"Sun Pharma Advanced Research Company Ltd. (SPARC)

Transcript of Investor Call held on January 06, 2024 Update on PROSEEK Program"

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Moderator: Ladies and gentlemen, good day and welcome to SPARC Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing star, then zero on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Jaydeep Issrani. Thank you and over to you, sir.

Jaydeep Issrani: Thank you, Michelle. Good evening, ladies and gentlemen. My name is Jaydeep Issrani, I head the Business Development and Investor Relations at SPARC. On behalf of SPARC, I welcome you to today's call and appreciate you for taking the time out on a Saturday evening to attend the call.

I'm joined by our CEO, Mr. Anil Raghavan and the senior management team at SPARC.

Anil will walk you through the presentation, which we have shared earlier. And after his presentation, we will open the call for questions.

Before we start, I would like to remind you that our discussion today includes forward-looking statements that are subject to risks and uncertainties associated with our business, hence the actual results may be different from those projected in the presentation today. I will now hand it over to Mr. Anil Raghavan for his presentation. Over to you, Anil.

Anil Raghavan: Thank you, Jaydeep. Good evening, everybody. Good morning or good afternoon if you are joining internationally. Thank you for taking this call on short notice.

I have four key objectives for this call. I wanted to provide an update on the Vodobatinib Program. I want to set up our immediate priorities going in 2025-2025 financial year for Vodobatinib particularly after the data events that we're expecting. And also want to provide some perspective in terms of how to look at this program in balanced way. We've spoken about the opportunity

extensively in our investor call earlier this year. Also, want to give a sense of some of the risks in the program that are or customary to this kind of programs. Finally, and probably most importantly, this is an opportunity to answer any questions that you may have before we go into a quiet period on the interim analysis.

So, with that, let's move to Slide 3. We have a recap of the status of the program. We have touched upon some of this in our earlier call. Vodobatinib PoC program, it's called PROSEEK completed its enrollment target last year around October of 2023. Our target was 506 evaluable patients, we ended up with 513 patients globally. And the interim analysis as communicated earlier is planned with 85%- 86% of patients. That's the enrollment cut off was May of 2023. So, we have 441 patients going into this interim analysis and that is planned for late March-early April of 2024. As we communicated earlier, the broader organization will be blinded, not just a broader organization, the external ecosystem or investigators and others who are participating in the trial will also be blinded because we'll still have around 70-odd patients in different stages of treatment and protecting the integrity of status in those patients is an important consideration for the trial and also for the regulators in different countries. In that sense, we are committed to maintaining the blind and protecting this information to ensure that we don't induce unnecessary bias in conduct of the trial.

The design of the program we have covered that in many earlier conversations, but just to give a very brief overview, it has two doses of Vodobatinib 168 patients in each arm 384 mg on the top dose and 192 mg on the lower dose against the placebo arm. As we have spoken about in the past, MDS-UPDRS Part-III is the primary endpoint. We have a host of secondary endpoints and biomarkers which are mostly exploratory. And the study also has Part-II long-term extension study, where patients are on the drug for another forty weeks, that's roughly around 10-months. So, the patients on Part-A and Part-B combined are for almost 80-weeks and those patients go through this 80-weeks period without any symptomatic therapy. So, that's the

design of the program and I have already talked about some of the milestones like interim analysis in April. The full top line data for PROSEEK is expected in August-September of 2024, that's when we will have full disclosure on the data.

Now, moving on to the next slide, has a listing of our near-term priorities post availability of data from PROSEEK. The primary objective in 2024-25 financial year is to ensure that we move on to the next phase of development without a phase lag if we're fortunate to have positive data in line with expectations of the hypothesis. That requires several steps, most importantly, an agreement with the regulatory agencies globally in terms of the nature of registrational studies required. So, that would happen during the end of Phase-II consultations with USFDA and other important regulatory agencies globally. And we hope to do that in short order after the August-September data readout.

And in parallel, we will be continuing the long-term extension study of PROSEEK. And as soon as we have clarity in terms of the nature of the registrational studies required, we hope to initiate the pivotal Phase-III programs globally and our strategic intent would be to minimize that lag between end of Phase-II and initiation of Phase-III. And we will also be using this time right from the availability of interim analysis data to explore and execute a partnering strategy so that as we move into late stage development post PROSEEK we can do that with a partner who we may be going with for commercialization of the asset.

And as I said, the regulatory agreement is an important element in triggering this and it is not just about additional clinical studies required, we may also require additional pre-clinical studies, particularly toxicity studies, and also additional steps to be taken for ensuring manufacturing our business, particularly given the size and potential of this drug.

So, let's go to the next slide, when we met you in the last quarter of 2023 for our annual investor's update, we have spoken extensively about the program,

the potential of the hypothesis and its implications on the standard-of-care in Parkinson's disease and also more broadly about the possibilities of diseases driven by alpha synuclein and in the outer rung of possibility, diseases that are driven by other proteins impacted by oxidative stress and Abl-linked activation.

We have spoken about the opportunity clearly. We thought that it is important given some of the communication and coverage that we are seeing on this drug and recently it's important to also highlight some of the risks which are inherent in programs like these, especially in translation programs in neuroscience. So, we want to highlight three-four major risks that you may want to keep in mind as you kind of think about these programs.

One is the translatability of animal models in diseases like this which we have seen. These animal models built with intent to mimic the underlying mechanism and create the manifestation of disease which can be addressed with the drug. While they are fine from a science standpoint, their true validation will come, when programs which are developed with these models go on to clinic and get validating clinical data and go into market.

In diseases like Parkinson's, we haven't seen significant clinical translation in the long-term, especially in disease-modifying therapies which are designed to bend the neurodegenerative arc. So, we are one of the early companies which is trying to translate the oxidative stress pathway and therefore these models carry a certain level of risk and it is important to keep that in mind as you evaluate this program.

A couple of other risks that I want to highlight:

One is about target engagement and dose. If you've been following this program, we have used the top dose in our animal model that is 45 mpk as a marker for deciding our dose for the Phase-II clinical program. The max brain exposure associated with the top dose in animal studies which is the most efficacious dose in animal study. And in early clinical studies, we matched that

exposure in Parkinson's patients CSF, which we believe is a good proxy for levels in the brain. So even though the translation process is sound, this field clearly lacks a target engagement marker because we cannot open the brain and see what happens. So, there are challenges in terms of clearly getting appropriate doses in humans. So, there is a certain level of approximation that is done by extrapolating animal data that may create certain level of risk which needs to be factored in.

The third point that I want to highlight is the reproducibility of early clinical proof-of-concept studies as you think about repeating dose results in later stage clinical setting. And typically, if you look at companies which are doing early proof-of-concept studies and they're more smaller pilot studies and much of this risk comes from inadequate powering of early studies. And that we have tried to address some of that in the design of the PROSEEK trial. PROSEEK is the Phase-II program. It is an extensive study with 500-plus patients which is powered at around 80%. So, in that sense, even though we have tried to address some of the translation risk i.e. some of the risks associated with reproducibility of early-stage clinical results in late stage clinical programs, that is still a risk in the sense that it needs to be reproduced in the larger study in Phase-III setting.

And the last point is which will require extensive additional work in terms of Phase-III programs and resourcing that and actually executing that in a timely manner.

We have also in the earlier presentations talked about the opportunities for Vodobatinib beyond Parkinsons disease and that would require additional preclinical and clinical work and we are in the process of doing some of that. These are mainly in two buckets, which are driven by alpha synuclein like lewy body dementia and MSA.

So, I was talking about additional indications for Vodobatinib which would require additional preclinical studies and clinical studies and some of those studies are currently underway. You may know that we have been working

with Georgetown in investigator-initiated trial to explore this program in smaller proof-of-concept study for lewy body dementia. We're also working in early stage preclinical work in Alzheimer's disease with this mechanism with academic investigators. So, there is additional work that needs to be done to fully explore the potential of this program in other indications and other diseases, but also in other settings in Parkinson's. If you look at the design of Vodobatinib PROSEEK trial, we're looking at early stage Parkinson's patients who are pre-symptomatic that those are patients who are very early in their disease process and before they get into symptomatic therapies like L-Dopa. If you demonstrate disease modification or bending of the neurodegenerative arc in the setting, clearly, there is justification for exploring this program in other settings in Parkinson's disease like the combination of symptomatic therapy. Both these settings that would require additional studies.

Success on PROSEEK would be the beginning of an exclusive journey, which would then validate the program in the early setting, it should be our first registrational program, but also it will initiate a significant number of opportunities outside, but all of that would require an additional investment and additional exploration from a pre-clinical and clinical standpoint.

That takes me to my last slide. I just wanted to highlight a few market-related risks here in this slide. We have seen in a recent coverage on Vodobatinib which in our view captures some aspects of the program not all aspects of the program comprehensively. So, for investors who intend to price in Vodobatinib's potential to their decisions and deliberate analysis of the potential of the program both from a sales standpoint and also extension into other possibility standpoint along with an understanding of cause and risk, and also time-to-market, it's important before you take those calls. In a setting like this early-stage biotechs go into data events like these, there is significant risk of price volatility. And that is somewhat magnified in the market like in the absence of informed analyst coverage, which looks at these programs carefully. So, when you look at reporting that is coming in, we urge

you to take a balanced view on the program which balances both the potential of the program as well as the risk of the program.

And finally, I want to reaffirm our commitment to this area. We're going to see significant data coming from this program in the rest of this year with interim analysis and also in the final analysis. That's going to teach us a lot about c-Abl's role in neurodegeneration and teach us about how the moderation of stress pathway is going to have a role in treating neurodegenerative diseases. And there is a significant number of possibilities in this data that you can have clear validation of this hypothesis. You can also have a clear debunking of this hypothesis, but there's also a lot of gray space in between. So, this data we're looking forward to contextualize in what we're going to learn and then finding ways to move forward with continuing exploration of this program. Not just in this area as in this hypothesis, we also want to reaffirm our commitment in the neurodegenerative disease. In fact, if we go back several years that was the bet that we have taken in that neurodegeneration in spite of conventional wisdom going the other way, we believe that the neurodegeneration is an area is maturing from a science standpoint and that has also been validated recently with several transactions happening in this space. So, we will continue to be interested, continue to be excited about making a dent on these difficult diseases in the neurodegenerative spectrum. So, with that, I will conclude my comments and open up this call for the questions you may have. Thank you very much again for attending this call on short notice.

Moderator: We will now begin the question-and-answer session. We'll take the first question from the line of Ketan Gandhi from Gandhi Securities. Please go ahead.

Ketan Gandhi: In the November 2nd presentation, you indicated on Slide 19 that approximately 87% of the eligible patients enrolled in part-II from part-I. However, in current presentation, there is no update. Do you have any update on that, sir?

Anil Raghavan: That is true, 85% to 87% of eligible patients who are completing part-I of the study are eligible for continuation into a phase and long-term extension study. We don't have additional data. That trend continues.

Ketan Gandhi: Do you interpret the rollover rate to part-2 as indicative of patients positively embracing the treatment or is it possibly as a result of patient not experiencing the desired improvement, what is your thought process on that?

Anil Raghavan: It's very difficult to conclusively say that because we have significant number of patients on placebo. Even if they're not improving, they may want to access the drug in the long-term extension settings. There are a lot of motivation that patients are feeling better and they may want to continue. If patients feel that they're not feeling better, but they may be on placebo and they may want to transition to drug. So, there are significant number of different motivations that may be driving that conclusion. So, while it maybe encouraging, but it's difficult to draw any definitive conclusions based on that.

Ketan Gandhi: On Slide 5, under the section, “Expanding Evaluation of Vodobatinib” it is mentioned that SPARC would explore initial registration in an early treatment and naive setting. Can you throw some light on regulatory pathway post the announcement of PROSEEK top line data in August '24, whether we would go for regulatory approval or we would go after Phase-III, can FDA help us in getting approval post EoP2?

Anil Raghavan: So first let me give you a little bit of context to this statement in this presentation, which would explore initial registration in early treatment naive setting. And that is the most logical way to plan a registration like for this program. The patients who are coming into PROSEEK are early-stage patients who are treatment naïve from L-Dopa and symptomatic standpoint. So, if you're getting a positive readout from that trial, the least risk option from a registration standpoint is to repeat those studies and reproduce those results, which would become the basis of registration. The intent of that statement is that early or the initial registration setting would be a repeat of what we have explored and studied in PROSEEK. Now, the second part of your question is

"in terms of what would be an actual registration program and regulatory ask," that is subject to the discussions that we need to have with the regulatory agencies. We are going to have end of Phase-II conversation as soon as we have data. And there are very many possibilities. I mean, traditionally, the agencies would require two additional Phase-III studies and that's the classical ask in these kinds of settings. But there are also other possibilities of like factoring into a registrational package in some form or fashion, but that is all strategies that would require validation and agreement with the agencies around the world and we intend to do that as soon as we have data from the PROSEEK program. So, final shape on the registrational package can only be clear after we have these discussions with the agency.

Ketan Gandhi: Is my understanding right that we will be starting partnership program between interim data analysis and the top line data between that period?

Anil Raghavan: That is true. We expect to initiate conversations with the potential partners. We may not be able to conclude that before a final data disclosure in August - September, but we intend to kind of use this time to engage and create interest and work towards a partnership as we kind of get to September.

Moderator: We'll take the next question from the line of Ishita Jain from Ashika Stock Broking. Please go ahead.

Ishita Jain: Hi, Anil. Thanks for the update. Appreciate this reiteration of the risks associated to drug development. My first question is so our enrolment concluded in October 2023. Was the enrollment timeline as anticipated or did we face any challenges in recruiting?

Anil Raghavan: Your voice is a bit muffled. I couldn't hear you.

Ishita Jain: My question is that our enrollment concluded in October 2023. Was the enrollment timeline as anticipated or did we face any challenges in recruiting?

Anil Raghavan: So, if you remember, we started this program even though technically in 2019 the actual dosing, started in early part of 2020. Exactly when health systems

around the world started shutting down because of the pandemic. The initial couple of years have been rough for the program because most of the hospitals were not seeing patients in-person in hospital settings, and many of our endpoints require practitioners, assistants at site. So, in that sense we clearly have seen slower than anticipated in the first part of the study, but it has clearly picked up in the last 18-months or so, which helped us to conclude this program, almost in line with the revised timeline. We did a revision of the timeline during the COVID phase. So COVID induced certain delays. But other than that, in the last 18-months to a couple of years, the program has been tracking to the plan.

Ishita Jain: What I'm trying to understand is that if we go into Phase-III, what would mean Phase-III in terms of phase and then enrollment concerns in Phase-III, is that significant, I mean, obviously not withstanding existing drug development concerns?

Anil Raghavan: I won't be able to comment on the actual size of the Phase-III program. There are a significant number of statistical considerations that will go into defining that size and it will also be informed by the data that we are seeing in PROSEEK in terms of the doses that are effective, what is a registrational dose that we want to carry and the effect size that we are seeing in the Phase-II setting. So, there are a lot of variables which can only be informed by data from the PROSEEK trial. I won't be able to clearly indicate the size of the Phase-III program. We expect to maintain the momentum that we had in the later part of PROSEEK in terms of recruitment going into the Phase-III program. Because we have relationships with the investigators across and the other service providers in this ecosystem, and we understand this space probably better than when we started off. So, I think we are confident that we can maintain the momentum that we had in the second half of this trial from an actual recruitment rate standpoint, but actual size of the program in terms of number of patients that would be required is a function of where we land with PROSEEK is difficult to extrapolate that now.

Ishita Jain: I think I'm not sure if you already mentioned it and did I miss it, but meeting with the agency would only be post final data, right, there would be no agency meeting with interim data?

Anil Raghavan: Yes, the agencies would require completion of the trial and data from the ITT population before we can have the end of Phase-II meeting.

Ishita Jain: You mentioned that we may require additional preclinical studies. What kind of studies would these be, I mean I know it would be around efficacy, concentration of drug in brain or I mean checking for a specific biomarker, what kind of additional preclinical studies would be required?

Anil Raghavan: So, there are several toxicity studies, which are standard expectations in the registrational package, to give you an example, carcinogenicity studies, is a standard expectation in the registrational package. And there may be additional clinical trials like drug-drug interaction studies or other toxicity studies in preclinical settings. So, there are a part of customary expectations in a registrational setting in both preclinical studies and certain additional clinical studies. Clinical studies are not major clinical studies, but they are the studies which explore safety endpoints.

Moderator: We will take the next question from the line of Bino Pathiparampil from Elara Capital. Please go ahead.

Bino Pathiparampil: Could you please make some comments around the IP estate around Vodobatinib, do you have a drug substance patent, till how long does it run, etc.?

Anil Raghavan: I don't have the exact dates in front of me, but I can indicate that he compensation of matter and the regulatory compensation for the development time, we will go into late second half of 30s from IP coverage and we may also have some additional patents which are covering this space in the method of treatment patent and also potentially formulation patent. So, we are confident that we may go into late second half of 2030s for sure.

Moderator: We'll take the question from the line of Tushar Bohra from MK Ventures. Please go ahead.

Tushar Bohra: Sir, just a couple of points. So, while the end of Phase-II discussions with the FDA would happen only after the final data, but trying to assume that with the interim data analysis, whatever the readouts that we would have, the same would be shared with FDA as well, and that may be useful in whenever we have the final discussions, this would be something like a pre-read or an advance discussion item that is shared with them?

Anil Raghavan: We do not have current plans of sharing the interim analysis outlook, I mean, the data with the agency. Our next planned interaction with the agency on PROSEEK data would be post full data disclosure in September of '24.

Tushar Bohra: In the November interaction, you had mentioned with regards to my question only, about two or three drugs, especially in the case of Alzheimer's, where FDA has shown inclination for a faster registration pathway. Is it fair to assume that a similar pathway is potentially one of the options for SPARC as well as in PROSEEK trial is large enough and pivotal enough that FDA may in one of these situations have that as an option that this can itself be used as a registrational study?

Anil Raghavan: If I answer that, it would be speculative, I mean because it requires the agreement with the agencies, but I want to highlight a couple of points. We have a significant number of endpoints in PROSEEK, both clinical endpoints and biomarker endpoints. The possibility of an accelerated approval would be based on how the data comes in where all the chips fall. Especially, I mean if you look at the precedents in Alzheimer's or ALS recently, they have used conditional approval pathway which was based on validated biomarkers in those areas. Alzheimer's because of the tracers and data because of the validation of neuronal death marker called neurofilament light had significantly more clarity in terms of the correlation of these biomarkers with clinical outcome. So, we may see similar trends and similar correlation in PROSEEK, but in the field at the moment we don't have validated markers like

Alzheimer's had going into those events. So, in that sense there are some challenges inherent in the indication, which kind of differentiates with AD or ALS setting. But, there may be possibilities and I think it is highly speculative from our part to indicate that as a possibility at this point, because it is a function of what we see in the trial and also how the regulatory agency is reviewing that.

Tushar Bohra: In previous discussions at one point I think we mentioned that there is a backup compound to Vodobatinib that we are looking at potentially for Alzheimer's as well. And I think in a previous discussion in November it was highlighted that Vodobatinib can also work for Alzheimer's, the alpha synuclein pathway if I get that right. So, which one is it? It's maybe a bit early, but just to understand the thought process, whether it is Vodobatinib itself that we may look for Alzheimer's also at some point or is there another compound maybe a similar domain that we may look for Alzheimer's?

Anil Raghavan: I think if we continue to see preclinical data coming in the expected lines, we think Vodobatinib can be explored in Alzheimer's disease with activity seen in mechanistic studies in vitro in IPSC-derived cell, we have seen proteins like activated or phosphor-tau, A-β 40 and 42 moving in a positive direction with Vodobatinib. So, this mechanism of cAbl inhibition may have legs in diseases which are driven by other proteins other than alpha synuclein, and that is a key part of the data that we have already presented and disclosed. And that is what gives us the confidence to look at these other indications like a beta-driven diseases or ALS. But from actual strategy standpoint, we have spoken about this in the past. We have a backup program for Vodobatinib. There are additional assets in that package, and we may develop an additional backup compound which will give us a longer IP life from a composition of matter standpoint of additional indications. So, we may choose to develop a backup compound in all the indications driven by other proteins.

Tushar Bohra: On the Parkinson's, beyond PROSEEK, assuming that we need to do a Phase-III trial, how prepared are we for launching the trial, I mean, typically phase

two to phase three, there is a decent lag in a number of programs, because of lack of preparedness on the trial design or regulatory clarity or even funding clarity for that matter, assuming we have a very strong positive data on PROSEEK and we are required for another trial, how well prepared are we, have we already started working in that direction, sir?

Anil Raghavan: There are multiple components to that question. If you look at various different variables of preparedness from a late stage, one is what to do in terms of regulatory and scientific clarity about the nature of our registration trial, pivotal program that we want to have, and activities that we need to obtain that clarity, and then an ability to kind of design a trial according to those expectations and execute that. And there's a competency and scale-related aspect which is substantial in a Phase-II to Phase-III because kind of competencies that you require and the scale that you require in Phase-III setting maybe somewhat different from a Phase-II program. As you rightfully pointed out, resourcing expectation is significantly more in the Phase-III because you may need to conduct multiple global trials to complete the traditional Phase-III package. So, on all these accounts, we want to address in the next few months and we already started working on some of the aspects thinking about what could be the nature of the Phase-III program from a science standpoint and also try to put together a sense of the capability gaps that we want to bridge and also the extent of resourcing that is required. So, we are actually doing some of those regulatory activities as well. But, we can only get full steam once we have clarity from PROSEEK both from the data standpoint and also induce certain ability to discuss this more openly and transparently with the other players that we need to discuss this with, for example, for resourcing. It's a nuanced answer. Yes, to the extent that is possible now, but we are extremely aware of the extent of work that needs to be done and it will all get in focusing those data in September.

Tushar Bohra: Sir, even in the eventuality that two outcomes, one where unfortunately let's say we don't get the relevant data outcome in PROSEEK, and two, where we have a very strong outcome and the trial goes through well and maybe we go

through to a registrational study, in both these situations also, in any case, you will do a trial for Vodobatinib for a symptomatic setting, right, in combination with L-Dopa and the existing regime, so that Part-In any case, you would be already working on some kind of a trial setting which is something any which ways do?

Anil Raghavan: No. So, let's look at the spectrum of possibilities that can come on the PROSEEK trial. On the positive side, you can have a full validation of the hypothesis data in line with the design expectations of the trial. On the other end, you can have a full rejection of the hypothesis, in the sense that going in assumption about this mechanism producing a certain level of difference on the trajectory in neurodegeneration was not correct. So, there can be a rejection of hypothesis and there can be a host of possibilities in between, that is, it is working in patients with a certain disease severity or it is working with the patients who may have morbidity in the data as a background there. So, there are a lot of other possibilities in terms of that gray area between a full rejection and a full validation. The question was pertaining to the full rejection of the hypothesis if I understand it rightly. In that case, we don't believe that there is a justification for exploring this program further in any setting because it rejects primary mechanistic hypothesis. But, in all the other possibilities, whether it is full validation or validation in parts in different settings, that's difficult area. We think there are possibilities to move forward with an appropriate registration package.

Tushar Bohra: I was just wondering that if the trial is successful as well, then as you said that you would look at Vodobatinib for the extension of the entire Parkinson's program, so that Part-In any case you would already be working on, right?

Anil Raghavan: That if the program is successful. If Vodobatinib is proving, is validating the cAbl hypothesis in PROSEEK, then there is justification in extending this to other settings in Parkinson's disease. If it is slowing down the trajectory of the disease, then it can be a companion for L-Dopa and slow down late stage PD,

or you can think about exploring this condition. But, if it is not slowing down, then there is no basis. That's the point I was trying to make.

Tushar Bohra: But if it is slowing down or if it is having some reaction, but maybe not sufficient enough to meet the trial design, in that case, is there still a scope or a reason to study it in symptomatic setting?

Anil Raghavan: We have to take a close look at the data at that point. What we are indicating is that you're seeing a trend, but you may not be meeting statistical significance because the trend is not as strong as we initially thought. We will take a close look at that trend and take a call based on the data that we're seeing. But that is the possibility. I don't want to reject that possibility.

Moderator: The next question is from the line of Jigar Valia from OHM Group. Please go ahead.

Jigar Valia: Sir, if you can help understand the administrative interim approach versus the full interim? And while you still maintain that there might be a requirement for proper Phase-III and would certainly go with a partner approach and there would be challenges in terms of getting a leeway on the Phase-III. So, would want to understand with regards to the administrative and is there a slight possibility that it may be thought for a Phase-IV direct, so we're in a full phase this thing happens, but post approval?

Anil Raghavan: The difference between the interim analysis or administrative interim analysis, the full data set is the number of patients who are going into, we have 441 patients going into the interim analysis in end of March or early April, and 513 patients going into the full data set, which would happen in early September next year. So, essentially, we will have practically all of the clinical endpoints and many of the biomarker endpoints in interim analysis, but not all, some biomarker endpoints would require additional time. So, we will have all endpoints, the primary endpoints, all the secondary endpoints and all the biomarker endpoints as part of the final in September, while we may have a substantial subset of that in the interim analysis. Substantively,

those are the two differences -- the number of patients and also the extent of data from an endpoint standpoint. Your second question is tricky, in the sense, I don't want to get into speculative realm. There are possibilities in terms of the nature of registrational expectations from different agencies. But, me giving a guidance in terms of what is possible at this point is dangerous in the sense that it is subject to significant change based on data and how the regulatory agency is going to see that data. So, I would refrain from taking a position in terms of what could be a possible registration package till we have those discussions with the agency.

Jigar Valia: Sir, other is, since the additional patient subtypes now would require additional investment time, if you can help understand the partnership approach, would it be only for the Parkinson's disease right now or would it also try to cover the additional subtypes?

Anil Raghavan: We are getting into this partnership process with a certain level of openness in terms of the kind of partnerships that we want to have. We would like to have a relationship which maintain some level of participation in both development and also commercialization of this program, plus some flexibility in terms of additional indications retained within SPARC. But, at the same time these discussions can take a life of its own once you get into them. So, in that sense, we are open-minded in terms of approaching our partnership strategy. Our baseline expectation is that we will continue to retain some level of role in development and commercialization, but in actual nature of partnership would be a function of what we are going to see in this process. But, we will explore that fully post the interim analysis data in March.

Jigar Valia: To understand, since the partnership is going to be for the PD perspective, etc., would you be looking at funding for any other programs or I mean only this would be a priority until this is settled? So, you also have the fundraise approval, etc., those in place apart from the partnership what we could get.

Anil Raghavan: I don't want to throw a hard line and say, partnership would only be for Parkinson's disease. One of the objectives for a partnership or one of the

drivers for seeking a partner is to expand the program aggressively. So, in that sense we would like to leverage both the resources and also competency muscle of larger partners in terms of fully exploring this program in Parkinson's and also in other indications. But, how we actually carve out those different spaces in terms of ownership and extent of deletion is a function of the discussion. So, we don't have a set view that the partnership is only going to be for a limited PD setting and SPARC would continue to resource everything else, that's not the intent at least going into this process.

Jigar Valia: Just a hypothetical this thing is that, god forbid, in case of a negative outcome, will it remain open to pursue the CML indication given that this would be only -?

Anil Raghavan: Yes, we already have clinical proof-of-concept for CML and it would require an additional study, we have some clarity in terms of what the study is and then we have to take a decision that SPARC will invest additional resources into conducting those trials or whether we need to see the partner today. That's the call that we can take once we have clarity on the data.

Moderator: The next question is from the line of Bino Pathiparampil from Elara Capital. Please go ahead.

Bino Pathiparampil: If you're not going to share the administrative interim analysis with pretty much anybody like you said, what is the purpose of this administrative interim analysis?

Anil Raghavan: On a question that we just had, we spoke about the partnership strategy and one of the key objectives of the interim analysis is to engage with the potential partners early on so that we can try and minimize the time that we require post the full data in September. So, it is not correct that we are not sharing this with anybody, we will share this with the potential partners under CDA at an appropriate level with a limited number of potential partners, that's the expectation at this point.

Moderator: Ladies and gentlemen, that was the last question of our question-and-answer session. I would now like to hand the conference over to the management for their closing remarks. Over to you, sir.

Jaydeep Issrani: Thank you, everyone for taking out time for today's discussion. We now end the call. In case you have any follow-on questions, you can reach out to us on the e-mail and the numbers provided on our website. Thank you again. Have a nice weekend.

Anil Raghavan: Thank you, everybody.

Moderator: Ladies and gentlemen, on behalf of SPARC, that concludes this conference. We thank you for joining us and you may now disconnect your lines.