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Scrip Symbol: SPARC

Scrip Code: 532872

Dear Sir/Madam,

Sub: Transcript of the Investor's call on Vodobatinib Parkinson's Disease program

This is with reference to our Investor Call which was scheduled on April 15, 2024. Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we hereby attached the Transcript of the said Investor Call for Vodobatinib Parkinson's Disease and the same is also available on the website of the Company on the below weblink:

<https://sparc.life/presentations/>

This is for your information and dissemination purpose.

Yours faithfully,

For **Sun Pharma Advanced Research Company Ltd.**

Kajal Damania
Company Secretary and Compliance Officer



**“Sun Pharma Advanced Research Company (SPARC)
Transcript of Investor Call on PROSEK’s Interim
Analysis Results held on April 15, 2024”**

**MANAGEMENT: MR. ANIL RAGHAVAN -- CEO, SPARC
MR. JAYDEEP ISSRANI – HEAD, BUSINESS DEVELOPMENT &
INVESTOR RELATIONS, SPARC**



Moderator: Ladies and gentlemen, good day and welcome to the SPARC's Conference Call for Update on PROSEEK's Interim Results.

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 "*" then "0" 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 Sagar. Good evening, ladies and gentlemen. My name is Jaydeep. I head the Business Development and Investor Relations at SPARC.

On behalf of SPARC, I welcome you for the update on the interim analysis of PROSEEK study.

I have with me, Mr. Anil Raghavan, CEO of SPARC. Anil will provide a brief update on the outcome of the "PROSEEK Study," following which we will open the call for question-and-answer.

Before I hand it over to him, I would like to remind you that our discussion may include forward-looking statements that are subject to risks and uncertainties associated with our business.

I will now hand it over to Mr. Anil Raghavan for his presentation. Over to you, Anil.

Anil Raghavan: Hello everybody, thank you for joining the call today. Thanks, Jaydeep for the intro setting up the call. As he mentioned we plan to provide an update on the Interim Analysis of our PROSEEK study and briefly talk about the next steps and the way forward for SPARC. The primary objective though, is to try and address your questions and concerns as much as possible. So, I will keep my opening comments brief.

But before I begin, I would like to apologise for the delay in convening this call. We received data from the PROSEEK interim analysis last week and made a disclosure of the results through a press release within a day. Our intent was to provide an update and talk to you as soon as possible. However, the immediate focus thereafter was to initiate the study-close out activities and think through the near-term priorities which took a few days to complete. We believe it was important to map out key next steps for Vodobatinib before we can have a productive conversation with you. But again, we understand the sensitivity, and sincerely apologise for not following up immediately after the release.

You may recall that our initial plan was not to disclose the interim results before completing the review of all the 513 patients randomized on the study. However, in the interest of patients, our investigators and the larger investor community we decided to unblind the study and share the results immediately given the trend lines seen.



As we disclosed, we completed the review of 442 patients who finished the part I of the study by March 2024. The data suggested that the Vodobatinib arms, that is the low dose and high dose arms didn't meet the primary endpoint of change in score from baseline in MDS-UPDRS part III at week 40. Key secondary endpoints have also shown a similar trend. Overall incidence of serious adverse events was low in this trial, indicating an acceptable safety profile.

That was indeed a disappointing outcome, and certainly not what we hoped for our patients, especially after having generated significant body of evidence in preclinical model systems in collaboration with some of the most important thought leaders in this space demonstrating the neuroprotective role of Vodobatinib in multiple pre-clinical studies.

Based on our statistical projections that suggested that the study is unlikely to show clinical benefit in the overall study population, we decided to close the trial. Having said that, we will review the full data set which is not expected to change the primary endpoint of the study however it can provide meaningful insights on the mechanism, the drug and the trial. We will keep you informed as we complete the planned analysis.

Once we have reviewed the full data, we will also evaluate the expectations for and the value of the Lewy Body Dementia Investigator Initiated Trial and pre-clinical programs for the back-up series of Vodobatinib as they target the same mechanism of action as Vodobatinib did in PROSEEK. But as of now, we have parked all activities in these studies.

Obviously these results represent a setback for SPARC which will pose questions on certain parts of our portfolio and challenge our ability to pursue an aggressive R&D agenda. As we complete the data analysis of PROSEEK, we will also work towards resetting our portfolio, optimizing our operating model and cost structure. This is really important considering the additional cards we have got, to turn. As we have indicated previously, SPARC's pipeline has significant optionality including multiple clinical assets and a late-stage preclinical program which is expected to enter clinical testing in the last quarter of this financial year. Please allow me to take a minute to highlight these assets with short to medium term milestone visibility.

The most advanced program is SCO-088, which is Vodobatinib's oncology leg, for treatment of CML. We have completed the Phase 2 study and the data provides validation of its hypothesis in Leukemia with excellent response even in patients who have exhausted all available therapeutic options. As next steps, we are discussing the registration study design and expectations with the USFDA, in fact later today, to decide future development strategy for SCO-088. Since SCO-088 has established human PoC, we may explore licensing the asset to a partner to raise non-dilutive capital for developing other late-stage assets i.e. SCD-153 and SBO-154.

SCD-153 is under Phase 1 evaluation in India and we hope to complete the Phase 1 study by FY25 and subsequently an early patients' study in Alopecia Areata in India by FY26 at which point we would have established human PoC for SCD-153. Similarly, for SBO-154, our Antibody Drug Conjugate targeting a novel epitope of Muc-1, we have initiated IND enabling



studies and we expect to file the IND by the end of current financial year. Both these opportunities represent first in class positioning for SPARC across multiple indications.

Additionally, Vibozilimod is under Phase 2 assessment and the top line results of the SOLARES AD study is expected in Q4 2024. This, as you know, is licensed to Sun Pharma and the development costs are borne by the partner.

The continued development of these programs would require additional resourcing and our current cash balance and approved credit may be sufficient to cover the expenses for 12-15 months if we factor in expected cost savings from Vodobatinib and related deprioritizations. We are also eligible for additional milestones from Vibozilimod and Phenobarbital depending on certain outcomes that can increase the runway for SPARC. We may require additional resources to get to the next set of milestones in certain scenarios. We will tightly manage the portfolio and spend to get to the next set of data events.

As I indicated earlier, we will review our current clinical and pre-clinical portfolio to identify and prioritize high value programs and optimize the cost base to extend our runway.

While the PROSEK interim results set us back definitely, we have additional assets especially the clinical assets that carry significant value which we will pursue using appropriate resourcing models which may involve partnering early if that makes sense. We will keep you posted as we make progress with the full analysis of the PROSEK data and complete our strategy review. Thanks again for joining us today.

And at this point, we would like to open the call for any questions, concerns, suggestions that you may have. Thanks again for your time.

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

Ketan Gandhi: In the November call, you said, we have a clearer option for Vodobatinib for CML. So, in terms of timeline, when can we expect the licensing deal to happen and what are the opportunity size for this molecule?

Anil Raghavan: Thanks, Ketan. I think as we've explained in the last investor call, we had parked the CML development till we have the results of Vodobatinib study as in the PROSEK study. We have planned conversation with the FDA to have a clear visibility to the regulatory pathway and we are now in the process of reinitiating potential business development activity on the CML, part of the program. In terms of giving you a specific timeline for closing out of that licensing transaction, I think probably we are a little too early in the process. We just started this process now and we may need additional time to kind of scan and go through the process and conclude a transaction for Vodobatinib. In terms of the opportunity size, I think we haven't disclosed specifically sales potential, but it is significantly lower than the Parkinson's disease opportunity



and here we are talking about potentially several hundred million dollars as against several billion dollars in the case of Parkinson's disease.

Ketan Gandhi: Sir, I want the timeline in terms of whether it will happen in this financial year or next financial year or a year after the next financial year, can you give some sort of ballpark understanding so that we can model that into our -?

Anil Raghavan: We're definitely targeting in this financial year and that's our objective.

Ketan Gandhi: So, in terms of cash burn, we have enough cash position to go ahead for other programs or we need to raise some equity in near-term?

Anil Raghavan: We are not contemplating any near-term equity raise. If I look at our current cash balance which should be in the range of around \$20 million and we also have access to approved credit, and if I actually look at both approved credit and the current available cash, we should be able to basically go beyond the current financial year. We're looking at the broad window of around 12-to-15 months. And this also factors in some of the cost savings from the reprioritization, and if you're not spending on the Vodobatinib clinical program and also the backup program that we have, that is a significant part of our budget for this year. So, in that sense, if I take out that from the provision, this cash balance and access to credit is sufficient to take us to 12-to-15 months runway, but we're taking a deeper look at our portfolio priorities. Clearly, the assets that I spoke about in the call earlier are important and we have clinical validations coming from mostly in India-based trials in these cases except MUC-1. So, beyond that we may need to have additional cash infusions but that's depending on how some of these outcomes pan out, we have milestone visibility on Vibozilimod which is reading out later this year and Sezaby can also provide additional milestones. So, there are additional milestone opportunities which can augment this beyond the 12-to-15 months window. We will take a call as we kind of move towards that, but we will take a hard look at the portfolio and our cost structure in the interim.

Ketan Gandhi: Sir, can you throw some light on the Phenobarbital, what happened there because I believe we have filed some case in District Court of Columbia in 2nd of April, so, what is that about and where are we in terms of launching it?

Anil Raghavan: The case that we have filed against the FDA has nothing to do with the launch of the product. The product is launched, and the takeoff is expected when we get the exclusivity established. And there is a whole work stream going on and our expectation right from the beginning is that by end of the second year or beginning of third year of launch, we will be able to establish the exclusivity or enforce the exclusivity and take out the unapproved products in the market. But the case is about a different matter. We believe we are eligible to get a pediatric rare diseases voucher. And that pediatric rare diseases voucher was denied because of certain interpretations of statutes involved and we disagree with that. I cannot dwell into this matter more than that since this is sub judice at the moment. So, I don't want to talk a lot about our position and the specific nature of our disagreement. But we believe that we have a defensible case and that's the reason why we initiated this process.



Moderator: Our next question is from the line of Ashutosh from Zydus Investments. Please go ahead.

Ashutosh: For PROSEEK study, sir, when can we expect full analysis results?

Anil Raghavan: I couldn't follow the person. Did you ask the availability of the full analysis results of PROSEEK?

Ashutosh: Yes, sir.

Anil Raghavan: We are looking to complete the full analysis of PROSEEK by the second quarter of this financial year.

Moderator: The next question comes from the line of Vishal Bohra from MK Ventures. Please go ahead.

Vishal Bohra: Sir, just want to understand, are there any qualitative data points that you can share further on the PROSEEK trial or while we did not meet the primary endpoint, was there actually no efficacy outcome at all or like no response at all or was the response there, but not sufficient to cross the hurdles, what was the case here?

Anil Raghavan: In the PROSEEK interim analysis, we looked at the primary endpoint, which is Part-III of MDS-UPDRS and few secondary endpoints, which is Part-II plus Part-III and the time to treatment as in the time to systematic therapy. So, this was a subset of the secondary endpoints we have in the trial plus we also looked at three biomarkers, which is neurofilament light, we've looked at alpha-synuclein assay, which essentially diagnose the disease and then in CSF fluid look at the trends of alpha-synuclein. So, in the primary endpoint and as we have indicated we did not meet the significance between placebo and treatment arms and we have a similar trending for these set of secondary endpoints that we've looked at. In both these cases, what I can say at this point is that we have an extraordinarily high placebo response. In fact, the placebo curve stayed flat for almost the study period, but we are not disclosing the specific data at this point and we will take a look at all the secondary endpoints and also all the biomarker endpoints. In biomarkers, we have conflicting data points coming from that biomarker study. So, we will take a look at both the clinical outcomes across all secondary endpoints. We have looked at the first nine month period data in this analysis. We also have an additional nine month data for a subset of this patient pool. And we will also take a look at how this trajectory kind of pan out with that. That's obviously an uncontrolled data as in it doesn't have a placebo control in the second part of this trial. So, we will take a look at both the second nine-month period, all biomarkers and make a final, view on the target and trial and the drug.

Vishal Bohra: So, a couple of related questions. So, just to understand, we are saying that the trial did not fail because of poor outcome or a poor data on Vodobatinib but more because your placebo response was extraordinarily good. Could it be a case of maybe a trial design or an externality? Do you think that there is a possibility that you may want to look at a retrial when maybe revise the trial design or revise the endpoint and look at it again, is there a possibility for that, sir?



Anil Raghavan: I wouldn't frame the way you framed it. I think when the study was designed for showing a 35% difference between placebo and drug, 35% improvement over placebo. Obviously, the analysis that we have seen so far did not show that difference. And we have to wait till the full analysis of the data for any additional steps that we may have to take. In terms of actually factoring in Vodobatinib into the financial model, our advice at this point is discount Vodobatinib fully based on the trend lines that we have seen, and if there is a room for any kind of reframing this hypothesis or reframing based on any additional trials, we will definitely come back and advise you on the basis of additional review that we are going to take.

Vishal Bohra: I may just want to frame the question differently. In terms of Vodobatinib PROSEEEK trial out next steps is a retrial. One of the possibilities, sir, even if it is, let's say, 1% possibility, is that one of the option that is still available to us or that is completely closed out?

Anil Raghavan: I cannot close out anything at this point because we haven't seen the full data set. Unless we see the full data set and we understand what happened in the trial fully. All of these options are possible, but there are very remote options based on what we've seen on the primary endpoint and secondary endpoint. That's why we are advising you to discount the program in the model.

Vishal Bohra: What is the backup option we said, I think was it referring to the Alzheimer's disease or are you referring to backup as Vodobatinib for CML and LBD?

Anil Raghavan: So, the hedge for Vodobatinib as in the hedge for PROSEEEK was essentially CML. Even though we have other preclinical programs for Vodobatinib and this backup series in neurodegenerative diseases. We always considered that as one package, one battery which will come alive if we have a positive response in PROSEEEK. In the absence of that, the real alternative for Vodobatinib is leukemia program, which is what we just discussed.

Moderator: The next question is from the line of Manish Jain from GormelOne LLP. Please go ahead.

Manish Jain: I just wanted to understand that in CML given that the way Asciminib has been ramping up to \$450 million sales already at an annualized run rate, does it make sense for us to take it all the way to the final approval?

Anil Raghavan: If the question is about SPARC spending the resources to take this to the regulatory approval in the US, the answer may not be yes. It may not be an appropriate use of SPARC's capital to take that all into regulatory approval in the US, given other options or opportunities that we have in the portfolio. But there may be other midsize, some critical companies for sure who may be interested in a program like this which can give significant enough opportunity from a commercial standpoint for a smaller sales force. And with opportunities to go up against a product which is ramping up fast and there are not very many options and especially the safety profile that we have seen for the product and the activity that we have seen for late line patients makes it a developable option. And we are seeing validation for that. Even after we kind of deprioritized the program we get several requests for off-trial access for that drug because of its activity in patients who exhausted all lines of therapy. So, that's an interesting proposition for



someone who is looking to build a \$200, \$300 \$400 million product, but that may not be a right opportunity to kind of prioritize our capital over the ADC or over the potentially first-in-class dermatology product.

Manish Jain: My second question was that in phenobarbital, given that we have licensed it to an external party, should we win the PRV case, the entire PRV value belongs to us or we have to share some proceeds with the partner as well?

Anil Raghavan: The PRV is with SPARC.

Manish Jain: So, 100% value of PRV is with SPARC, right?

Anil Raghavan: Yes.

Moderator: The next question is from the line of Chandpal Singh, who's an individual investor. Please go ahead.

Chandpal Singh: Is this the end of the c-Abl hypothesis for other drugs that are in trial for Parkinson's?

Anil Raghavan: Well, at the moment I don't think PROSEK interim analysis is certainly not the last word for the mechanism. I mean it's a serious setback for the mechanism. But we need to basically look at the full data set. We are practically sitting at a Treasure Cove of information in terms of how the mechanism actually behave. So, in that sense, whether it is a tractable hypothesis is something that needs to be determined based on the full analysis of the data set.

Moderator: The next question comes from the line of Rohan Parekh from Home Stock Brokers. Please go ahead.

Jigar Valia: Hi, this is Jigar Valia. So, my question is while Vodo failed on the primary and secondary, it did cross the blood brain barrier through, so it's a question, did it actually go through with regards to the 442 patients and is that anything of value or nothing happening?

Anil Raghavan: Can you just repeat the last line of your question?

Jigar Valia: So, my question was that did the results show a successful crossing of the blood brain barrier while it did not meet the primary, secondary endpoint? If indeed, then is that of value for either us or as far as the therapy or a study is concerned generally?

Anil Raghavan: That's an important question, Jigar, because the interim analysis did not include PK analysis. Even though we have access to both blood cross from our patients and also CSF data for an appropriate number of patients, we haven't analyzed that to determine the exposure that we have both peripherally and in the brain. So, that is an important part of the analysis that we will be doing as part of the complete review.



Jigar Valia: Second question is with regards to the CML, the failure that happened for the PD thing, those primary, secondary endpoints would be entirely listing as far as the CML is concerned, and this is completely linked to PD and that would be linked to CML, is it fair that there is no correlation between?

Anil Raghavan: Primary and secondary endpoints of the Parkinson's trial is very specific to Parkinson's and the progression of that neurodegenerative condition, and it has got nothing to do with leukemia and it's proof-of-concept for leukemia. It's already available from our earlier Phase-II study. And if anything, the safety data from this trial is supportive of its dose in leukemia, which is actually lower than the doses that we have used in the Parkinson's trial. We don't see any negative fallout of PROSEEK in the leukemia program. If anything, it is positive because of the safety profile.

Jigar Valia: And for the leukemia program we continue after Phase-II as Imatinib plus one more as a Line-III product, right?

Anil Raghavan: No, we are essentially in the process of having conversations with the FDA and actual treatment line for the trial will be decided based on the feedback that we receive from FDA. But the study that we have done so far was in three lines failed patients. That is the original proof-of-concept, and that is probably the most difficult setting to go after because they've exhausted all available lines of therapy. If we have an opportunity to move up and test a different line would be a function of what we hear from the agency.

Jigar Valia: As far as the funding is concerned, it would have nothing to do with the timelines for the final study which will be in Q2 and it would also be a function of you having the discussion with FDA or -?

Anil Raghavan: No, no, the fundraise is not a function of our conversations with the FDA. Because as I explained earlier to another question, we are not looking to allocate our capital for developing this program in leukemia. We are initiating a process to actively look for licensing partners for leukemia. So, in that sense from a cash flow funding standpoint, these conversations and our actual plans for leukemia may not be a major factor.

Moderator: The next follow up question is from the line of Ashutosh from Zydus Investments. Please go ahead.

Ashutosh: I wanted to ask, what is the trial cost?

Anil Raghavan: The overall budget for PROSEEK was in the range of \$45 million. But we may not end up spending all of \$45 million because that assumed completion of the trial all the way to visit level, that's 40 weeks for the Part-I and completion of the Part-II study. So, now because of the early termination, we may be able to have some savings on that \$45 million original allocation.

Ashutosh: Sir, can I ask you how much you have spent?



- Anil Raghavan:** Currently, it may be in excess of \$35 million and original budget was \$45 million.
- Ashutosh:** Currently, how much?
- Anil Raghavan:** I don't have an exact number right at the moment, but it is certainly between 35 and 40, but closer to 35 than 40.
- Moderator:** We have the next question from the line of Mr. Vishal Bohra from MK Ventures. Please go ahead.
- Vishal Bohra:** Sir, if you can highlight the next steps on your specialty pipeline, if you can just highlight the liquidity events, monetization events therein and also what kind of milestones and we look at what next steps across SEZABY and ELEPSIA and the other one?
- Anil Raghavan:** I think the major milestone payment from programs which we already licensed, SEZABY on clearance of the market, we have additional milestone payments which will happen as we move forward and clear the other products from the market and get our exclusivity established. PDP-716, which is our ophthalmology program, we're going in for refiling in September timeline and we have milestones on approval of that product and Vibozilimod which is the Phase-II program in psoriasis and atopic dermatitis and successful completion of those programs would have additional milestone events. So, those are the three identified milestones for us. Other than that you have further clinical and developmental and regulatory milestones for Vibozilimod. We also have these two other programs which I talked to you about, which is SCD-153 and SBO-154. SCD-153 is a collaboration with Hopkins in alopecia areata and that we just started our Phase-I clinical trial in India. We are on a dose escalation phase. And our intent is to establish a clinical proof-of-concept for that program in alopecia areata before we start looking at the partnering options, SBO-154 is antibody drug conjugate targeting new epitope of MUC-1 and we are in the process of scaling up our manufacturing for the clinical program and its non-clinical program started. Our hope is that we will be able to do the IND for this program before the turn of this financial year. So, those are the two major programs which are closer to encash other than the three I spoke about license program.
- Vishal Bohra:** And there's not much mention in the last couple of presentations about Vibozilimod for psoriasis. So, in the call today I think you mentioned atopic dermatitis. So, can you highlight for what's the status for psoriasis as well?
- Anil Raghavan:** Our commercialization partner, Sun hasn't given a timeline for the completion of the psoriasis program. The psoriasis program is behind atopic dermatitis program. So, it will follow the results of atopic dermatitis program and we don't think that we will have data availability from that program this year. That's why we're not talking about that. But that program also is progressing and probably Sun can give an update on specific timelines for the psoriasis program.
- Vishal Bohra:** What would be your estimate as to SEZABY we when do we start seeing the commercial going in meaningfully once you have the exclusivity established, would you have a timeline sense to it?



Anil Raghavan: We had filed a citizen's petition with FDA and FDA came back to us asking more time. They said that this is a complex matter, and it will require additional time and they did not set a specific timeline in terms of when they will act on the citizens petition. In this process, we are also adding additional leverage points in terms of working with patient advocacy groups and also directly engaging with some of the unauthorized manufacturers. If I look at what happened with other programs which came into a market similar to SEZABY usually takes two to three years before the product gets full exclusivity established. So, we just completed the first year and now into the second year and we have a full-fledged process going and our hope is that we will be able to maintain a similar timeline.

Vishal Bohra: For ELEPSIA and XELPROS, any further updates?

Anil Raghavan: We are in the process of transitioning ELEPSIA to a different partner, but we don't have finalization of that process yet. So, we're still in the process of decision there.

Vishal Bohra: Just one more thing on Vodobatinib for CML. In terms of head-to-head, what are the options if we have to go for a frontrunner trial, do you have any specific options earmarked or highlighted that you have decided that this would be most relevant comparison?

Anil Raghavan: So, if you were to do a comparative study which looks like that's what we should do, and most relevant comparative product would be Bosutinib but we will take that final call based on the FDA feedback.

Vishal Bohra: Is it possible for us to do maybe more than one arm of study given that couple of the other products are more prevalent where it's Dasatinib or Nilotinib.

Anil Raghavan: That's again a function of the design, which we agree with FDA. I'm assuming your question is about multiple comparative. Is that what you're saying?

Vishal Bohra: Yes, because Dasatinib being the largest and it's a \$2 billion molecule in that ballpark in any case. So, would it be not fair for us to target that trying to do head-to-head comparison against something like Dasatinib and if you're able to do equally well, or maybe better, that opens up a faster, bigger commercialization possibility you have, then the \$200 to \$400 million, so is that ballpark of a few hundred million that you highlighted?

Anil Raghavan: I think it's not just a regulatory question. It's also a clinical science question in terms of how you actually maximize your probability of success with the program. And if you look at the second or third generation trials that happen in leukemia and if you look at what has been the comparator for those programs, that will give you a clear sense of what is the preferred comparator program for even programs like Dasatinib or any other like second or third generation program that has been pursued. It's a complex question which is driven by both commercial calculus and also probability of success and the ability to kind of reduce the risk in the program. So, we will take that call based on what we hear from the agency.



- Moderator:** The next question is from the line of Manish Jain from GormalOne LLP. Please go ahead.
- Manish Jain:** I just wanted to understand on SCD-153. Till what level will we develop it on our own and when will we explore partnering 153?
- Anil Raghavan:** So, the development program for SCD-153 has three identified steps so far. One is completing its healthy human volunteer as in single ascending dose trial which is where we are at the moment. That establishes early safety for the program. And typically in a program like this, this would have been followed by a 14-day multiple ascending dose study. So, instead of doing that 14-day multiple ascending day study, we are proposing to do a patient study in multiple ascending setting, in a sense, we will test this trial in ascending doses in alopecia areata patients. So, that will give us two things. One, it will give us a better sense of safety profile in actual patient setting and even though we are not powered to detect that it may provide an early signal on efficacy and then we will follow that up with Phase-II study to determine the dose and also get proof-of-concept for the mechanism. And we are planning that in two steps. The first part is an India-based study where we will go up to 250 patients in India and do an interim analysis for those India-based patients. And if we get a proof-of-concept for 250 patients, that protocol will have a provision to expand the study to the rest of the world. But that India-based proof-of-concept for 250 patients is what we believe as an ideal licensing opportunity given where we are.
- Manish Jain:** The second clarification I wanted is for ADC which manufacturing ramp up that we're talking about. Is it in-house manufacturing capability that we have developed?
- Anil Raghavan:** No, we are working with the San Diego-based CDMO for scaling up this program.
- Moderator:** The next question is from the line of Rohin Kumra, who's an individual investor. Please go ahead.
- Rohin Kumra:** Just to be sure, when we say that Vodobatinib will be out-licensed in the next two or three years, that means we will also outlicensing it for our front runner program also?
- Anil Raghavan:** Sorry, your line was very blurred and I couldn't hear you properly.
- Rohin Kumra:** When we see that Vodobatinib will be outlicensing in next one or two years?
- Anil Raghavan:** You're talking about the CML arm of Vodobatinib, right?
- Rohin Kumra:** Yes, sir, CML arm. Is it a fair assumption to assume that we are out-licensing it for our front runner program also?
- Anil Raghavan:** So, I understand your question as whether the CML part of the Vodobatinib would be out-licensed in this year or next year. The answer is that's our objective, right? We are initiating this



process and as I said earlier, our objective is to finalize that process this year. I didn't quite follow the second part of your question.

Rohin Kumra: I mean that we are also trying Vodobatinib in the front line settings.

Anil Raghavan: Yes. If it is out-licensed, it will be for all settings of Vodobatinib in leukemia not just the last line.

Rohin Kumra: Then that means that milestone payment that we are going to see while keeping in mind the potential of process and settings.

Anil Raghavan: That you need to model, but yes, it will cover both the front line setting and the earlier line as well as the last line.

Moderator: The next question is from the line of Ashutosh from Zydus Investments. Please go ahead.

Ashutosh: Sir, for Vodobatinib is there any corporate presentation deck available on the recent reports?

Anil Raghavan: There is a presentation on the website. You're asking about Vodobatinib, right?

Ashutosh: Yes.

Anil Raghavan: Yes, yes, it's on the website.

Ashutosh: Where it is?

Anil Raghavan: It's on the SPARC website.

Moderator: As there are no further questions, I would like to hand the conference over to Mr. Jaydeep Issrani for closing comments.

Jaydeep Issrani: Thank you, Sagar, and thank you, everyone for joining the call today. In case you have any additional questions, feel free to reach out to us on the e-mail IDs and numbers that are shared on our website. Thank you again for being with us on the call.

Moderator: On behalf of SPARC, that concludes this conference. Thank you for joining us. You may now disconnect your lines.