Dr. Reddy's Laboratories Limited
Management Call

Kedar Upadhye:

Good Morning and Good Afternoon to all of you. Thank you for joining this conference call organized to discuss the queries relating to the warning letter received by us. We have the leadership team of Dr. Reddy's comprising Mr. Satish Reddy – our Chairman; GV Prasad – our Chief Executive Officer and Saumen Chakraborty – our Chief Financial Officer here in Hyderabad. We also have Abhijit Mukherjee – our Chief Operating Officer joining in from US.

Before we proceed with the call, I would like to remind everyone about the Safe Harbor: This discussion will contain certain forward-looking statements which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. For more detailed information on the risks and uncertainties associated with the company's business activities, please see the company's Form 20-F for the fiscal year ended March 31, 2015 and Form 6K for the quarter ended June 30, 2015 and our other filings with the Securities and Exchange Commission.

Now, I would like to turn the call over to GV Prasad – our CEO.

GV Prasad:

Thank you, Kedar. Greetings to all of you and welcome to this Conference Call.

You would have seen our press release issued on last Friday about the warning letter that we received from the USFDA. We also shared brief comments later with the media on that day. At this stage, we have just begun to compile the response on our comprehensive plan for the corrective and preventive action (CAPA) for submission to the agency. This call is meant to give you a broad idea as to how we are approaching the matter. During the call, we will avoid discussing any specific observation made in the letter and we will also avoid any speculative comments or the next steps likely to be taken by the agency since that would be very clearly inappropriate. The letter mentions our three sites – the API sites at Srikakulam and Mriyalaguda and our Formulation site at Duvvada, Vizag. We have been given 15-days' time to respond and till this matter is resolved the agency may withhold approval of any new applications which involve these sites. The issue cited in the letter are cGMP violations relating primarily to (a) documentation, practices and control, (b) laboratory testing procedures, (c) incident investigation practices as well as (d) some standard operating procedures. At this time, we feel confident in the safety and efficacy of our products; however, we plan to do a comprehensive assessment of any risk to the quality of our products. This time there is no directive from the FDA to stop the manufacturing activity or shipment of any products from these sites. As we respond to the agency, it is imperative for us to continue to strengthen our quality management systems and processes and enhance the infrastructure for training and development of our staff on the current cGMP practices. We have instituted corrective actions to address the 483 observations received earlier in each of these sites which formed part of the updates shared with the agency. The recent letter underscores the need for us to reevaluate the work done in light of the observations raised and continue to implement CAPAs fully, assess the impact of FDA's observation on our products as well as enhance our overall quality management system. We would also need to perform additional detailed third-party assessments of our quality systems and evaluate our global manufacturing operations to ensure compliance with cGMP regulations. While this work is on, we will parallelly attempt to derisk supplies by transferring select products to alternate sites. We have already taken steps to implements such transfers and there is a dedicated team actively focused on this activity. However, considering the amount of work involved in such transfers and capacity constraints, we should be prioritizing only select products for this process. Clearly, we are not happy with the fact that we could not resolve the Form 483 observations to the agency's satisfaction. We have always taken quality and compliance matter seriously and we will continue to remain focused on the remedial measures. We have embarked on an initiative to revamp our quality systems and processes as a top organizational priority. We will obviously not compromise on making any required investments in

terms of training, consultancy as well as other areas as may be required to bring us back into compliance.

Finally, always been our endeavor to be transparent with all our stakeholders on material and important matters like this. We shall continue to update you further at periodic frequency.

With these initial comments, I would like to open the call for Q&A.

Neha Manpuria: Sir, the fact that we have got one warning letter for these three facilities, does that mean that the issues raised in the Form 483s were similar for all of these and therefore this one letter or is it the USFDA is taking a more corporate approach to the entire process?

GV Prasad: There have been one or two common elements, but not across the board. So, I would assume that it is a corporate action that the FDA wants us to take in improving the quality management system.

Neha Manpuria: You also mention that you would obviously be taking correction actions to address the observations raised in Form 483, which have not been satisfactory as per the USFDA and hence the warning letter. How would you go about identifying as to what additionally needs to be done to address what is required in the warning letter?

GV Prasad: The FDA has also given us some areas they would like us to see specifically. It is in the area of third-party evaluation of product quality and third-party verification of some of the actions we have taken and things like that. So, we have fairly good idea of what their expectations are from the warning letter itself as well as from the observations that they cited in the warning letter are a subset of the 483 observations which clearly carry a few themes. We understand those themes and we are using expert advice to help us understand what else should we be doing other than the actions that we have taken so far to meet the FDA's expectations. We are seriously working on that. In the next two weeks, we will come out with a comprehensive plan and then submit it to the FDA.

Prakash Agarwal: Just trying to understand this procedure better. In October, you got this OAI and it results in a warning letter. So, is there a typical procedure that 483 and then OAI, and then the warning letter. If you could help us understand the process, that would be really helpful?

GV Prasad: The fact that it is OAI is not very clear when the observations are given. The FDA maintains a website where they indicate OAI or potential OAI or VAI. I think this has been a recent change in the FDA's way of working. So, we are also learning this process as we go forward. We have been giving regular updates and responses but we did not have any feedback clearly from the

FDA on this matter. So, beyond this I am not clear how the system really works within the FDA.

Prakash Agarwal: Just trying to understand with respect to this warning letter, was the OAI been informed to us in the past or it came just in October with the customer approval getting rescinded?

Saumen Chakraborty: It came with the customer ANDA approval rescission that we got to know about these two API sites from where the API was supplied for the customer. But along with initial observations, there was no indication recd.

Prakash Agarwal: Secondly, just trying to understand, so as you said clearly it might delay the new approvals and two comments here -- one is, is it also fair to assume that the filings from this facility will not be one of your priorities now and it would come into priority once it is totally resolved or you would continue to file from this site?

GV Prasad: We are looking at all aspects of this remediation plan. Our first priority is products in the market. How do we ensure that the FDA and others are assured of their quality of the product, that is number one priority. Number two is our remediation process. After that we will also evaluate the filings that we made here and we will also take risk mitigation steps in terms of alternate sites for our filings as we go forward.

Prakash Agarwal: You talked about in the 2Q call that Gleevec is one of the big products which we are already working on the de-risking, we also see there is a DMF file for us. So has this been totally de-risked now or it is in the process of getting derisked and hence the statement that we would be coming a few quarters later than Sun's approval?

Kedar Upadhye: At this stage we will avoid getting into a product-by-product conversation. So as we said, we are less concerned on the new launches because we have several mitigation options possible.

Abhijit Mukherjee: I actually clarified in the last call; it is an external API. It has nothing to do with our internal API. API is from another external source.

Prakash Agarwal: We have good certainty on launching this product as of now?

Abhijit Mukherjee: You asked about the API and the risk. Naturally, it is an important product, all efforts will be on. I would not comment on certainty and other things, but since you said which site API, API is from an external source.

Anubhav Agarwal: Just wanted to confirm one thing that in the warning letter, what has FDA expressed disappointment with -- is it more towards the initial corrective action plan suggested by Dr. Reddy's or the implementation of the corrective action plan?

GV Prasad: It is primarily the initial response to the plan.

Anubhav Agarwal: So, you are saying the scope of the plan is what you may want to enhance because to earlier question, you said that FDA has mentioned something like third-party verification, etc., which is more like implementation, right?

GV Prasad: Yes, but I think we did not include these aspects in our initial response and FDA wants us to focus on these issues, also get third-party verification and third-party evaluation of certain things. Also do it across our manufacturing network.

Anubhav Agarwal: Just to get it right. So, one is like getting an external agency validation of what you have done, but beyond this what you suggested, let us say what you need to come back in compliance with the FDA deviations, does any of that thing is changed or the scope just needs to be augmented with validation by third-party?

GV Prasad: No, there is significant more work. We are working on it. I cannot give you that level of granularity today. We are still working with several advisors, and we are also fine with this. So, it has to go beyond our original response that is clear to us. So, we are still working out what that means to us.

Anubhav Agarwal: Is there any physical constraint on doing site transfer because theoretically on paper, it is possible to do site transfer for all the affected products, right?

GV Prasad: There is a lot of work involved, it is not just simple transfer, in some cases, we are not transferring also, we are just changing the source of the API. So there are various strategies to address this issue.

Anubhav Agarwal: Why I am asking this question is, of course for n-number of months, till the time warning letter is effected, you may have plan of launching 15 products. But I was asking that, out of 15 products, maybe 5 or 7 maybe more relevant, but even doing site transfer 5, 7 products in a year, is that physically possible or that is very much doable?

GV Prasad: I do not want to talk too much about product level discussions but I think our first priority today is products in the market, ensuring thereof we will meet all requirements and ensure there is no risk to anything. That is our primary focus. We will also mitigate the filings as we go forward. But our first priority today is remediation, risk assessment and ensuring products are available what we are producing in the marketplace.

Charulatha Gaidhani: My question relates to what is the impact on Injectables in terms of revenues and in terms of profitability.

Abhijit Mukherjee: Not much at the moment. About a very large part of the injectables manufacturing is outsourced. In the course of lifecycle of these products we brought this into the site. The manufacturing continues. Since now it is both outsourced and in-house, it is happening with a certain ratio and we keep that ratio depending on the financials on how we want to drive that, but broadly it is a mix of same products, two options.

Charulatha Gaidhani: The impact on profitability?

Abhijit Mukherjee: If the impact on manufacturing is less slightly then our profitability will be less slightly, but this is based on currently as we understand, but as I said, gReclast, gZometa are certainly outsourced, whereas gDacogen gVidaza are outsourced plus in-house, both options.

Charulatha Gaidhani: Relating to Azacitidine and Decitabine, the Oncology Formulations as a percentage to total revenue?

Kedar Upadhye: Roughly, 20% of the US business.

Charulatha Gaidhani: Oncology would be contributing more to the profit?

Kedar Upadhye: It would be relatively higher, but let us avoid product level margins conversation on that at this stage.

Girish Bakhru: When you say you will have to instill some of these measures across the network, I am just trying to figure, is there any impact on say facilities outside these three that you would need to also be cautious on and put probably some more measures?

GV Prasad: Absolutely, any corrective measure we take has to be implemented at all our sites and we have been doing that already; in the last several months we have done a number of enhancements and they have been rolled out across the network. We still have to work out whether we have a third-party verification across the network or only the affected sites, so that is something we are still determining.

Girish Bakhru: Let us say Bachupally, I am just trying to assess when is the next inspection due according to you for that particular site?

GV Prasad: It was recently inspected.

Girish Bakhru: When you say there is emphasis on third-party verification. Is FDA trying to suggest that whatever third parties you have used currently are inadequate and you might need to either add more or change? So in terms of consultants, are you looking to change that part?

GV Prasad: No, we think we are in good hands there.

Girish Bakhru: No, I did not understand, what then third-party verification?

GV Prasad: Scope of the work has to increase. So that is the only thing now. More confidence and more scope of the work that they are doing. We have not done any third-party verification till today. So we do not have that yet.

Girish Bakhru: Is there any particular number that FDA comments on what kind of verification it needs or...?

GV Prasad: There is no specific guidance.

Girish Bakhru: Just on the ANDA side, I know, warning letter per se does not stop you from selling the products, but has there been any removal of any ANDA approval because of this warning letter?

GV Prasad: For the APIs indicated in these sites, approvals have been stopped.

Girish Bakhru: But those are only customer ANDAs, right, not your own ANDA, right?

GV Prasad: Some of our ANDAs are also there.

Abhijit Mukherjee: Those ANDAs which are removed have specifically or have been approved after audits took place in the sites. They were by mistake approved because once the sites are audited but not fully resolved in terms of the observations if any approval goes out. They realized that and then withdrew those and those are for our customers. In one of those products, we never got approval in the first place itself. At the moment there is nothing before or after exact period after which or it took place till date.

Girish Bakhru: So, from the inspection to this date, just number wise, how many ANDAs were these?

Abhijit Mukherjee: As we said in the Call, two of our customers, ANDAs were rescinded?

Girish Bakhru: Two customers, ANDAs, right? Not any that which you thought was your own ANDA, right? I am just trying to understand this.

Saumen Chakraborty: What Abhijit is saying that we did not get approval at all, because it is not like ANDA approval does not come?

Abhijit Mukherjee: You are not talking of not getting approval, you are not getting approval. That is a separate issue. Rescinding is a term where you have got approval and that has been withdrawn.

Sameer Baisiwala: You talked about recent inspection at Bachupally FTO-III. I see there are some 483s which were issued over there June '15. Can you talk a bit about it?

GV Prasad: Yes, around five months back.

Sameer Baisiwala: When you say that, these three warning letters were so to say corporate-wide action, why did they not impose a same thing on FTO-III?

GV Prasad: I think FTO-III was not considered that severe. They were all correctable issues and I think we have already addressed some of that and I think the observations were of relatively less serious nature.

Saumen Chakraborty: FTO-III they did not link at all in this warning letter. Actually, Mriyalaguda and this have been linked is also a surprise, we did not expect that link.

GV Prasad: Sir, we have had several inspections after this incident also. In some cases, there were no 483s, in some cases there were some small 483s.

Sameer Baisiwala: Those sites where there were 483s, but not included in the recent warning letter, should we assume that they will remain out of that or the chance that they can also be included?

GV Prasad: To the best of our knowledge, I think they will not be included.

Sameer Baisiwala: Is there a distinction that you would make between your older sites and newer sites because Srikakulam and Duvvada, I would imagine are far more recent sites versus Miryalaguda and others which are older ones and they in general have never given you any such problems?

GV Prasad: Srikakulam is almost a 25-year old site.

Saumen Chakraborty: In Srikakulam we have a new site, that is the SEZ facility, both are in this place called Srikakulam district. The SEZ site where we got a lot of 483 is the old site, that is not the new one.

GV Prasad: It is one of our oldest sites. FTO 7 (Duvvada) is a reasonably new site.

Sameer Baisiwala: Would you make a distinction between old and new whenever we do site visit, we are told that the new sites, your investments are far more higher, they are far more advanced, the installations like keeping next five years in mind etc., what FDA may issue guidance. So surprised to see a newer one also being part of this warning letter.

GV Prasad: This is also relatively new but the Injectable site is one of our early ones. And these are not related to equipment or infrastructure observations. They are primarily around documentation practices and control, laboratory testing procedures and incident investigation. In the case of Injectables facility there is added issue of how we manage the sterility in the system.

Sameer Baisiwala: In Duvvada, you have got two blocks, the other is the non-Cyto. So this warning letter specifically relates to Cyto or does it include both?

GV Prasad: It is only Cyto.

Saumen Chakraborty: The other facility is a different facility, it is not only different block, a different inspection will happen for that.

Sameer Baisiwala: But it is in the same premise I thought they were using the common gates?

GV Prasad: It has a different identity and establishment.

Saumen Chakraborty: There is a physical demarcation.

Sameer Baisiwala: Is there now a risk of escalation at these three sites from warning letter to an import alert?

GV Prasad: I cannot speculate on that but we are doing our best to respond and address all the FDA concerns as comprehensively as we can. So beyond that I cannot speculate about what FDA will do.

Sameer Baisiwala: As a matter of process, after 483, we are generally left in maybe 9 months, 12 months or even 15 months, wondering whether it is going to get better or worse. But after warning letter, is uncertainty so long or do you think within once you respond 15 days and then maybe a month or two months, FDA will take an action either which way?

GV Prasad: I really cannot answer this question. I think it really depends on what FDA thinks of our response and our approach to remediation and we are doing our best; we are fully committed to doing whatever we should to ensure that FDA gets assurance about our intention of actions.

Surjeet Pal: I have two questions; as you stated on Bachupally, is there any other plant for your still 483 pending and you were concerned for that?

Kedar Upadhye: I think we clarified, in case there is anything reportable we would have reported. There is is nothing to be reported.

Surjeet Pal: How many pending ANDAs to be impacted out of the three plants which currently under scanner?

Saumen Chakraborty: ANDA comes only from the Formulations site, we are basically talking about Duvvada facility.

GV Prasad: Or we will be using the APIs.

Kedar Upadhye: Surjeet, we would avoid getting into that at this stage.

Surjeet Pal: I was just thinking is that as you say it is that there could be some approval particularly since your basic theme of developing pending ANDAs on Oncology and Oncology Injectables in near to medium term as complex products with limited competition drugs, so, from that perspective, how much those kind of future could be impacted, even if not numbers, even if you could give some qualitative analysis on that?

Abhijit Mukherjee: I do not recall exact numbers, but could be the ones which is filed and pending would be four or five. One or two maybe some slightly more near-term and the rest are little further down which provides ample time for looking at alternatives if need be. So broadly that is where we are. This is also global Oncology site, so caters to the other parts of the world as well.

Surjeet Pal: The third-party oncology product which you manufacture which you might be supplying API from here. So are you supposed to source from third-party API or you were supposed to supply your API to continue your third-party Formulation?

Abhijit Mukherjee: The way you have filed the ANDA, you have to follow the same procedure. With the third-party API, third-party dosage and ANDAs, the same is the way one has to continue. If you have filed in alternate site of in-house API or in-

house dosage manufacturing, then you can have the alternatives. So depending on what you have filed, you have to continue.

Surjeet Pal: So, what it implies is the post warning letter, if you want to derisking the scenario, so, you might be looking for third-party source of API?

Abhijit Mukherjee: If need be, for sure, yes. Anyway this is normal for all companies, not just for us to look at the alternatives at any point in time.

Surjeet Pal: So I am just wondering, it will definitely impact your operating margin?

Abhijit Mukherjee: In the type of products one is talking about, the tech transfer to other sites, buying in APIs may or may not make very-very significant impact of course, some impact, but these are a little more on the higher end specialties.

Surya Patra: In the OAI indication or communication, whether USFDA has already indicated about certain kind of corrective measure that is required in all of your facilities which are…?

GV Prasad: OAI is only a status indicator. The warning letter has some directions in terms of where they want us to go and we will use that to respond.

Surya Patra: Sometime back you had indicated that your Srikakulam facility is to be de-risked for the near future by site transfer and all that. So, you still stand by that statement or you are revising that considering the kind of recent development?

GV Prasad: I do not think we said Srikakulam is derisked. We said certain key products are derisked from that site. So it is not that the entire site is derisked.

Surya Patra: Any idea about the kind of budget for the remediation activities?

GV Prasad: It is too early

Surya Patra: We have indicated that 10% to 12% kind of revenue implication. Could you say that what was the mix between the APIs and kind of Formulations?

Saumen Chakraborty: Not at this stage.

Manoj Garg: Abhijit, just want to understand from an Injectable perspective. Do we have any other USFDA approved Injectable facilities apart from this?

Abhijit Mukherjee: The one which we were referring a little while back in the same premise which is not approved, but the filing has started. That is non-Onco Injectables.

Manoj Garg: Meanwhile, till the time these remedial measures will go on this facility, are our filing still remain in process or we may have hold down filing for the time being before this plant comes under compliance?

Abhijit Mukherjee: Depending on the time scale in which we would see the asset in market, many assets have three years, four years, there are lots of forward-looking assets, those will fall in one category, and the category which are very near-term will fall in other category where there will be more of a partnership approach transfer.

Manoj Garg: So net-net our filing process will not stop whatever the status of the facility at this point of time, is the understanding correct?

Abhijit Mukherjee: I do not think one can do that with a very kneejerk reaction. The assets which are a few years away, I think certainly filing would continue.

Manoj Garg: Mr. Prasad, like in your opening remarks, you said that this is going to take significant time in terms of obviously do the course correction. I understand most of the corrective action, which you were supposed to take and you have taken apart from third-party validations and bringing third-party consultants out there. But when you talk about significant time, how much it could be -- three months, six months or maybe more than that?

GV Prasad: This is an ongoing journey, it is not that we can quickly fix everything in one go, this is going to take significant effort and time. We cannot predict when the FDA will come back. It all depends on the plan that we present, the action that we put in place the progress show. I cannot talk to you today about timelines.

Manoj Garg: We have spoken about doing the site transfer for our future filings out of Srikakulam. I understand that there are a lot of large products, which have

been linked to Srikakulam where the API is being supplied from Srikakulam. Any plan to de-risk even those kinds of products also?

GV Prasad: We have to look at value and prioritize accordingly, but that is our second priority, our first priority is remediation.

Prakash Agarwal: Just trying this on the process again. Normally, we see import alert to be much more faster post the 483 and it is not necessarily seen that, import alert is always followed by warning letter. So have you looked at history and would it be fair to say that the chances of import alert is now very remote because if it would have had to happen, it would have happened in the first three months to six months, not on your case, but just looking at history, because you must have looked at various data points?

GV Prasad: I cannot respond to this question. I cannot speculate on this. It is difficult.

Prakash Agarwal: One clarification; you spoke about the observations on this warning letter. So if you could please repeat once more that would be great.

GV Prasad: If you categorize them, they are in four broad categories; documentation and control, practices and control, laboratory testing procedures, adequacy of standard operating procedures and incident investigation practices. These are the buckets, but within them there are some nuances, some of them are computer controls, some of them are paper controls, some of them are how we handle chromatograms and all that. The warning letter should become public in a few days where it will be posted on the website of the FDA, I think you will get more details there.

Chirag Talati: A couple of them; first, just to understand the procedure a bit better. When you go for a site transfer of a product that is not yet approved, you would necessarily need to file a PAS rather than going for a CBE-30. Is that understanding correct?

Abhijit Mukherjee: Yes, that is right and you have the option of later even pulling out the earlier this thing.

Chirag Talati: In that case, you would need to go for complete 6-months stability data from the new API source?

Abhijit Mukherjee: Again, it depends on case-to-case and depends on product-to-product, in certain cases, it is the products. There are some broad guidances. There are some variations as well which can be pursued depending on how critical is the product for the market. We are following the right procedures and doing what needs to be done.

Chirag Talati: On the Vizag SEZ Onco block, I would assume that you got your understanding with your partners fairly kind of set out so that there is no issues in terms of disruption in supply is one. Two, given that this is a fairly new facility, can you help me understand, first, was it on microbiology data capture that you had the observations coming up, and are these observations similar in terms of capturing of data that you had in your Srikakulam facility as well?

GV Prasad: It is nothing to do with Srikakulam. This facility is not that brand new, it is a 6-7 year old facility. The broad areas is when incident occurs, the time taken to raise an incident, one of them was that incident in investigation, other one was how the whole system hardware operates and how it is reconciled, things like that, but nothing to do with actual microbiology or sterility itself but largely are around procedures.

Chirag Talati: Because you see from the Miryalaguda, Srikakulam 483 and also the Vizag the observations that you are talking about, it seems like there has been this consistent pattern of hardwares on at least the control site not being in place properly. So, is that why the FDA is asking you for a global corrective action plan in a way?

GV Prasad: I think there are some themes, document control, computer control, investigations, which are probably themes across.

Chirag Talati: Were these also raised at Bachupally?

GV Prasad: No.

Kedar Upadhye: Thank you, all for joining Dr. Reddy's senior management on this conference call. In case of any additional clarifications, please feel free to reach out to Investor Relations team. Thank you and good day.