine ER for a while till there were generics and it continues to maintain a significant share of 225mg prescriptions because of the convenience of one tablet over two tablets. And in the same way if we look at the prescription on 300 mg in the country, the numbers are comparable. So there are opportunities that we see will allow us to leverage the convenience and compliance because especially in case of epilepsy as well as in case of depression poly therapy or multidrug therapy is quite common. So there is a significant element of pill burden. So doctors would prefer to reduce the frequency as well as the number of tablets the patient takes. These are our preliminary assessments of the market opportunities.

**Sameer Baisiwala :-** I do not want to belay too much on this point but the fact is that even Levetiracetam has 500 mg and 750 mg ER forms available in the market and if I just look at not the value but just prescription that does not seem to have an awful lot of switch that has happened. So therefore I think the price becomes quite critical despite there being an unmet demand. We are not seeing a huge volume switch.

**Dilip Shanghvi :-** Sure, I think as you rightly say we do not want to reflect too much on one product but we are sharing with you our view. Maybe we have to wait for a few months to allow so that we have a greater clarity.

**Moderator :-** Thank you. The next question is from Khyati Thakrar of MP Advisors. Please go ahead.

**Khyati Thakrar :-** Actually I would like to know the market about SUN-706. So it is for the T315I mutation patients which are currently on available oral drugs like Glivec. So how what percentage of patients develop such kind of mutation?

**Narendra Lakkad :-** As of now the data from USA is that some 300 patients are annually diagnosed but the diagnosis is still not a very standard practice. So maybe we will have a greater clarity over a period of time.

**Khyati Thakrar :-** How much percentage of patients you believe that are getting registered for CML?

**Management :-** Annually, some 5000 new patients are diagnosed in US with CML and over a period of time when they start taking Kinase inhibitors over a period of two to four years they start developing resistance. Now for resistance there are several types of mutations that may occur. And T315I is a mutation for which as of now there is no drug except this newly approved Ponatinib which is being active.

**Khyati Thakrar :-** Out of this 5000 can we say roughly 50% or 30% develop resistance?

**Dilip Shanghvi :-** We do not have exact details I think to respond to this with information which we do not have would not be fair but our product I think we are focused on its ability to act on T315I mutation but I think it also works across various other known mutations. It is not that that it works only against T315I mutation. So to that extent it addresses a much larger market and it will also address markets where nothing else works.

**Khyati Thakrar :-** And my last question is based on in vitro study, it is binding potency to which Kinase if you would just put some light on that, it is a Tyrosine Kinase but particular oncogenic BCR ABL gene or which kind of binding potency towards which kind of Kinase originally is this?

**Dr. C T Rao :-** Unlike Ponatinib which is T315I BCR ABL and also Pan BCR ABL Kinase, it is active on several Kinases, our molecule is more specific and it is more specific to BCR ABL and its mutants, so we see less potential for side effects.

**Moderator :-** Thank you. Our next question is from Nimish Mehta of Research Delta Advisers. Please go ahead.

**Nimish Mehta :-** If it can throw some light on the trials that you are conducting on product named Goserelin Acetate intramuscular depot injection, I think it was not covered?

**Dilip Shanghvi :-** Which product you are saying?

**Nimish Mehta :-** I think it is the generic version of Zoladex that is Goserelin Acetate.

**Dilip Shanghvi :-** No, we're not working on Goserelin Acetate, that information is not correct.

**Nimish Mehta :-** I saw it on the clinical trial website which is why this question it mentions, it is being compared against the subcutaneous version of Zoladex, so just curious to know?

**Dilip Shanghvi :-** No, I do not think we have filed anything.

**Moderator :-** Next question is from Nirav Shah of Harmony Capital. Please go ahead.

**Nirav Shah :-** My question pertains to the royalty and milestone payments mentioned in the slide, to the best of our knowledge SPARC is not getting any revenues from Doxorubicin sales of Sun Pharma in USA and what are the corrective measures you are planning to fast forward either product approvals cycle or monetization cycle, generally to bridge the burn rate in the cash flow?

**Dilip Shanghvi :-** our observation is correct whatever Sun has sold till now in the US there is no royalty payment to SPARC but once Sun starts selling approved products, which is generic of Doxil which we have already started, SPARC will get a milestone as well as royalty payment.

**Nirav Shah :-** Can you care to elaborate on the terms?

**Dilip Shanghvi :-** No, I think generally it is in line with the industry terms of products close to market and it will be in line with those terms.

**Nirav Shah :-** And just across the portfolio level what are the product corrective measures one can take to fast forward the product approval cycle or to prepone the monetization because of the burn rate which you have mentioned about?

**Dilip Shanghvi :-** I think it is like a child growing, you cannot find a way to short-circuit that time which is required for development of products, so there is a certain gestation period, you can develop some product which have low potential but a shorter gestation period, so they will help you reduce your burn rate.

**Nirav Shah :-** You anticipate further funding from the shareholders going ahead?

**Dilip Shanghvi :-** I would like to find a way to not raise any more money but if that is required then we may have to.

**Moderator :-** We have the next question from Kartik Mehta from ICICI Securities. Please go ahead.

**Kartik Mehta :-** On the inhaler to be launched in India, are there any extra costs on the training or in terms of the promotion of the product that you envisage?

**Dilip Shanghvi :-** For SPARC you are saying?

**Kartik Mehta :-** No, actually for Sun to get more market share, there will be some amount of royalty or milestone with that will be earned by SPARC on the market share that is received by Sun, so now that we're re-launching it, is the cost of relaunching also to be shared by SPARC?

**Dilip Shanghvi :-** No, I think it is Sun's responsibility.

**Kartik Mehta :-** Will Rs. 200 crores would be enough for the next two or three years on the opportunities that are disclosed on this call and if any additional rights issue is actually required, would it be on account of taking the product ahead or actually entering more cost on actually marketing the NDAs?

**Kartik Mehta :-** We have three products, so we have two NDAs filed and we'll be filing one can actually in Q2 FY14 and there are several products which are there where we will need to incur an overall cost for the patients, etc. Is Rs. 200 crores enough for taking all the existing products ahead or will there be any new opportunities where-in extra funding would be required at that point of time?

**Dilip Shanghvi :-** Your question is whether we will be able to bring all the products that we have discussed with investors in this presentation to market based on money that we have raised?

**Kartik Mehta :-** And also adding all the royalty that we would have actually receive on the three products?

**Dilip Shanghvi :-** I understand, so the royalty plus money we have whether that is enough to pay for all the clinical development, the answer is no. It also depends on at which stage we license some out the products to someone so that we can then reduce the extent of our burn rate, so if we decide to develop all the products all the way up to the market then we do not have enough money even if we look at royalty and the money we have. If we license out early in the development than depending upon it which stage we license out will determine whether we need to raise money or not. Generally we have looked at our ability to find the high returns for shareholders carrying a large amount of risk for a longer period of time as an approach.

**Kartik Mehta :-** And would it be fair to assume that all the NDAs would be sold by Sun Pharma or can there be any other option also available?

**Dilip Shanghvi :-** I think you should not assume that everything will be sold by Sun Pharma. Sun has a right of refusal for emerging markets but other than that you should not presume that any of these products will be marketed by Sun.

**Moderator :-** Next question is from Krish Shanbhag of Wodehouse Capital. Please go ahead.

**Krish Shanbhag :-** My question is on Starhaler DPI. Which countries have you done clinical trials using Starhaler besides India and if so what is the minimum patient size and cost for each of these markets?

**Kirti Ganorkar :-** We have done Phase-III studies in India and now we plan to do a clinical study in Europe as well as in the emerging markets, so in some of the emerging markets like Russia we are talking about a clinical study in the range of about 200 patients for approval. And of course in Europe the study size would be bigger and they require an approval of about two Phase-III studies with the size of 500 patients each.

**Krish Shanbhag :-** And what is the cost for each of these markets?

**Kirti Ganorkar :-** It is difficult to give you the cost for development because it depends on a lot of things like what I am telling is an approximate number but once we have protocol details and discussions with the agencies then we will be in a better position to give the cost.

**Krish Shanbhag :-** The other question is on what we understand is that China needs customized clinical trials for again the Starhaler DPI, so the question is will SPARC bear the cost of this trial or will it be the Merck-Sun JV?

**Dilip Shanghvi :-** We do not know. We have not shared anything about Merck-Sun JV products, so difficult to respond but your assessment as to what is required for China, I think China has specific requirements for approval of product both DPI or other products and regulatory processes are different from other markets that we are working in.

**Krish Shanbhag :-** Is there any requirement that manufacturing of DPI has to be done in these markets like you have to do it in China or any of these other targeted markets?

**Dilip Shanghvi :-** No, I do not think so because Glaxo and all other people export their ready to use devices to these markets.

**Krish Shanbhag :-** Do you think that SPARC has taken much longer than its own targets to get into the US market and if so is there anything that is that you can do at your end to improve your revenues going forward?

**Dilip Shanghvi :-** I said that in the beginning is that if we know that today when we started we would do a few things differently and we would do a few things the way we have done in the past and the result would have been that maybe some of the projects would have moved faster but also some of the promises that we initiated we would not have made because we under estimated the complexity and the time required by some of the studies and expectations of the regulators. So there would have been many differences and many similarities.

**Moderator :-** Thank you. Our next question is from Samit Vartak of Ascent Capital. Please go ahead.

**Samit Vartak :-** My first question is on Starhaler DPI. Do you have any sense of what is the commercial opportunity for this product in the major markets, India, emerging markets, Europe, USA and Japan?

**Dilip Shanghvi :-** I think commercial assessment without understanding regulatory challenges has very little value. I can tell you that it can be a $300 million product for US but it does not help in any way if let us say the cost of study would be $150 million and time taken will be six years. So I think we have to evaluate the context of markets and studies in the context of what is the complexity of each market.

**Samit Vartak** :- Any sense on what is the timeline for getting the approvals in each of these markets for getting it commercial?

**Kirti Ganorkar :-** As we have said earlier like we have now begun some trials in the emerging market as well as Europe and giving specific time for product registration is very difficult.

**Samit Vartak** :- And is Starhaler DPI applicable for multiple products? How many products do you plan to use it to?

**Dilip Shanghvi :-** No, the basic platform is capable of handling other drugs but it will need to be adopted, the device as it is well not be able to handle anything other than the existing product.

**Samit Vartak** :- One last quick question on Baclofen, especially on anti-alcoholism, what is the commercial opportunity there in the US and the non-US markets or it is the same as Starhaler?

**Dilip Shanghvi :-** No, I think that is much less challenging but we have to see how good it is and also how it will compare it with other drugs which are also under development for alcohol de-addiction. There are other few other products also which are in Phase-II, Phase-III clinical development for alcohol de-addiction, so how it compares with them we will get clarity once we have our data.

**Moderator :-** Thank you. Our next question is from Parin Gala from Gandhi Securities. Please go ahead.

**Parin Gala :-** So my question is relating to the Sun-Merck JV, what has been the key learning from the Merck relationship till date and when will the JV have its first product launch in the markets?

**Dilip Shanghvi :-** I think we cannot give any clarity unless and until it is given by both the partners, it is a JV relationship, we need to share information together, both the companies remain excited about the relationship and we keep on continuing to increase our involvement and investments in the relationship.

**Parin Gala :-** The next one is the patent life of your product is getting shortened with the delay in the US launch, so what is the strategy of protecting the commercial patent life of the product?

**Dilip Shanghvi :-** No, there are many regulations which allow you to recover the number of days that you have lost in terms of clinical development so if you study that I think you will have a greater clarity.

**Parin Gala :-** On the larger thing, is there a leadership change that is required just in the R&D to achieve the true potential of the company?

**Dilip Shanghvi :-** I don't know what you mean because the leadership is what has delivered and what it is till now.

**Moderator :-** Thank you. Our next question is from Anubhav Agarwal of Credit Suisse. Please go ahead.

**Anubhav Agarwal :-** I actually could not understand that when you mentioned that SPARC was not earlier getting the royalty on Liposomal Doxorubicin but now it is getting it, what is the technicality here, just getting the product approval? How does it work?

**Dilip Shanghvi :-** It works because many proprieties tools and techniques developed by SPARC were used for getting the product is approved. The Lipodox was marketed in India, it was a product which was of Sun Pharma, but to get it approved the amount of work required a significant level of SPARC involvement for ensuring that consistency and reproducibility of the process is shared with the US FDA.

**Anubhav Agarwal :-** Just to understand it better, so the technology, Liposomal, that is not SPARC technology, that is basically Sun Pharma's technology?

**Dilip Shanghvi :-** No, I mean the product which will currently go to market in the US involves many-many changes and those changes have happened over a period of time with SPARC involvement.

**Anubhav Agarwal :-** My confusion is when you were selling this product in the US before you got the formal approval in February 2013, is there difference in the product before your selling it February '13 and after February '13?

**Dilip Shanghvi :-** No, there is no difference in the product that was sold as well as the product being sold now, the product remains the same. The approval process and also the complete automation of the process so that it meets GMP and other requirements required significant involvement of SPARC for achieving that level of performance.

**Anubhav Agarwal :-** And the royalty and milestone on this product will be similar to any let's say other product, I mean to ask that, let's say if any product of similar market size and of similar competition, royalty and milestone for this product will be very similar to other products as well?

**Dilip Shanghvi :-** But we also have to factor that this is a generic product. It is not an innovative product with patent protection. So I don't think you can do any comparison and we are not sharing specific royalty, I think as we continue to report quarter after quarter you will get clarity about how much royalty SPARC will get.

**Moderator :-** Thank you. Our next question is from Krishna Prasad of Kotak Securities. Please go ahead.

**Krishna Prasad :-** You have commented on Sun's right to refusal and just to clarify Sun would have the first right of refusal on all products in all markets for SPARC products?

**Dilip Shanghvi :-** No, what I said is for emerging markets.

**Krishna Prasad :-** And as far as the regulated market is concerned Sun does not have the first right of refusal?

**Dilip Shanghvi :-** That is correct.

**Krishna Prasad :-** And SPARC would independently assess what is best for SPARC and therefore from the partnerships?

**Dilip Shanghvi :-** That is correct.

**Krishna Prasad :-** Just to follow on and therefore for Levetiracetam and Venlafaxine, would it be possible to say at this point whether, would Sun be one of the partners or is that not on the scheme of things?

**Kirti Ganorkar :-** SPARC is looking at various options which also include Sun as one of the partners here.

**Krishna Prasad: -** But I'm considering the use of the field force to promote these products, is that the consideration as well?

**Dilip Shanghvi :-** Yeah, that is the main consideration.

**Moderator :-** Thank you. Our next question is from Sachin Kasera of Lucky Investment Managers. Please go ahead.

**Sachin Kasera :-** It has been six years since we started SPARC, are you happy with the progress that you had made in terms of timelines especially on the non-NCE portfolio or do you believe that from what you had envisaged six years back, the timelines have taken longer?

**Dilip Shanghvi :-** I'm never happy with what I have achieved even in Sun I remain very unhappy with many things that we could have achieved and we have not and the same is I think is my mindset about SPARC. If I look at what we have learned over the last six years in running SPARC, I think I'm very excited and happy and if we continue the same rate of development, I think we will become a very successful innovation-based company.

**Sachin Kasera :-** What is the marketing turn for PICN as you are going to have separate field force or existing field force for market and if something on royalty also, if you can give some clarity?

**Kirti Ganorkar :-** We are filing PICN in India where Sun Pharma is the partner with SPARC and for other markets we still have a long way to go because we need to understand the regulatory requirements in the US and Europe market and royalty and the revenue depends on what kind of label we get and what kind of reimbursement price we will get so currently we are talking of only launching it in India.

**Sachin Kasera :-** What would be the current market size in India?

**Dilip Shanghvi :-** My understanding is Abraxane is selling around $5 million in India.

**Moderator :-** Thank you. Our next question is from Ketan Gandhi of Gandhi Securities. Please go ahead.

**Ketan Gandhi :-** This DICN can be ahead of PICN in US clinical trials and what are the factors that can determine this aspect?

**Kirti Ganorkar :-** No, DICN is into Phase-I and Phase-IB and PICN has already completed Phase-II/Phase-III in India, so PICN will be much ahead of DICN.

**Ketan Gandhi :-** Regarding Levetiracetam, what kind of sales force is required for this product and when you will be starting the hiring?

**Kirti Ganorkar :-** No, I think, let me clarify, we are not saying that SPARC will have sales force or SPARC will hire you for promotion. SPARC is looking at an option of partnering with the company who had a sales force or who may not have sales force and they want to set up their own sales force. So these are some of the options. Today we do not know exactly how many medical reps are required for promoting this product in the US.

**Ketan Gandhi :-** Last month you have said in the regulatory filing that there is a change in plans for right's issue proceeds, I just wanted to know what is that?

**Dilip Shanghvi :-** I think that would reflect as Kirti would have said that we are re-evaluating some of the product development plans in the context of the changed regulatory reimbursement environment.

**Ketan Gandhi :-** Last question is regarding Baclofen, if XenoPort does Phase-II-III-IV for spasticity in Horizant can we have effect on our product?

**Dr. Nitin Dharmadhikari :-** I think, XenoPort is a BD product that's what I understand and our product is an OD product, once a day product so that is the difference.

**Moderator :-** Thank you. Our next question is from Chirag Talati of Espirito Santo. Please go ahead.

**Chirag Talati :-** On Octreotide what is the rational going for 505(b)(2), do you think there is no possibility of any ANDA road emerging for the depot formulation and secondly in light of Pasireotide Phase-III data how do you see Octreotide depot being positioned in the market?

**Dilip Shanghvi :-** We cannot file the ANDA because it is a different polymer, so it will have to be a 505(b)(2).

**Chirag Talati :-** How do you see that product being positioned if Novartis manages to get Pasireotide LAR approval in due course?

**Dilip Shanghvi :-** We see a role for continued use of Octreotide even if the new Novartis product gets approved.

**Moderator :-** Thank you. Our next question is from Sameer Baisiwala of Morgan Stanley. Please go ahead.

**Sameer Baisiwala :-** Just a question on Starhaler, are Mylan and Teva ahead of us in getting the generic form into the market and I understand the product is going to be quite different between the three of them?

**Dilip Shanghvi :-** Yeah, my understanding that at least Mylan is working towards getting approval as a substitutable generic product whereas our product will require a 505(b)(2) non-substitutable approval but we will have a significant benefit in terms of convenience and as well as in terms of low dose of steroid usage.

**Sameer Baisiwala :-** I think, Kirti mentioned somewhere in the call that it is very hard to quantify the development time that this product will take but I will just try yet again. Assuming that end of 2014 is where you have a pre-IND meeting with FDA, assuming all goes well, what could be the clinical development time on this product, I'm asking this because this looks the most interesting candidate in the whole portfolio?

**Kirti Ganorkar :-** Yeah, it is very broadly like we need to do two Phase-III studies with a large size like I said, which involves like more than 500 to 600 patients and Asthma studies are long-term studies. You are asking about Starhaler, right?

**Sameer Baisiwala :-** Absolutely yes.

**Dilip Shanghvi :-** I don't first of all agree with your assessment that it is the most interesting product.

**Sameer Baisiwala :-** Which one you think is the most interesting?

**Dilip Shanghvi :-** I personally find that we have many exciting products so I don't want to specify one or two of them but I think if you look at PICN and if you look at Octreotide long-acting product, if you look at potential for Baclofen GRS once which comes to market these are all very exciting products and each of them can become very attractive and comparatively low competition product.

**Sameer Baisiwala :-** Just a question on Latanoprost and Timolol combination, I think you talked that, you are exploring options for Europe, you did not say much on the US?

**Dr. Atul Raut :-** Yeah because looking at the regulatory environment in the US for fixed dose combinations specifically ophthalmic, if we see that from the last combination that is Combigan, there is no approved FDC in the US and all the companies who are pursuing that they halted that program because it is the biggest challenge to meet regulatory requirements in the US and based

on past experience if you see like last 10 or 11 years with the FDA approvals, we don't think that at this point we can prioritize that program for US.

**Sameer Baisiwala :-** Levetiracetam and Venlafaxine, talking to the innovator like UCB marketed the product, was that an option at all because I would imagine it is the win-win situation for both the companies?

**Kirti Ganorkar :-** That is one of the option we are considering.

**Moderator :-** Our next follow up question is from Chirag Talati of Espirito Santo. Please go ahead.

**Chirag Talati** :- Just want to understand the overall landscape for these extended release oral products in the US market. I mean, we have seen a lot of the product technologies like we may say an OROS or Geoclock technology you are seeing a lot of generic competition appearing before the patents are well set to expire, so within that landscape, how do you foresee the Wrap and Grid technology to kind of differentiate or stand out in the emerging generic competition or what would be the life of such a product?

**Dr. Nitin Dharmadhikari :-** You mentioned about OROS and Geoclock or Geomatrix technology, I think OROS is already off patented and the bi layer OROS is almost coming out, so if you look at the Wrap Matrix, it will have a patent up to 2000 something like that.

**Dilip Shanghvi :-** He is saying that how do you see that your product does not get competition? How do you protect that from a generic competition?

**Dr. Nitin Dharmadhikari :-** Our product is not only protected by the patents but also it is protected by the formulation technologies and not only the formulation technologies but how the formulation technology behaves in the bodies so that you create a very different pharmacokinetic profile which is difficult to copy so that can be one strategy and which I believe Wrap matrix is capable of. Another thing is creating a strong IP like we created for Baclofen, a strong IP where the indication is patented as well as the side effect profile is patented, so these technologies are used to give those advantages to the patients so that kind of a patentic activity we can take up, so these are the strategies, how we protect your product from the generic competition.

**Dilip Shanghvi :-** Ultimately I think of formulation which is difficult to mimic for a generic company to file will give you protection from being filed and then subsequently your portfolio of patent will help you in protecting your continued market.

**Chirag Talati :-** But conceptually in your observation do you think that the life average for such products over the past five years or seven years has gone down?

**Dilip Shanghvi :-** Yes, I mean, if you say that from generic products getting filed after introduction of product then clearly that is gone down. Some of the products are able to protect the exclusivity over a longer period of time and as we learn more this learning will help us in devising an appropriate strategy to extend the exclusivity period.

**Chirag Talati** :- Just one question on any potential generic products that come out of the SPARC table, is there a possibility of actually a profit share being there with Sun or any other partner or it just works to a straightforward royalty model?

**Kirti Ganorkar :-** No, we have only one or two examples where the generic product has come through SPARC technologies and where we have only given a royalty, there is no profit sharing.

**Moderator :-** Thank you. We will take the next question from Manish Jain of Axis Holdings. Please go ahead.

**Manish Jain :-** I just need a clarification, I had seen that for a combination Latanoprost and Timolol the way you were mentioning, Bosch & Lomb has started a Phase-III drug for a combo in February this year and they are doing trials on 800 patients which will get over by May 2015, so this question was in relation to that?

**Dilip Shanghvi :-** Which drug is this Manish?

**Manish Jain :-** I don't remember of-hand.

**Dilip Shanghvi :-** I think our view is not that it is not possible to register any combination product. Our view is that in case of Latanoprost and Timolol, it will be very difficult to meet the FDA expectation for approval in terms of various time points and reductions and clinical outcome that

FDA is looking for. It is possible for one to develop combination product, if it is for Glaucoma than it is also possible to meet these time points as long as products are different and they have a different profile.

**Management :-** Manish, Xalacom was not approved in the US.

**Management :-** Xalacom and some other products, all these products are approved in Europe and not in US.

**Manish Jain :-** And on Latanoprost you all had mentioned in one of your speeches Dilip, that it had not met few criteria in the clinical protocol, this was way 6-7 months back, so if you could just throw some light on those aspects and how those have been taken care of when you are contemplating filing of them in NDA?

**Dr. Atul Raut** :- So that was our preliminary analysis and there are different ways to look at data and different companies present it in different ways and we kind of discussed the data from all the aspects from FDA and then we got a feedback that in particular way our data can be submitted as an NDA. So actually there is nothing, no change in the data by the way of the analyses FDA accepts different ways, so that was just a preliminary observation what we said few months back but after relooking at data we came to conclusion that it can be submitted.

**Manish Jain :-** So will you start looking for a partner once you file your NDA or have you already started that process?

**Kirti Ganorkar :-** We have started that process already.

**Moderator :-** Ladies and gentlemen due to time constraint that was our last question. I would now like to hand over the floor back to Mr. Nimish Desai for closing comments.

**Nimish Desai** :- Thank you everybody for joining us on this call. If any of your questions have remained unanswered, we would request them to send it to our IR desk and we will have them answered.

**Moderator :-** Thank you very much sir. Ladies and gentlemen on behalf of SPARC that concludes this conference call.