

DOR BioPharma Corporate Update Conference Call
October 22, 2007
9:00 a.m. Eastern Time

Operator: Welcome to the DOR BioPharma Corporate Update conference call. At this time all participants are in a listen-only mode. Following management's prepared remarks, we will hold a Q&A session.

To ask a question at that time, please press the star key followed by one on your touchtone phone. If anyone has difficulty hearing the conference, please press star zero for operator assistance.

As a reminder, this conference is being recorded today, October 22, 2007. I would now like to turn the conference over to Keith Thornton, Director of Corporate Communications. Please go ahead sir.

Keith Thornton: Good afternoon, this is Keith Thornton, Director of Corporate Communications with DOR BioPharma, Inc. Thank you all for participating in today's call.

Joining me from DOR BioPharma are Dr. Christopher Schaber, President & Chief Executive Officer; Mr. Evan Myriantopoulos, Chief Financial Officer and Dr. Robert Brey, Chief Scientific Officer. Also, joining us today is Dr. George McDonald, Professor of Medicine, University of Washington and Head of Gastroenterology at the Fred Hutchinson Cancer Research Center. Dr. McDonald is also the inventor of orBec and a Clinical Advisor to DOR.

Before we begin, I would like to caution that comments made during this conference call by management will contain forward-looking statements that involve risks and uncertainties regarding the operations and future results of DOR BioPharma.

I encourage you to review the Company's past and future filings with the Securities and Exchange Commission including, without limitation, the Company's Forms 10-K and 10-Q, which identify specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, October 22, 2007. DOR BioPharma undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

With that said, I would like to turn the call over to Dr. Chris Schaber. Dr. Schaber.

Christopher Schaber: Thank you, Keith. Good morning everyone, and thank you for joining us.

Once I've completed my prepared remarks, we will take any questions you may have.

As most of you joining us on the call today are aware, we issued a press release on Friday October 19th summarizing the FDA Not Approvable Letter we received after the close of business last Thursday for our lead product orBec in the treatment of acute gastrointestinal Graft-versus-Host Disease (or GI GVHD), which is a common and potentially life-threatening complication of hematopoietic

cell transplantation (HCT). The Not Approvable Letter is an official notification that the FDA has completed its review of the orBec[®] New Drug Application (or NDA) and that, due to specific deficiencies noted, the NDA is not approvable at this point in time. Unfortunately, in the letter the FDA stated that the existing clinical data did not support regulatory approval and that additional prospective, randomized, controlled clinical trials are required. Additionally, comments and requests were also noted with respect to other sections of the NDA. It is important to note that the FDA letter is not an indication that FDA is unwilling to ever approve orBec, but rather a request for additional data before approvability can be re-considered.

Since we believe that orBec has demonstrated a significant amount of corroborative and positive data, we have no hesitation in informing you that we fully intend to drive the orBec program through toward ultimate approval. As was noted in the press release, we have requested a meeting with the FDA's Division of Drug Oncology Products to discuss next steps. Once we gain further clarity, we will be able to provide more accurate guidance moving forward.

Our interactions with the FDA during the review process have been collaborative and productive. Coming out of the meeting of the Oncologic Drugs Advisory Committee (or ODAC) on May 9, 2007 where the panel voted that substantial evidence of clinical efficacy had not been demonstrated with orBec, we were encouraged with some of the closing remarks made by Dr. Richard Pazdur, Director of the Office of Oncology Drug Products regarding orBec. These comments provided an important starting point for further discussion with the FDA regarding the clinical benefit of orBec in treating this life-threatening disease.

In fact, on June 13th, we had a face-to-face meeting with the FDA to further discuss our NDA. We discussed with the agency potential strategies for further elucidating the full clinical effect of orBec in the treatment of acute GI GVHD. At

the completion of the June 13th meeting, at the FDA's request, we agreed to review existing data from both randomized, double-blind, placebo-controlled trials submitted in our NDA, and highlight data which reinforced that clinical effect. This supplemental submission to the FDA was made on July 13, 2007. Following the agency's review of this submission, this report was classified as a "major amendment", and resulted in a 3-month extension of the original PDUFA date to October 21, 2007.

I am truly disappointed to announce that the collaborative effort on the part of our team and the FDA review team has culminated in a not approvable decision communicated to us via letter on the evening of October 18, 2007. The FDA has stated that additional prospective, randomized, controlled clinical trials must be conducted. While we were obviously hoping for a different outcome, given the consistent clinical effect we believe we had demonstrated in both of our double-blind, randomized, placebo-controlled trials, we firmly believe in the pharmacology of orBec, and its potential to help address the overwhelming need for a safe and effective treatment for patients suffering from GI GVHD.

At this time I would like to introduce Dr. George McDonald, Head of the Gastroenterology/Hepatology Section at the Fred Hutchinson Cancer Research Center and also the inventor of orBec and DOR's key clinical advisor to provide an important medical perspective on the FDA's decision. Dr. McDonald.

George McDonald: Thank you Dr. Schaber.

I am very disappointed that the FDA has required additional clinical data, thus delaying the availability of orBec to patients that need it. In the next few minutes, I want to give you my view of the orBec data to date. By way of background, I have been in academic medicine for over 35 years and published over 200 peer-reviewed analyses of data. I come to the table with experience in both data analysis and implementing advances in practice based on these analyses. In addition, I am a practicing physician who takes care of these very sick patients.

The data on oral BDP for GVHD do not suggest any safety concerns—BDP has been used in patients for over 40 years, its metabolism and effects are well-understood, and in the data submitted to the FDA, there was no data, in my opinion, suggesting that safety issues should be a concern here.

Two randomized, double-blind, placebo controlled trials showed that a statistically significantly greater proportion of GVHD patients were well at the end of treatment if they received oral BDP, compared to placebo. Being well means that they were not nauseated, not vomiting, not having diarrhea—and not on high-dose prednisone or having prednisone side effects. At the June 13th meeting, the FDA asked for more evidence of patient benefit, in addition to absence of symptoms and avoidance of prednisone. In order to gather this information, we reviewed all adverse events for the phase 3 randomized trial and sent these data to the FDA. As would be expected, more patients randomized to placebo, had bacterial and viral infections and pulmonary infiltrates, compared to oral BDP. In my opinion, oral BDP has clearly demonstrated its substantial clinical benefit.

In two randomized, placebo-controlled trials, patients who were free of GVHD symptoms and feeling well at the end of the treatment period were followed off of therapy to see how durable the treatment effect was. A statistically significantly greater proportion of GVHD patients remained completely well at the end of the follow-up period if they received oral BDP, compared to placebo, differences that were statistically significant in both trials. What does this mean for patients? It means that a larger number of patients in the oral BDP arms were well for almost 3 months after their onset of GVHD, compared to placebo. A larger number of patients free of vomiting, free of diarrhea, free of prednisone side effects. In my opinion, the durability of oral BDP's treatment effect on gastrointestinal GVHD has been demonstrated.

The pivotal phase 3 randomized, placebo-controlled trial showed a highly significant reduction in mortality at transplant day 200 among patients randomized to oral BDP, compared to placebo. Day 200 in the transplant field is regarded as the time by which the immunologic fires of acute GVHD have run their course for most patients. In addition, data was submitted to the FDA that showed clearly that there was a statistically significant, 45% reduction in the risk of mortality one year after randomization in the oral BDP arm, compared to the placebo arm, in the pivotal phase 3 trial. Remarkably, mortality data at one year post-randomization in the phase 2 clinical trial revealed the same 45% reduction in the risk of mortality—the exact same magnitude of reduction in the hazard of death. In my opinion, the evidence that oral BDP improves the outcomes of patients who have GVHD is compelling.

As my colleague Dr. Keith Sullivan, Professor of Medicine at Duke University Medical Center noted at our May 9th ODAC panel meeting, the orBec[®] clinical results are unique in that over the past 30 years of clinical research for the treatment of GI GVHD, only the Phase 2 and Phase 3 orBec[®] trials have demonstrated statistically significant efficacy in treating GVHD as well as improved survival. All other immunosuppressive agents studied in the treatment of GVHD have either been ineffective or have led to increased mortality. The two BDP trials are the only exception to date.

It is unfortunate that orBec will not be approved in the near-term, while thousands of patients with acute GVHD will be deprived of a useful drug in the interim, before the next trials are completed. It is my opinion that the data presented to the FDA made a compelling case, but I am confident that orBec will ultimately be approved. As one experienced transplant oncologist told me, “It works, and it’s safe.” Thank you – Dr. Schaber.

Christopher Schaber: I apologize that Dr. McDonald may have cut out of his portion of the script. I don’t know if it’s just our line or the entire conference call.

Operator, can you confirm?

Operator: I do not hear him cut out.

Christopher Schaber: Okay. That's the other phone then. So I will continue. Thank you, Dr. McDonald.

As you would anticipate, we will be meeting with the FDA in the near future to gain a better understanding of the points made in the Not Approvable letter. Once we have additional clarity regarding the most direct clinical development path moving forward to potential marketing approval, we will be able to provide guidance with regard to a timeline to trial completion. We also plan to discuss with the FDA the potential for an orBec treatment IND, including cost recovery, to allow clinicians and their acute GI GVHD patients access to orBec over the near-term.

Additionally, we anticipate continuing our discussions with potential business partners to ensure DOR is properly resourced to complete the execution of the Phase 3 program. Our mission with orBec[®] remains unchanged; to bring this potentially life-saving therapy to the patients that need it as rapidly as possible.

DOR will continue to pursue its goal of transitioning into a fully-integrated product development company by:

1. designing and conducting the FDA-requested Phase 3 orBec clinical trial(s);
2. pursuing the European orBec marketing authorization application (or MAA) currently under review by the EMEA; and
3. continuing to develop and operate our development pipeline programs under the various NIH grants currently in place; including enrollment in the

new orBec Phase 2 clinical trial, which is currently underway in the prevention of acute GVHD.

This clinical trial, which is actively enrolling, is a double blind, randomized, placebo-controlled study with orBec to **prevent** or reduce the morbidity and mortality associated with acute GVHD in patients undergoing bone marrow or stem cell transplantation. In this trial, which is funded in large part by NIH grant monies, a total of 138 patients will be treated at the time of transplant and for a period of 75 days after transplant with the objective of preventing the emergence of GVHD, or reducing its severity. Enrollment in this trial is currently targeted to complete by mid-2008.

Further studies evaluating orBec and its active ingredient oral beclomethasone dipropionate or BDP, are currently in preparation. These include preparing for the conduct of a clinical trial in the treatment of chronic GVHD, as well as preparing to initiate preclinical studies of oral BDP in radiation injury, which is the subject of a \$1M NIH grant to investigate oral BDP in a well established animal model of radiation exposure.

In addition, we have a robust pipeline behind orBec and oral BDP that we are actively developing. We are progressing with our proprietary LPM oral drug delivery system. LPM stands for Lipid Polymer Micelle and it is designed to enhance the intestinal absorption of therapeutic peptides that are not ordinarily absorbed or are degraded in the gastrointestinal tract. As the first pharmaceutical application of the LPM system, we are developing an oral formulation of the peptide drug Leuprolide. Leuprolide is an inhibitor of the gonadotropin releasing hormone, a key hormone for the control of fertility in humans. Leuprolide and other agonists of the gonadotropin releasing hormone are used for the treatment of prostate cancer and endometriosis among other conditions, and command a market of over 1.5 billion dollars annually. Due to

current delivery limitations, Leuprolide must be administered as an intramuscular or subcutaneous injection.

The value of LPM Leuprolide was first demonstrated in rats and further in dog studies. With the LPM system, we have successfully increased the bioavailability of Leuprolide in these species from about 2% with the control formulation to about 30% with LPM.

Based on these promising preclinical data, we anticipate preparing for a Phase 1 study in humans during 2008 to confirm these findings. We anticipate that our formulation technology can then be applied to other peptide therapeutics that are currently only marketed as injectable drugs.

We have also recently announced the issuance of US and European patents for our compound Oraprine (or azathioprine) a well known immunosuppressant with a well established safety profile. These issued patents focus on the use of Oraprine as a liquid mouth rinse for the treatment of oral lesions of the mouth associated with chronic GVHD. This is an orphan indication which you will potentially be hearing more about in the coming months.

We are very excited about the potential of our development pipeline, and expect the coming year to be one where we make meaningful progress on this front.

Moving to our Biodefense programs ...

In September of 2006 we announced receipt of NIH funding of approximately \$5.3 million for continued development of two vaccines that address significant bio-threats. These awards follow an award of \$6.4 million in the fall of 2004 to develop a preventive vaccine for ricin toxin.

We have focused our efforts on our ricin toxin vaccine, known as RiVax, and our botulinum toxin vaccine, known as BT-VACC. We expect that these vaccines, if approved, will at some point garner sizeable procurement orders from the US government under the Project BioShield Act and its successors, and will be an integral part of civilian and military stockpiles as major deterrents against use of these biothreats.

The first of these programs is RiVax – a vaccine that protects against exposure to ricin toxin, which is a poison that can be made with relative ease from castor beans. Ricin toxin can be easily aerosolized and cause not only death at high doses, but also long-term lung damage in survivors. The other program is BT-VACC, which is an orally administered vaccine to prevent paralysis from exposure to botulinum toxin. Botulinum toxin is one of the top Category A biothreats identified by the CDC and the NIH and is an incredibly potent bacterial neurotoxin.

We have recently made you aware of an important step in the development of BT-VACC with demonstration in animals that a multivalent vaccine based on non-toxic recombinant subunits can be given by the mucosal route and elicit protective immunity against all three deadly serotypes of botulinum toxin. This has never been done before with a botulinum toxin vaccine. These results were recently published in the Journal of Infection and Immunity. An oral vaccine for botulinum toxin is feasible because the subunits bind to cells in the GI tract, a property distinct from the majority of subunit vaccines. The possibility of mucosal administration would make the dissemination of this vaccine easier and more convenient for an end-user in the event of an emergency. We have obtained a significant amount of initial R & D funding for this program through grants and expect to continue development through further grants and contracts, as this segment of our business is driven solely by civilian government and military priorities.

For RiVax, we have also obtained funding in the form of several competitive challenge grants and cooperative grants from the NIH over the past several years. These current grants have so far totaled over 11 Million dollars and enable us to conduct process development for production and scale-up of the vaccine subunit, and to move into advanced state of formulation development and testing of the vaccine. To date, we have developed a scalable process for the manufacture of the active component of RiVax, a non-toxic subunit of ricin toxin that is devoid of the known toxicities of the natural toxin. It should be noted that the total program is also supported through NIH grants to our academic development partner, the University of Texas Southwestern Medical Center, where Dr. Ellen Vitetta has separately obtained NIH funding to conduct basic and translational research into immunological mechanisms of ricin protection in animals. This has resulted in numerous publications underlying the technology during the past few years. We also conducted a small clinical trial with the University of Texas that has demonstrated the safety and immunogenicity of an early form of the vaccine. We now are progressing this work towards evaluation of a new stable adjuvant form of the vaccine. Additionally, the University of Texas has recently received a \$1M dollar orphan drug grant to conduct additional human clinical trials.

On the corporate strategy side, we are employing a two-pronged approach to Biodefense:

- We are actively looking to partner or sell our biodefense assets in a way that would further support development of these vaccines even beyond that which our NIH grants provide;
- While also conducting diligence on several new product candidates that would enhance our biodefense pipeline so that it can be a stand-alone business. These new product candidates have the potential to be funded by government grants, while some have the potential to generate near-term revenue for DOR.

On the Biotherapeutics side, we also have several product development candidates that we are in the midst of diligence on. These compounds have the potential to be synergistic with our existing orBec portfolio, including treatments of diseases of the GI tract or byproducts of cancer and its treatment.

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This has been, and continues to be, a very important time for DOR BioPharma. We have received feedback from the FDA for our lead product orBec in the treatment of acute GI GVHD. The next step will be to outline with the FDA the plan for moving forward and to agree on a study design for the next clinical trials, so that we can make this product available to the many patients that need it as soon as possible.

We believe DOR's development pipeline offers a diversification of risk and considerable opportunity in a number of areas of unmet medical need. As discussed, we plan to step up our product development efforts in 2008, leading with the Phase 3 orBec clinical program, which is the subject of the FDA letter, as well as the Phase 2 orBec GVHD prevention study, which is currently actively enrolling in an expanded allogeneic transplant patient population.

Our Biodefense division continues to pursue its goals with new NIH funding, and we look forward to entering human studies with our RiVax vaccine against ricin toxin.

We believe the remainder of 2007 moving into 2008 will be a pivotal year for DOR as we continue to move forward with our plans for growth and development.

In closing, I would be remiss if I did not make note of the potential business development opportunities we potentially have before us as a result of this recent news from the FDA. There are a number of companies we have been interacting

with over the last several months that have been waiting with great interest for the outcome of the FDA review. As we look forward to further development activities with orBec, we could see potential collaborations ranging from acquisition to co-development and promotion which will need to be seriously evaluated in our ongoing mission to bring therapies to the patients that need them most while maximizing shareholder value.

With that, Dr. George McDonald, Dr. Robert Brey, Evan Myrianthopoulos and I would be happy to take any questions you may have. I will now turn the call back over to the Operator. Operator.

Note: This portion of the transcript has been modified for clarity.

Operator: Thank you, sir.

Once again, everyone, if you do have a question or would like to make a comment, press star-1 now.

Our first question or comment comes from Bill Knox.

Bill Knox: Good morning everyone. Dr. Schaber, I'd like to go back to the May 9 ODAC meeting. And at the end of the meeting, towards the end of the meeting, after the vote, Dr. Link specifically asked what would be the results if you had started the clock on the date of randomization.

And your response effectively was that the drug would have shown statistical significance and my question is on the follow-up supplemental submission, did you present that data?

Christopher Schaber: Bill, first, thank you for the question.

As you could imagine, that data was included in our original NDA that we filed, was the point of discussion and key review during the process, as was indicated and discussed at the ODAC panel meeting. So to answer your question, that information was made apparent very early on in the review process.

Bill Knox: Okay thank you.

Operator: Thank you, sir. Our next question or comment comes from Stanley Brenner.

Stanley Brenner: Yes, hi. I just want to talk about - it sounds like you have, you know, interesting pipeline but I don't think there's much cash and I was just wondering, isn't it imperative that you'd partner orBec now to try to get like 15 million or 30 million in cash and royalty of 15% or something like that.

And that will really enable you to strengthen your balance sheet, enable you to go forward with all your, you know, your - the programs that you've outline because it seems like unlike many biotech companies, you don't have cash but you do have some interesting product possibility.

Christopher Schaber: Thank you Stanley, very good question. And let me first say that on the partnering front, obviously, we have been in potential discussions with a number of partners and that process will continue obviously so that we may move these very important programs forward.

With regard to our current cash position, we've - as you could imagine, we've managed cash very carefully during this process and, that will continue as we move forward.

Maybe I'll have Evan Myrianthopoulos, our Chief Financial Officer, add any statements he may have as well.

Evan Myriantopoulos: Yeah, in answer to your question, this is Evan Myriantopoulos speaking, we have a comfortable amount of cash, which is about \$3 million. Our existing cash can last us through next year.

Actually, there's a couple of points I'd like to make here. We're a small company which operates frugally and has always been able to do more with less.

We do not need to raise money over the near-term. We will first assess, as Chris mentioned, all of our M&A and business development opportunity before us.

Remember also, that most of our R&D as well as a portion of our overhead is covered through existing NIH grants and we expect more in the future.

We have come a long way and going forward, we will finance the company in thoughtful ways that will keep our shareholder concerns about dilution in the forefront of our mind. We would not go to market to raise cash until we have a new Phase 3 treatment study open in enrollment. We also expect to be able to derive significant fees from the eventual sub-licensing of orBec around the world.

Stanley Brenner: Is there a market - what's the market in the European Union for the product. Let's say you do get approved there.

Christopher Schaber: The market in Europe, from the data that we've been able to derive is comparable to the US from the patient population side.

Stanley Brenner: And when do you expect to hear from the EU or the EMEA?

Christopher Schaber: As you could imagine, the European filing came after the US application, as we led with the US filing. We anticipate being able to hear with regard to their review of the application in the first half of 2008.

Stanley Brenner: Okay thank you.

Christopher Schaber: Thank you.

Operator: Thank you, sir.

Our next question comes from Michael Metter.

Michael Metter: Good morning. Part of my question was answered, but just sort of a hypothetical which might not be timely, but if you had gone in with to the FDA with a large pharmaceutical as a collaborator of the project, do you feel that if you had teams of lawyers is really on top of them that it would have been given more substance to it? It appears from what you're saying and your belief and that everything that's here is here works and there is an approval.

Are they not flexible or do you have to go in and manhandle them to get something through?

Christopher Schaber: Well, Michael, I can hear the frustration in your question, - as you could imagine, we're disappointed and a little frustrated as well. I, having worked in both big pharma as well as start-up companies, don't think a big pharma partner would have had any impact on our process here with the FDA.

I think that we had a very strong team, which included not only internal personnel and key medical consultants like Dr. George McDonald, very experienced in the field, but also had a regulatory team including food and drug law consultants that were actively involved in our process and interactions.

And so from that standpoint, at the end of the day, I think we put our best foot forward and in my opinion it would have been the same whether it was a big pharma or small company.

Michael Metter: Well saying that, I mean, is there any other major pharmaceutical companies or small pharmaceutical companies working on something similar?

Christopher Schaber: There are; off top of my head, I can't rattle off the companies, but there are small companies working on orphan diseases and indications and for many small companies that is the primary focus, the unmet medical need, the orphan indication.

So there are numerous companies operating in this area, small as well as large, but predominantly small.

Michael Metter: And how much impact does the FDA decision have on the European outcome here?

Christopher Schaber: Well by definition, the European Union, the EMEA has its own infrastructure, its own experts that evaluate, will evaluate, and are evaluating our data and application.

Having said that, there have been products in the past that the FDA has approved that Europe has not. There have been products that Europe has approved that the FDA has not. It all comes down to, as you would imagine, the review process with each individual health authority.

The European Medicines Agency will obviously have heard about the FDA decision here but we are taking an approach with the EMEA that includes not

only what we provided to the US NDA but with some aspects that are unique to the filing in Europe. And we will have to wait and see.

Michael Metter: Okay. And now, I mean, sorry about that. Do you feel that the FDA was - with all the data that's been presented, do you really feel that you'll get a fair (shot) in front of them again, especially with this overriding feeling that the drug really does work?

Christopher Schaber: I'm sure, you cut out a little bit, but obviously, one thing, and Dr. McDonald I think has spoken to this very clearly, is that the pharmacology of the drug is there. It has been shown, I think, very clearly from the Phase 3, with its secondary endpoints, to the Phase 2 trial showing statistical significance even though it is a small supportive study. You know, at the end of the day, we believe that the drug has an effect, as I'm sure many of you on the phone and many of the transplanters out there also believe.

We need to continue to work to get this product out there to the patients that need it and that is what our focus is and that's what will continue to do.

Michael Metter: Okay, thank you.

Christopher Schaber: Thank you.

Operator: Thank you, sir.

Our next question or comment comes from Jeffrey Benison.

Jeffrey Benison: Yeah, hi everybody.

Christopher Schaber: Hello, Jeff.

Jeffrey Benison: And I was going to go here and read through a load of your data because I don't think the drug is getting enough credit in all the endpoints that it made.

But I'll just kind of mention two of them, the - your 50-day endpoint which time to treatment failure, which didn't meet the statistical significance because of the early failures before orBec had a chance to work at 80 days which was just an increase in the matter of time of that endpoint, had a P value of 0.0226.

So there's no question that the drug works. The 80-day proportion of treatment failure endpoint, which is the endpoint that would tell the doctors that your - that people at 80 days that didn't have to undergo high dose prednisone, that endpoint met statistical significance with a P value of 0.003, which is a factor of 10 times more statistically significant than you needed in the primary endpoint.

The primary endpoint was the least important endpoint in the trial. Your survival endpoints are - as you said, the first time a drug has ever shown a survival benefit in this disease.

With data like that, although you people can't say anything negative about the people you're dealing with at ODAC, maybe I won't either because I don't know what was in their heads.

But I've seen where drugs and companies appeal decisions at the FDA. I don't want you to meekly go there and say what kind of clinical trial can we run to get this approved, because you've already run a clinical trial to get this approved.

Is there a way to appeal a decision to another part of the FDA? And the other question would be, well a point that I want to make is that I've seen plenty of ODAC transcripts and seen some other ODAC panel meetings and Dr. Pazdur has never said positive things about any drug at any of those meetings and he

did hear - he not only said he would entertain a treatment IND which I believe means in some kind of way that he wants to get the drug out to patients.

But he also said personally this drug because of this discussion irrespective of the vote has a different impact in my mind.

Now, is that a different impact than in his mind from when he got to the meeting and when - that when he heard the drug, because he was so involved with other things like Dendreon's product and IDMI's product that he really didn't look at the briefing document that his people put out.

Or does that mean a different impact in his mind that the ODAC panel said that the drug was ineffective and he believed that it was.

Well in either case, he believed the drug was effective. He said - he thought it worked and the fact that he wanted to do a treatment IND. And here they turned it down, maybe he has political pressure that he couldn't approve it.

But if you go to a different division at the FDA, he might actually be a supportive voice in that meeting.

And because the drug works, everybody that looks at the data knows that it works and it's going against the drug that hasn't even been approved and the other thing is, that if you fail orBec, the worst thing that happens is you get treated with the standard of care.

So it's not even a situation where someone may take a drug that doesn't work and not be getting a drug that does work, which is a problem.

Here if you fail orBec, you get prednisone. So it's a no-brainer that it should be approved.

And so I guess my big point is, the appeal process. I'm sorry I went in such a long winded way to get there.

Christopher Schaber: No, Jeff, obviously you've been with us for some time now, you've been a big supporter of both DOR as well as orBec and you probably know the data and understand this product as much as all of us that are on the line here at DOR.

So I appreciate your comments.

As you could imagine from our standpoint, we were expecting and hoping for a different outcome; unfortunately that did not occur.

Our focus is getting back in front of the FDA and gaining clarity around the points made in their not approvable letter, and understanding it more clearly and then deciding what is the best approach moving forward.

So obviously that is our first step. We need to go there. We need to gain that clarity. We need to gain that understanding.

So from there I'll be able to provide at least a little bit more guidance and color hopefully.

Just to maybe circle on your item with regard to a treatment IND, we still remain relatively hopeful that a treatment IND is still possible.

As you may or may not know, under the FDA's regulation, whether you have an approvable or not approvable letter, they are only supposed to cite the deficiencies in the application.

So since the treatment IND is not considered a deficiency, there would have been no reason for the FDA to mention the treatment IND in the letter.

It would have been helpful. It would have been nice if they did it but they were not required to.

So this does not mean that a treatment IND is not an option, we intend to have that as part of our discussion as well. But hopefully, we can get some time in front of them soon.

Jeffrey Benison: I guess the only problem with the treatment IND is if you have a treatment IND, how can you get a trial to - and Dr. McDonald said at the ODAC panel and Dr. Pazdur seemed to agree with, because he said, would it be possible to run a trial if there's a treatment IND.

And that's a question I guess, you'll have to resolve.

Christopher Schaber: That's absolutely right and obviously, with a treatment IND as well as another clinical trial, you need to stage these different studies properly so you're absolutely correct. We want to make sure that any follow-on clinical trial for approval that we need to conduct is properly in place before any treatment IND is rolled out to allow for expanded access of the drug while potentially recouping cost.

So the timing of that if the FDA was agreeable to a treatment IND, will need to be discussed as well.

Jeffrey Benison: All right.

Well I think you guys and Dr. McDonald, you designed a great trial and you had a great drug.

And I think that the transplant centers that are using the corn oil mixture are pretty much scratching their heads this morning also.

And I think some people at the FDA should be ashamed of themselves, but - all right. Again, try that appeal process, I've seen other companies do it. Epix has just done one and they're getting their data re-read instead of having to do an additional trial after being told to do additional trials.

So good luck everybody. Bye-bye.

Christopher Schaber: Thank you, Jeff.

Operator: Thank you, sir.

There are no further questions in the queue at this time.

Christopher Schaber: Well thank you, operator.

Operator: You're welcome.

Christopher Schaber: OK, so in closing I trust that on this call we conveyed the regulatory status of our lead product orBec in the treatment of acute GVHD, and the confidence that we at DOR BioPharma have for our company's future. We look forward to keeping you abreast of our progress with the FDA regarding orBec, as well as with our other important development programs, but in the meantime I would like to thank you for taking the time to join us this morning. I would also like to convey a special thank you to all of you that have stood by DOR during this last year. We greatly appreciate your support and rest assured, we will continue to work hard for you.

I hope everyone has a good day. Thank You.

Operator: Thank you, sir.

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