

Corbus Pharmaceuticals Quarterly Update Conference Call and Webcast August-8-2019



Operator: Good morning. Welcome to Corbus Pharmaceuticals' Quarterly Update Conference Call and Webcast. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press *0 on your telephone keypad. Please note, this conference is being recorded.

I would now like to turn the conference over to your host Mr. Ted Jenkins, Senior Director, Investor Relations and Corporate Communications. Thank you, sir. You may begin.

Theodore Jenkins: Good morning, everyone, and thank you for joining us for the Corbus Pharmaceuticals Second Quarter 2019 Update Conference Call and Webcast.

At this time, I'd like to remind our listeners that remarks made during this call may state management's intentions, hopes, beliefs, expectations or projections of the future. These are forward-looking statements that involve risks and uncertainties.

Forward-looking statements on this call are made pursuant to the Safe Harbor provisions of the Federal Securities Laws. These forward-looking statements are based on Corbus' current expectations, and actual results could differ materially. As a result, you should not place undue reliance on any forward-looking statements.

Some of the factors that could cause actual results to differ materially from those contemplated by such forward-looking statements are discussed in the periodic reports Corbus files with the Securities and Exchange Commission. These documents are available in the Investors section of the Company's website and on the Securities and Exchange Commission's website. We encourage you to review these documents carefully.

Joining me on the call today are Dr. Yuval Cohen, our Chief Executive Officer; Dr. Barbara White, our Chief Medical Officer; Sean Moran, our Chief Financial Officer; and Craig Millian, our Chief Commercial Officer. With that, it is my pleasure to turn the call over to Yuval.

Yuval Cohen: Thank you, Ted. Good morning, everyone, and thank you for joining us today. 2019 is so far shaping up to be a busy and eventful year for Corbus, in which we are making important progress towards our corporate, clinical and financial objectives.

I want to remind you all of what our vision is as a company. We believe that targeting the body's endocannabinoid system, also known as the "ECS", holds significant potential to provide novel medicines for inflammatory, fibrotic and metabolic diseases. The ECS is a master regulator of these processes in the body, through it's main two GPCR receptors, through ligands and associated enzymes.



Since our founding in 2014, we have been focused on discovering, developing and now preparing to commercialize potential novel medications that modulate this powerful biological system. It is our belief that over the coming decade novel medicines targeting the ECS will potentially reshape treatment options for many diseases.

To provide further insight into this, on June 21st of this year, we held our Annual Research and Development Day in New York City. I think it's worthwhile summarizing the three topics we highlighted that morning.

First, lenabasum. We continue to advance our four clinical programs. They all remain on schedule. Dr. Barbara White our Chief Medical Officer will provide the latest updates for each. We look forward to next year, when topline results from our pivotal studies in systemic sclerosis and cystic fibrosis read out along with a Phase 2 study in systemic lupus erythematosus. Dermatomyositis topline data remains on schedule for 2021.

As we approach data readouts, we continue to execute on our vision for commercial agreements in Asia. Earlier this year, we successfully executed a licensing agreement for the rights to lenabasum in Japan with our partner Kaken Pharmaceuticals, including a \$27 million upfront payment, with an additional \$173 million in potential milestones and double-digit royalties from our future sales in Japan. We look forward to potentially conducting similar deals with lenabasum in other major Asian markets.

An important step in our growth as a company is to begin to lay the groundwork for the expected commercial launch of lenabasum following potential FDA approval. This starts with hiring the right people. Craig Millian, who some of you've got to meet at our Research and Development Day, was appointed as our Chief Commercial Officer earlier this year. We recently hired Brian Walsh as our head of our Global Marketing. Brian joins us from EMD Serono. We also hired Kaizar Lehri, as head of our Global Supply Chain, who most recently served as Director of Supply Chain Operations at Regeneron. In addition, Dr. Quyen Dinh has been appointed as the Vice President of Medical Affairs. A key function as we look forward to launching the lenabasum. Quinn joined us from Alnylam.

We are also appointing Dr. Robert Discordia to Chief Operating Officer. Bob joined Corbus as Vice President Pharmaceutical Development and Manufacturing in May of 2018. He brings more than 25 years of biopharmaceutical industry experience in CMC development and business operations to Corbus, most recently as Executive Director, Business Operations and Procurement at Bristol-Myers Squibb. In his new role, Bob will be responsible for optimizing the Company's operational efficiency, corporate planning, and performance optimization.



Our second topic in our Research and Development Day focused on our new investigational drug, CRB-4001, planned to enter its first clinical study later this year. CRB-4001 has demonstrated an effect on metabolism, inflammation, and fibrosis in a number of preclinical models that provide a strong case for moving forward into human testing as a potential therapeutic for use in liver, inflammatory, fibrotic diseases such as NASH. We look forward to first-in-human data next year in 2020.

Lastly, our third topic focused on our proprietary ECS-targeting discovery platform. We presented eight preclinical compounds with distinct structures and activity profiles. We expect these will pave the way for future clinical drug candidates and enhance our intellectual property portfolio. Our discovery program provides further validation of our scientific approach and opens the door to potential collaborations with partners focusing on novel indications and markets.

With that, I'll turn the call over to Dr. Barbara White, our Chief Medical Officer. Barbara?

Dr. Barbara White: Thank you, Yuval. We continue to advance our ongoing Phase 2 and Phase 3 studies. Last subject, first visit in the global RESOLVE-1 Phase 3 study of lenabasum in diffuse cutaneous systemic sclerosis, or "SSc," occurred on May 1 with 365 subjects enrolled. The last subject, last visit in the double-blind placebo-controlled part of this study will occur in June 2020. We anticipate topline data in the summer, 2020. The independent data monitoring committee has conducted safety reviews and to-date has recommended that the study continue without change. We are actively preparing for an NDA submission at the end of 2020, should the Phase 3 data be positive.

Safety and efficacy data on the SSc subjects who completed 92 weeks of dosing in the ongoing Phase 2 open-label extension study of lenabasum were presented at the EULAR 2019 conference. 29 of the 36 subjects who started the study, or 81%, remained in the study at 92 weeks. Lenabasum continues to be safely administered in this open-label extension study with no serious or severe adverse events related to lenabasum reported to date. The data showed durable improvement in multiple efficacy outcomes, acknowledging limitations of an open-label study. At the time of data cut, ACR CRISS score was 0.95 or greater for Month 12 through Month 21. Change in modified Rodnan Skin Score showed improvement of 9.8 or greater points during the same time. These levels of improvement are medically meaningful.

Our second ongoing global Phase 3 study is a 52-week study named "DETERMINE" of lenabasum in dermatomyositis. We estimate enrollment of 150 adults with classic or amyopathic dermatomyositis will be complete next year. Safety and efficacy data of the dermatomyositis subjects who completed 68 weeks of dosing in the ongoing Phase 2 open-label extension study of lenabasum also were presented at the EULAR conference. 18 of the 20 subjects who started the open-label extension, or 90%, remain in the study at 68 weeks.



As in the systemic sclerosis open-label extension, lenabasum continues to be safely administered in the DM open-label extension study with no serious or severe adverse events related to lenabasum reported in that Phase 2 open-label extension so far. Also, as in the systemic sclerosis open-label extension study, the data showed durable improvement in multiple efficacy outcomes. For example, at the time of data cut, the CDASI activity score showed a mean improvement of minus 21.8 points at Month 16, an improvement of minus four to minus five points in the CDASI activity score is considered medically important.

The Cystic Fibrosis-002 Phase 2b study will be enrolling about 415 subjects with cystic fibrosis, who are at high-risk for recurrent pulmonary exacerbations. This study has been done in North America and Europe and is funded in part by a development award for up to \$25 million from the Cystic Fibrosis Foundation. Enrollment is expected to complete this year and topline data are expected next summer. If the data are positive, we would plan to discuss potential next steps with regulatory authorities, including a potential marketing authorization application.

Lastly, the Phase 2 study of lenabasum in systemic lupus erythematosus, which is funded and managed by the National Institutes of Health, is enrolling subjects at 15 sites in the United States with a planned total of 100 subjects. We estimate data will be available next year.

The next clinical program for Corbus will be based on developing our first CB1 inverse agonist, CRB-4001, for treatment of non-alcoholic steatohepatitis or NASH. Extensive preclinical data on potentially beneficial effects of CRB-4001 on energy metabolism have been generated to date in large part by Dr. George Kunos and colleagues at the NIH. Corbus has generated additional preclinical data on effects of CRB-4001 on biomarkers of inflammation and fibrosis. These data were presented at our R&D Day in June.

Corbus now has an open IND for CRB-4001. We anticipate starting a Phase 1 single ascending dose, multiple ascending dose safety study of CRB-4001 at the end of this year. In separate studies, we expect the NIH will test CRB-4001 for blood-brain barrier penetration and then safety and effects on metabolism and disease biomarkers in subjects with metabolic syndrome or NASH.

To grow our pipeline, we have invested in assembling an internal team with expertise in the biology of inflammation of fibrosis, medicinal chemistry, DMPK, and modeling. We are generating new compounds to create a pipeline at Corbus. Our current pipeline focus is on CB2 agonist for treatment of diseases generally characterized by systemic inflammation without fibrosis.

We are also focused on generating additional CB1 inverse agonists for lung, heart, liver or kidney diseases with substantial fibrosis. As Yuval mentioned earlier, we presented eight compounds at our R&D Day in June and some are moving into animal testing. It is our intention to develop and



commercialize some of these compounds ourselves and we will also consider potential partnering options. We are excited about our progress in developing potential new medicines that target the endocannabinoid system for people who suffer from inflammatory fibrotic or metabolic diseases.

With that, I will turn the call back to Yuval.

Yuval Cohen: Thank you, Barbara. Before turning to my closing remarks I'd like to provide a brief update on our financial position. Corbus has a strong balance sheet having ended the quarter with \$73 million in cash. Regarding our finances, there is no change in guidance. We have sufficient capital to support operations, clinical development, and commercialization plans into the fourth quarter of 2020.

In summer of 2020, we expect to release topline lenabasum data from our completed RESOLVE-1 Phase 3 systemic sclerosis study and our Phase 2b cystic fibrosis study.

In closing, I would like to emphasize that Corbus is pioneering potentially transformative medicines that target the endocannabinoid system and we believe that this biological system holds the potential to transform how we treat multiple diseases. We are making progress with our late-stage clinical studies and have a pathway towards commercialization of lenabasum.

Corbus has a robust pipeline of early-stage assets including a panel of endocannabinoid mimetic compounds. We are identifying and investing in preclinical compounds. We are developing strategic partnerships to expand our growth beyond the U.S. that will increase our market access and allow Corbus to reach patients globally.

With that, I'd like to turn it over to the operator for any questions from our audience today. Operator?

Operator: Thank you. At this time, we will be conducting a Question and Answer session. If you would like to ask questions, please press *1 on your telephone keypad. A confirmation will indicate that your question is in the question queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key. One moment while we poll for questions.

Our first question comes from the line of Brian Abrahams with RBC. Please proceed with your question.

Brian Abrahams: Hi, there. Thanks very much for taking my questions. My first question was on the ongoing dermatomyositis Phase 3. I was wondering if you could talk about--a little bit about



how enrollment has been going so far? I realize it's relatively early days, but curious if there's any learnings there in terms of the types of patients you're seeing in the overall conduct? And then I have a follow-up.

Yuval Cohen: Barbara?

Dr. Barbara White: Certainly, Brian. This is Barbara thanks for the question. To date, enrollment is on target. We have activated mostly U.S. sites and most of the patients are from the U.S. and I would say as I look over the baseline characteristics of those subjects, they are just what we'd hoped for. I think there are some fairly sick patients who are in need of additional clinical benefit despite state-of-the-art treatment. So far, we're on target and I'm pleased with the initial baseline characteristics.

Brian Abrahams: That's very helpful. And the--

Dr. Barbara White: We have a combination I should say. Sorry, Brian. I just wanted to add as intended we have a combination of patients with classic dermatomyositis and if they have muscle involvement with varying degrees of skin activity or they have largely amyopathic dermatomyositis, which is mostly skin involvement with less or no degrees of muscle involvement. So as intended, we have both types of subjects in the study.

Brian Abrahams: Got it. That's really helpful. Thanks, Barbara. And then on 4001, can you maybe talk about some of the gating factors to moving that into the clinic? I guess one of the things-some of the things that would need to be accomplished between now and the end of the year? And can you give us any sense of the timetable for when we might see the NIH's PET data for that program?

Dr. Barbara White: Sure. Gating for the start of the Phase 1 study, which will be a reasonably standard SAD/MAD dosing study or the usual gating factors completion, availability of clinical supply for the study, which is well underway, and completion of all the selection of the vendors. It would be a single site study. I think--and we will update the IND. So, all of those things need to be done. I don't anticipate significant difficulties getting any of them accomplished. The one that may be most at risk for delaying time of startup might be final completion of the clinical trial supply. But our CMC group has that well in hand and underway.

I think that the timing of the completion of the blood-brain barrier study. And then following that, the study in patients with metabolic syndrome or NASH at NIH and will depend upon the NIH in part because they will be funding and running that. I would be optimistic that we will have the data that we need to complete the design of at least the blood-brain barrier penetration



studies probably in the end of first quarter. So, then it will take time to get that up. So I would expect results of that, again perhaps some time near the end of summer 2020.

Brian Abrahams: That's really helpful. Thanks again and congrats on all the progress.

Dr. Barbara White: Thank you.

Operator: Our next question comes from the line of Liisa Bayko with JMP Securities. Proceed with your question.

Liisa Bayko: Hi guys. I was wondering if you could just maybe comment a little bit on how you've sort of built out the commercial team a little more. Some of your kind of market research findings? And then any commercial preparation you're doing and any thoughts on plans - can you go alone for some of these indications in different world areas? I know you've partnered some. But just curious on how that's all evolving now that you've filled some of those more senior roles?

Yuval Cohen: Thanks, Liisa. I'll deal with one of these and then I'll turn it over to Craig. Just in terms of our commercialization strategy, geographically I think we've made it very clear. We're, obviously, at the moment, keeping the U.S. and Europe to ourselves. Those are key markets, in which we can actually have a direct impact.

In terms of Asia, those are very important markets. But for a company of our size and at this stage, it really doesn't make a lot of sense for us to build a commercial presence there. And I think, as we've demonstrated in Japan with Kaken, it's much better for us to find a very strong and experienced local partner. Now that we've done Japan, I think our eyes are turning to some pretty obvious other big Asian markets. And I'll turn it over to Craig to deal with some of your other questions.

Craig Millian: Yeah. Hi, Liisa, thanks for the question. So just to highlight some of what we've been focused on, obviously, early days in terms of commercial planning, but really starting with identifying some of the key hires for our leadership team. As Yuval mentioned, bringing on Brian Walsh and Kaizer on the supply chain side, as well as really a key hire reporting to Barbara with Dr. Quyen Dinh heading up Medical Affairs. And we're also actively recruiting for a Head of Market Access, which we expect we'll have in place certainly this year.

I think that really forms the foundation for a leadership team to bring lenabasum to market. We've kicked off launch planning activities, we've started thinking about go-to-market strategy, as well as very early thinking around value and access strategy. We've actually initiated some market research, specifically patient journey market research in both systemic sclerosis and cystic fibrosis.



Don't really have topline results yet, because we just really started the interviews, but that work will be ongoing in the coming weeks. We're working closely with Quyen, our Head of Medical Affairs, on the ramping up our KOL engagement planning and execution. And we're also looking at increasing our digital and social media presence to really raise awareness of the potential role of targeting the ECS in diseases with significant unmet needs such as systemic sclerosis and cystic fibrosis.

Just a couple of key insights at this point, I have had the opportunity to attend a couple of key conferences, actually global conferences. EULAR over the summer, was in Madrid, and then the a more niche meeting called the International Workshop on Scleroderma Research, which recently took place in the UK, and I had the chance to speak with several global KOLs. And I think what really comes across clearly is the tremendous need for new treatment options for systemic sclerosis patients. I think there's disappointment with the results from--certainly from recent clinical trials within the space, and I can say and I'm sure Barbara would agree, that there is great hope and anticipation for lenabasum to get to the finish line as a potential treatment for patients.

So again, we'll have some results from some market research. We're working with Med Affairs on some Advisory Boards for later this year to continue to build on our foundation of market insights. But I think at this point I'll leave it there unless there are any other questions.

Liisa Bayko: Okay, great. Thanks.

Operator: Our next question comes from the line of Maury Raycroft with Jefferies. Proceed with your question.

Maury Raycroft: Hi, good morning, everyone. And thank you for taking my questions. I'm just wondering on the recent DMC review for systemic sclerosis. Just wondering if you can remind how often the DMC meets? And if they have anything pre-specified that they're looking for on the efficacy side that could trigger a trial adjustment?

Yuval Cohen: Thanks, Maury. Barbara?

Dr. Barbara White: Yes, this is Barbara. They meet every six months or sooner, if we ask similar questions for any particular safety signal. They would also receive any, in writing the Chairperson would receive any, again, things such as you saw. And so, they look over--they have access to unblinded data. They focus on safety. They have unblinded safety data and efficacy data available to them should they choose to look at it. And so far, it's my understanding that they have been satisfied with the evaluation of the blinded data.



Maury Raycroft: Got it. Thank you. And for the mRSS endpoint. Just wondering if there's any general perspective that you can offer on how FDA will review and waive this endpoint even though it's now secondary?

Dr. Barbara White: I have--as you know, it's always difficult to speak for the FDA. So certainly, this is just my perception. I think they will look at it with great interest. It has been the standard that has been used as a primary efficacy outcome for many years and they are familiar with it. At the same time, I think they are very cognizant of its shortcomings, which include inability to date, in large part, to discern treatment effect when other data might suggest that a treatment effect is available. Its variability and measurement, and its difficulty in using in the new global study, especially if slightly less experienced investigators are involved.

So FDA told us directly, they will look at the totality of the data. I believe that they will look at each of the five components of the ACR CRISS itself, including several patient-reported outcomes. I think those will be of interest to them, as will be the mRSS, the nature of skin and forced vital capacity, a measure of lung function.

Maury Raycroft: Got it. That's helpful. And thank you for taking my question.

Yuval Cohen: Thanks, Maury.

Operator: Our next question comes from the line of Ted Tenthoff with Piper Jaffray. Please proceed with your question.

Ted Tenthoff: Great. Thank you very much for the update and I enjoyed very much the R&D day. My question has to do, sort of, with the earlier discovery efforts, and I was really impressed with this, the depth and breadth of the library and the ability to identify new candidates for inflammatory diseases. So, I wanted to get a sense of sort, of what you see as the productivity rate that you'd shoot for in terms of new discoveries? Appreciated that you can ever really control that, but what do you think is capable from the team in terms of generating new candidates like 4001? Thanks.

Yuval Cohen: Ted, thanks for that question. Oh, sorry, Barbara. I'll deal with the first bit and then Barbara will fill in the rest of it. What I wanted to say is I agree, we are very, very excited about this. Obviously, all eyes are on the lenabasum appropriately so, with a launch as early as 2021 and the type of impact we think lenabasum will have. It's perfectly normal that people will--and investors and shareholders will focus on that.

But if we think about Corbus and take a step back and think of us as a company that really wants to be a leader and establish dominance over what is really an entire biological system, this



endocannabinoid system, then it's clear that we need more than lenabasum. Lenabasum will be just the first of hopefully many successful drugs.

And to do so, I think that we have very proactively invested in first and foremost people and building this team, which I think is really unrivaled in terms of the expertise that it has, in terms of how they function together, and that they are laser-focused on the endocannabinoid system and on generating screening and then moving from pre-clinical, to clinical, these new chemical entities. And I think that as we see these compounds come to the floor ,and we started with just the first group out of the library, we will obviously give you updates starting from August, *in-vitro* as we did before and next you should expect to see key animal data, and then starting the dialogue around the potential indications for that.

And I also want to remind Ted, you and our audience, that the advantage of doing so isn't only bringing new drugs to the market. We will always, always have a limited ability in terms of how many drugs we can develop in-house no matter how big we become.

So, the advantage of doing what we're doing is, it opens the door for the first time to some real Pharma collaborations on the early stages of development. And we look around to some of our peers and some of our very successful peers and one of the things that we've at least concluded is to become a very successful company in our field, it is really imperative to start building those relationships. You cannot do this on your own. So, that was sort of the general overview. And Barbara, please fill in anything that I may have forgotten.

Dr. Barbara White: Thank you, Yuval. We think and we plan to, from our emerging compounds that undergo the initial screen, be able to generate probably two candidates that will--per year that would undergo subsequent, a more detailed DM/PK animal model testing with the goal of having one or two of those actually enter Phase 1 testing each year starting in 2020. So, we will move 4001 at the end of this year and our plan would be to move at least one additional compound into Phase 1 testing next year in each subsequent year from what we generate ourselves.

Ted Tenthoff: Great. I really appreciate that and thank you for the update.

Operator: Our next question comes from the line of George Zavoico with B. Riley. Please proceed with your question.

George Zavoico: Hi everyone, good morning everyone. Thanks for the update.

Yuval Cohen: Good morning, George.



George Zavoico: Hi. So, clearly, you're preparing for commercial launch with the slew of hires. I was going to ask-- wanted to ask about how that plan is going with regards to the number of different indications you're going after, scleroderma and dermatomyositis of course.

First, with regard to CMC are you planning ultimately to bring manufacturing in-house, which would require a much more individualized, or personalized as it were, CMC kind of work? And is there any overlap with the two diseases? Or would it require two separate sort of initiatives with your personnel, with medical affairs and marketing?

Yuval Cohen: George, good morning. I'll start with the CMC and then I'll turn it over to Craig. We have absolutely no intention of building CMC capacity in-house. As you know, one of the things we really pride ourselves on is a very, very lean and very capital-efficient model. We started Corbus again, just five years ago. And our pipeline I think is certainly a testament to the very rapid progress we've made and very, very efficient use of capital. So, we absolutely have no intention of doing CMC in-house. Craig, comment on George's questions in terms of the two indications.

Craig Millian: Yes, sure. So, thanks for the question, George. So, our initial potential indications would be systemic sclerosis and cystic fibrosis, with dermatomyositis likely coming later. So, I think our strategy would be to build out our go-to-market model really with an emphasis on optimizing our launch and commercial success first and foremost in systemic sclerosis which we view as a condition with significant unmet patient need. There are very few treatment options. In fact, there's none indicating specifically for systemic sclerosis and really a sizable commercial potential. So, we believe there's an opportunity to leverage certainly a customer-facing team as well as digital channels, first to target those centers of excellence that treat scleroderma specifically, there's about 50 of those. But also, potentially to branch out even into the community with Rheumatologists who are often making an initial diagnosis and then seeing systemic sclerosis patients early in the disease progression before they refer them.

So we built that, and we'll be able to leverage a lot of those commercial capabilities that we built, for example, you think about marketing, market access, commercial operations, all our CRM-type systems, then to also potentially launching into cystic fibrosis we would need to add a separate sales team, but a very small one I would say because that treatment is highly concentrated in about 130 or so CF treatment centers. So that would really be our starting point.

And then obviously there would be significant synergies with a potential launch in dermatomyositis which is also typically treated by Rheumatologists. And we'd be able to really leverage the infrastructure that we would have built for systemic sclerosis to then pursue to dermatomyositis. So hopefully that addresses the question. Thanks, George.



George Zavoico: Yes, that helps. When you mentioned Rheumatologists in the community level for referral, do you ultimately see the community of rheumatology actually diagnosing and taking over treatment? Or do you expect most of the patients to be referred to specialists?

Craig Millian: Right. Yes. No, it's a great question. I think one--right now, I think we're just generating hypothesis around that. Certainly, because of the dearth of current treatment options, a lot of treatment has happened in the Centers of Excellence. The current--again there's nothing specifically indicated for systemic sclerosis, so it often comes down to a particular specialist treating a particular manifestation of the disease based on organ involvement.

The opportunity obviously with lenabasum, of course, we have to wait to see what the data tell us. But depending on the ultimate benefit-risk profile, it could certainly be very attractive in terms of an oral option for Rheumatologists to treat patients earlier on in their disease progression which is important because a lot of the damage is done early on in disease progression before patients are even referred to those Centers of Excellence.

So, certainly, an opportunity, one that we have to do a lot more work to assess, but--and whether it's something that we need to hire salespeople to do that or if there's other efficient ways through multi-channel marketing, for example digital, etc., we'll figure that out in due course. But that's kind of the hypothesis at this point.

George Zavoico: That's what I was thinking about it because it is an oral option. Because it is an oral drug--and it's safe so far, and hopefully, it will stay that way. It should be--I'm looking perhaps to having community Rheumatologists actually do the prescribing early on as you suggest for perhaps for greater benefit. But as you say, I mean it is a hypothesis testing and hopefully, something like that will evolve in time in due course.

With regard to CF--this path has been followed with other CF drug companies, and so are you using some of those as a model? You don't have a precedent for sclerosis and dermatomyositis but with cystic fibrosis, there's a lot of marketing data and other information you can use. Are you leveraging any of that?

Craig Millian: So, I'll--yes. So, I'll take that George. Yes, I think there's obviously a really good precedent set with Vertex and the success that they've had with what I would say is, an extremely efficient go-to-market model with a very--with a very focused customer-facing team. I think probably 20 or so individuals highly trained focused on the Centers of Excellence that treat cystic fibrosis.

As you mentioned unlike systemic sclerosis and dermatomyositis, there's not a lot of mystery in terms of where the CF patients are, who's treating them - it's highly concentrated. So, that really



allows for a very efficient model that would combine obviously, calling on those Centers, as well as some mechanism to provide patient services directly to patients. And that would be kind of the model we would look at there.

George Zavoico: Okay, great. Thanks very much.

Yuval Cohen: Thank you, George.

Operator: As there are no further questions in the queue, I would like to thank everyone for their participation in today's call. You may now disconnect your lines. Thank you and have a wonderful day.