

Becoming the Leader in Treating Inflammatory and Fibrotic Diseases by Targeting the Endocannabinoid System

**Corbus Pharmaceuticals**  
**Quarterly Update Conference Call and Webcast**  
**May-09-2019**



**Operator:** Greetings. Welcome to the 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 star zero on your telephone keypad. Please note this conference is being recorded. I will now turn the conference over to your host, Ted Jenkins, Senior Director, Investor Relations and Corporate Communications. You may begin.

**Ted Jenkins:** Good morning everyone, and thank you for joining us for the Corbus Pharmaceuticals First 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 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 is Yuval Cohen, our Chief Executive Officer, Barbara White, our Chief Medical Officer, Sean Moran, our Chief Financial Officer, and Craig Millian, our Chief Commercial Officer. It is now my pleasure to turn the call over to Yuval Cohen.

**Yuval Cohen:** Thank you, Ted. Good morning and thank you everyone for joining us today. During the first quarter, we continued to make progress on our clinical programs, while beginning to lay the foundations of our commercialization strategy for lenabasum. As we execute our clinical and commercial objectives, we continue to build our internal team to ensure that we have the required skill sets to help execute our vision of becoming the leader in the treatment of inflammatory and fibrotic diseases using novel drugs that target the endocannabinoid system.

During the quarter, we strengthened our management team to start building out commercialization plans and increase our drug discovery expertise, including Craig Millian, as Chief Commercial Officer, to lead global marketing and commercialization strategies, Dr. Sergei Atamas, as Executive Director of Research to lead our drug discovery programs, and we also expanded the role for Robert Discordia, who is now leading our chemistry, manufacturing, and controls operations. In addition, we're very excited that Rachelle Jacques joined the Company's Board of Directors. Rachelle has more than 25 years of experience in the U.S. and global



commercial leadership and marketing companies, such as Alexion, Shire, and Baxalta. Her appointment compliments and enhances our Board's expertise, and we are pleased to welcome her to the Board.

During the quarter, we strengthened our balance sheet with the completion of a \$40 million public offering and receipt of \$27 million, in the form of the upfront payment from Kaken Pharmaceuticals, our Japanese partner. We ended the quarter with \$89.9 million in cash.

Lenabasum, our first endocannabinoid system modulating compound, is in a potentially registrational Phase 3 study in people with systemic sclerosis. This RESOLVE-1 study completed subject enrollment in the first quarter, and the study's primary endpoint is now the ACR CRISS score in the U.S. Data from the RESOLVE-1 Phase 3 study are expected in the summer of 2012. Lenabasum is also in Phase 3, testing people with dermatomyositis and in Phase 2b testing in people with cystic fibrosis. In addition, a first in patient Phase 2 study of lenabasum in people with lupus is being conducted by the NIH.

As we approach the completion of RESOLVE-1 study over the next year, we will focus on developing commercialization strategies for the lenabasum globally. Importantly, our unencumbered global patent rights for lenabasum increase the opportunities for strategic partnering for commercialization of lenabasum. As a reminder, we see significant commercial potential for lenabasum targeting about 360,000 patients in the major markets. Our first major expansion for lenabasum outside the U.S. remains on track. Our partnership in Japan with Kaken Pharmaceuticals presents an important opportunity for Corbus, as Japan itself represents a market of about 28,000 systemic sclerosis patients and 9,000 dermatomyositis patients, who have limited therapeutic options.

The Japan deal we announced in the first quarter has already resulted in a \$27 million upfront payment with additional milestone payments due of up to \$173 million, as well as royalties. We continue to evaluate other partnership strategies in international markets. And, as I've noted previously, we view the Kaken agreement as a model for pursuing similar licensing deals, in geographies less conducive to development by a U.S. company of our size, while providing near and longer-term capital to fund our growth.

Looking ahead, we anticipate that CRB-4001 will enter Phase 1 safety testing at the end of 2019. Upon a successful completion of this Phase 1 study, the National Institutes of Health has committed to sponsor and conduct a follow-on early Phase 2 study to test CRB-4001 for safety, and effects on metabolism and other biomarkers in patients with metabolic syndrome or NASH. It is our intention to develop CRB-4001 for the treatment of NAFLD or NASH.



We are on track to select our next candidates for pre-IND development. We are excited about the potential of the endocannabinoid system targeting compounds in our library, and we'll describe some of these compounds to you in the near future.

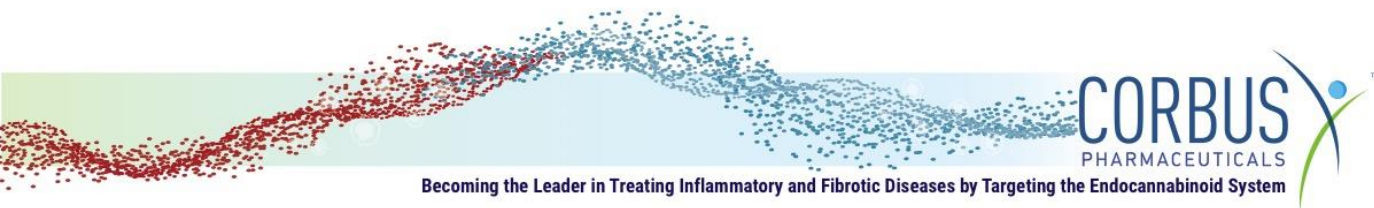
Our clinical development and commercialization opportunities continue to be supported by the strength of our balance sheet, which will fund our operations through the release of our pivotal Phase 3 data for lenabasum next summer and beyond to the end of 2020. We'd like to provide a more detailed update on our clinical pipeline. And with that, let me turn the call over to Dr. Barbara White, our Chief Medical Officer. Barbara?

**Barbara White:** Thank you, Yuval. Starting with our lead clinical asset, lenabasum is currently being evaluated in several late stage studies. The RESOLVE-1 Phase 3 study of lenabasum for treatment of systemic sclerosis completed enrollment on May 1st. This was an important milestone to support potential filing of a new drug application in the U.S. and marketing authorization applications elsewhere around the world. The RESOLVE-1 Phase 3 study has 12 months of active dosing with lenabasum with placebo plus one month of follow up. Database lock and then unblinding of treatment assignment in this study will occur in mid-2020, and we anticipate top-line data will be available soon thereafter.

Following a Type C meeting with the U.S. Food and Drug Administration, we announced that the ACR CRISS score at Week 52 will be the primary efficacy endpoint in the RESOLVE-1 Phase 3 study in U.S. and the change in modified Rodnan Skin Score, or mRSS, will become a secondary efficacy outcome rather than the primary. ACR CRISS stands for American College of Rheumatology Combined Response Index in diffuse cutaneous systemic sclerosis. ACR CRISS was the primary endpoint in the previous Phase 2 study. No changes to size or length for the Phase 3 study are required. As a reminder, systemic sclerosis affects approximately 200,000 patients in the U.S., Europe and Japan.

**DETERMINE** is our second Phase 3 program evaluating the efficacy and safety of the lenabasum for the treatment of dermatomyositis. The study is ongoing. The Phase 3 study design is consistent with guidance from the FDA at an end of Phase 2 meeting, formal consultation with Japanese Regulatory Authorities and scientific advice from European Regulatory Authorities. Dermatomyositis affects approximately 80,000 people in the U.S., Europe, and Japan.

As for our one genetic disease indication, enrollment remains on track for our ongoing Phase 2b study of lenabasum for the treatment of cystic fibrosis, with top-line data expected in 2020. As a reminder, our Phase 2b study in CF has rate of pulmonary exacerbations as the primary endpoint. Pulmonary exacerbations are responsible for about half of long-term decline in lung function in cystic fibrosis.



Despite major advances in the treatment of CF, there remains a need for safe and effective treatments to reduce number and severity of pulmonary exacerbations in people with CF. In our Phase 2b study, we are testing the opportunity for lenabasum to address this unmet need. We are grateful to the Cystic Fibrosis Foundation whom, to-date, has provided Corbus with the opportunity to receive up to \$30 million in awards to fund our CF program. Cystic Fibrosis affects approximately 70,000 people in the U.S. and Europe. With that, I'll turn the call back over to Yuval.

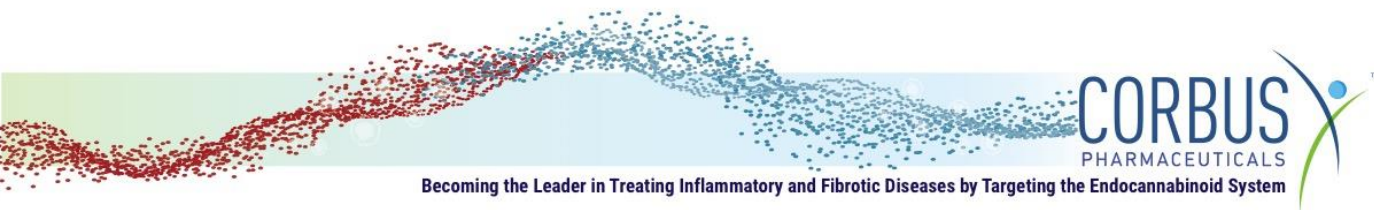
**Yuval Cohen:** Thank you, Barbara. Now let me briefly comment on our financial position, and as I mentioned earlier, we closed the first quarter of 2019 with a strong balance sheet with \$89.9 million in cash that funds our operations through lenabasum's pivotal systemic sclerosis Phase 3 data. We believe that the Company is well funded into the fourth quarter of 2020.

Before I turn the call over to questions and answers, let me reiterate the progress that we are making against our clinical programs and in laying a solid foundation towards commercialization. During the quarter, to summarize, we bolstered our leadership team and Board with key additions that bring commercial expertise. We continue advancing our commercial expansion outside of the U.S., for example in Japan, and we made progress with our late stage clinical programs.

With our financial strength, strategic optionality through unencumbered global commercial rights, and initial commercial planning, we are confident that Corbus is well positioned as we approach potential FDA approval for lenabasum and commercial launch. We look forward to continuing to update you on our progress as we plan to take CRB-4001 into Phase 1 testing, advance select compounds from our portfolio of novel drug candidates and develop our commercialization strategy.

On that note, I'm very pleased to announce that the Company will be hosting a Research and Development Analyst Day in New York City in June. We will be releasing the date shortly, and we're looking forward to seeing you there and sharing with you our roadmap to becoming the leader in the treatment of inflammatory and fibrotic diseases using novel drugs to target the endocannabinoid system. 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 a question, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. Our first question today is from Brian Abrahams of RBC Capital Markets. Please go ahead.



**Owen Ou:** Hey guys, this is Owen on for Brian. Thanks for taking our questions, and congrats on all the progress this quarter. Couple of questions on the CRISS - first question, I'm wondering if you could talk a little bit more about how the endpoint weights the different aspects that go into it, all of the secondaries, and what sort of profile you would need to show in those secondaries to sort of validate the primary CRISS outcome? And then, secondly, are you planning on looking at the median again? And if so, are there any additional analyses you think you might conduct that would perhaps demonstrate the effects of Lena on organ involvement, like looking at the percentage of patients in each group that had zero CRISS scores or something of that nature? Thanks.

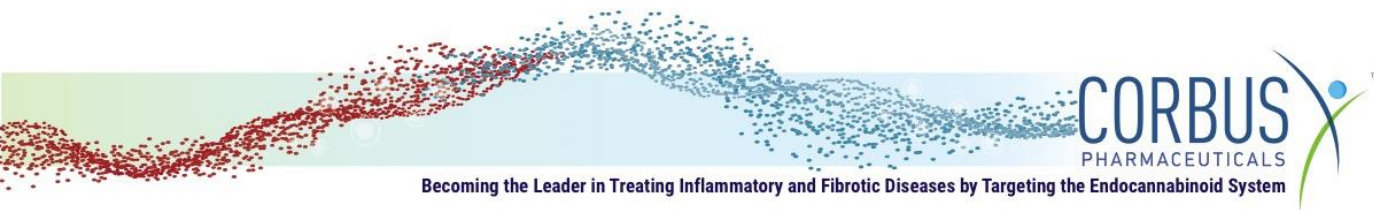
**Yuval Cohen:** Thanks, Owen. Barbara, I'm going to turn that over to you.

**Barbara White:** Thank you Owen for that question. Let me start with your question about the weighting of the CRISS score. The formula is published, and it's daunting when you look at it. The reality is that the change from baseline--let me pause; Everything is a change from baseline, so there is no ACR CRISS score when the patient started. After you calculate it. mRSS weighs most heavily, but the others all contribute. So, this is not simply mRSS with bells and whistles. This is a real composite outcome that includes a variety of core items, all of which are clinically relevant in the assessment of scleroderma patients.

So, the patient global assessment, the patient assessment of function with the HAQ-DI, the Force Vital Capacity percent predicted, which is a lung performance measure, and the physician global assessment of health, all contribute. We believe that is--their contributions to this composite make this an outcome that better reflects the totality of change in disease status in patients with SSc. We believe it is better for a primary look, for a drug that's going to go after an indication for treatment of scleroderma, to look broadly rather than just look at skin.

So, the way the actual formula works, and if you were to play with it, you would find that it's highly unlikely, at least in my opinion, that one would see a difference in ACR CRISS scores without a difference in multiple of these composite outcomes. That's just the way it works. So, I think that our expectation--I know that our expectation is that we will see improvement versus placebo in essentially all these outcomes. Some may not achieve statistical significance, but that's not necessary. I believe that the regulators will look at the totality of the data as they have promised to do, and that will include looking not only at the composite score, but certainly and importantly directional changes in each of the core set items. All of those would support efficacy of the compound.

In terms of subset analysis, certainly we will do those as these are very important in supporting the primary efficacy outcome. There would be subsets based upon what might be considered minimally important differences, there would be subsets based on geography, different disease characteristics, all kinds of things. There would be multiple analyses that are done.



I do want to say that, importantly, the ACR CRISS score itself has an initial step of scoring, in which people who develop new severe organ involvement are given a CRISS score of zero. That is new, severe, worsening interstitial lung disease, pulmonary artery hypertension, renal crisis or congestive heart failure. Those will be reported to the regulators as part of the ACR CRISS score. So, they will have that very important subset of the scoring available to them.

**Owen Ou:** That's great, Barbara. Thanks for all the color.

**Operator:** The next question is from Maury Raycroft of Jefferies. Please go ahead.

**Maury Raycroft:** Hi, everyone. Good morning, and thanks for taking my questions. I had a question on the endpoint change, too. So, you mentioned that it's not going to change the size or the length of the study, but I'm just wondering if there's any other actionable items that need to be implemented with this study that require some protocol modifications?

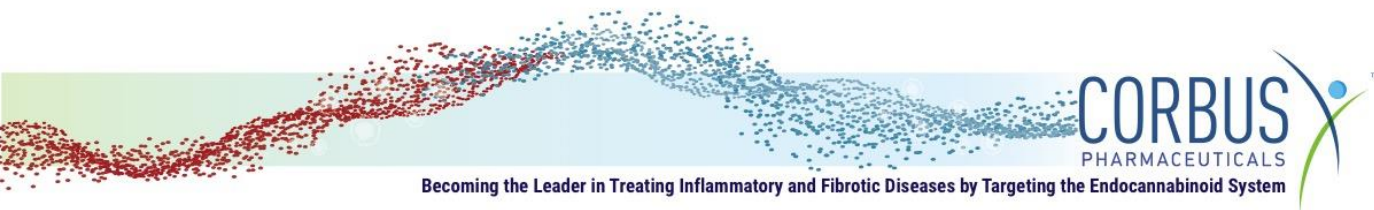
**Yuval Cohen:** Thanks, Maury. Barbara, it's back to you.

**Barbara White:** Yes, thank you, Maury. First of all, the statistical analysis plan needs to be changed. That's not part of the protocol, but that's the important change that needs to happen. There are some minor changes to the protocol that need to be done to accomplish this. First of all, we have to write the changes in. So, you've got to do that in your protocol. And we will also ask at the end of the study, questions of the patients and physicians to see if they believe they've improved during the study. This adds to our ability to validate the CRISS score further. We believe that there's significant validation of it already. This just augments it. So, there will be a single question added at the end of the study. So, the changes are really pretty perfunctory.

**Maury Raycroft:** Got it, that's helpful. And then, I had a question on CRBP-4001. So, with a minimal displacement of CB1 pet ligand from the brain, which I think has been shown before, do you think in the absence of the pet ligand would 4001 still show any activity in the brain?

**Yuval Cohen:** Barbara?

**Barbara White:** I think that that certainly needs to be tested. It is our assumption that it will not at the same time, and those are important things to show. That's the important aspect of the safety. There is a tremendous amount of preclinical data and even some clinical data with Rimonabant, that suggests that a CB1 inverse agonist, such as 4001, that does not have significant blood brain barrier penetration, has the potential to provide clinical benefit in diseases with liver inflammation fibrosis such as NASH. I think it's an essential question, because I think safety is the first hurdle for this compound. So, it is very important for us to



explore in humans, which is where it counts, what looks like blood brain barrier penetration and, importantly, the safety profile. So that's what we will do in the early studies.

**Maury Raycroft:** Got it, very interesting. Thank you very much.

**Yuval Cohen:** Thanks, Maury.

**Operator:** As a reminder, if you would like to ask a question, please press star one on your telephone keypad. Our next question is from Leland Gershell of Oppenheimer and Company. Please go ahead.

**Leland Gershell:** Good morning, and thanks for taking my questions. First question on the RESOLVE trial, again with the change to the CRISS primary endpoint, and I know the SAP is still being finalized and to be submitted, but wondering if you could share with us any changes in the powering of the study based on the change in the endpoint given the prior data that was seen with lenabasum? Thanks.

**Yuval Cohen:** Good morning, Leland. Barbara, it's you again.

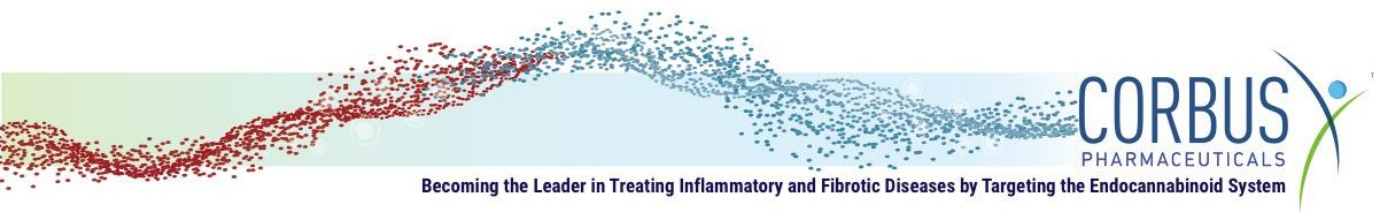
**Barbara White:** Thank you, Yuval. Leland, our power calculations indicate that we are still very well-powered with ACR CRISS as the primary efficacy outcome. And if there's a trend, we're probably better powered. We expect to see a significant treatment effect as the size of the treatment effect should be pretty significant, and that accounting for that, and--I forgot to say, of course, it will be an analysis based on median. It will be reported as a median - the analysis will be done based on rank data, an MMRM of ranked data. But accounting for those things, we're certainly still well powered--perhaps better powered.

**Leland Gershell:** Okay, that's helpful. And then a question on the CF program, given the design of the study, the primary endpoint, the unmet need, I wanted to hear if you may have any updated thoughts with regard to entering into an accelerated approval pathway based on the upcoming data, what the data that might need to show if that could be a possibility?

**Yuval Cohen:** Barbara?

**Barbara White:** For all of the studies that we have, based on the strength of the data, we would discuss with the regulators the opportunities to speed time to approval. Whether it's CF or SSc or DM, we would do the same for all of them. It is a very clear unmet need. Pulmonary exacerbations account for about half the loss of lung function in patients with CF. It causes significant morbidity and contributes to long-term mortality and need for lung transplantations. It is a very clinically relevant outcome that we're going after. So, again, we would, if we saw appropriately robust data, have that discussion with the regulators.





**Leland Gershell:** Okay, thanks. And then my final question just on the business development side. If you could share any further color on your discussions that you may be having with potential partners or licensors who are maybe either Pacific Rim or other geographies that you may be having? Thanks.

**Yuval Cohen:** Leland, could you just repeat that? I'm sorry. I lost you for a second there.

**Leland Gershell:** Oh, just want to ask about any color you could provide on your discussions as you advance outside the U.S., commercial opportunities for lenabasum. Obviously with Kaken having been secured, and I think you had mentioned in the past, you continuing to look, of course, at additional opportunities. If you could just share any thoughts as to where we might see the next deals occurring, if they could be this year?

**Yuval Cohen:** Sure. So, obviously, I have to be very careful as I answer this, but I think we have mentioned many times in the past, that Japan is one of several territories, primarily in Asia, that really don't make any sense for us to try and commercialize ourselves. I think the other two territories that come to mind other than Japan, will be its immediate neighbors, South Korea, and China. So, I think those two are very logical to look at next, they are major economies, and again, would fit into the pattern of the same logic as Japan. They're economies where it really doesn't make sense for us to be. So, we look forward--these things are obviously very, very difficult, especially from the outside, to try and guess in terms of timing, but it's something that we have been really committing a lot of thought and effort to. And I think we were really, very, very encouraged by the quality, the interest that we had in Japan, and we are cautiously optimistic that we will have the same experience in those two territories.

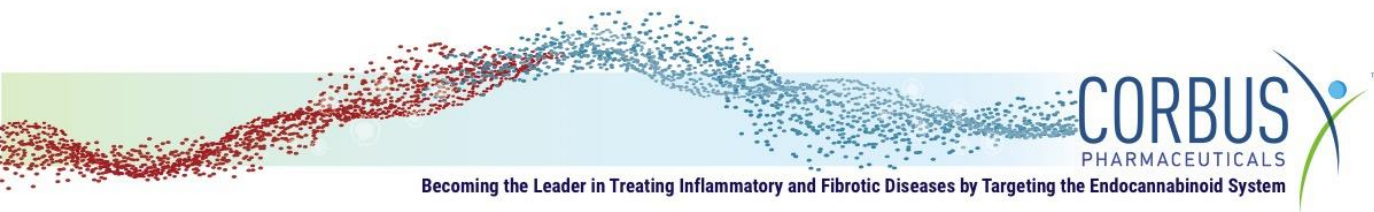
**Leland Gershell:** Okay, great. Thanks, Yuval. Take care.

**Yuval Cohen:** My pleasure.

**Operator:** The next question is from George Zavoico of B. Riley FBR. Please go ahead.

**George Zavoico:** Hi, thanks for taking my question. Hi, Yuval and Barbara, thanks for the update. First question I have is regarding the RESOLVE, also the change in the endpoint. It's not typical that in the middle of a trial that an endpoint changes, I just would like to know how that came about, especially since the CRISS score was the primary and the secondary in the Phase 2 trial. Was this something that you changed your mind about in the beginning? Or was it something you wanted from the very, very beginning of the RESOLVE trial?

**Yuval Cohen:** Good morning, George. Again, I'm going to turn it over to Barbara to give you all that background.



**Barbara White:** Good morning, George, and thanks for the question. As you said, the ACR CRISS score was the primary efficacy outcome in our Phase 2 study, which was short and relatively small. At the same time, we felt that it gave indication of the potential for clinical benefit, and that's why we chose it in the first place. Use in the Phase 2 allowed us to become more familiar with it. We did approach the FDA initially in our End-of-Phase 2 meeting with our thought of using the ACR CRISS score as the primary efficacy outcome in this Phase 3 study. So, our thoughts that it would be a reasonable primary efficacy outcome are not new, they go back a long time. After discussions at that first meeting with the FDA, based on their advice, we changed to "change in mRSS." Thereafter, there have been a number of things that have changed or have become more apparent. First, there's additional data that helps validate the ACR CRISS and its usefulness as a clinically relevant outcome in studies in systemic sclerosis.

There have been some reasonably high-profile failures to show treatment effect with change in mRSS, but the same studies did show treatment effect with ACR CRISS. There has been a shift in opinion of multiple Key Opinion Leaders around the globe thinking that ACR CRISS score may better reflect the totality of what happens to the patient when you are looking for an indication of treatment in systemic sclerosis. So, that's the goal of a clinical study, perhaps it's a better efficacy outcome to reflect effects--benefit, to the patient than just change in skin score. Although, again, that remains a very important outcome. We had advice from our steering committee, which is an international group of experts that--who felt that we should make this change.

So, with all of that, and acknowledging that it is unusual, we then went forward and had the discussion with the FDA. And again, we've announced the results that following that meeting, we decided to make this change.

**George Zavoico:** I'm also wondering whether--well thank you for that. I'm also wondering whether it positions you to approach a much broader systemic sclerosis population, because RESOLVE really focuses on diffuse cutaneous systemic sclerosis, which I presume means more skin involvement than organ involvement. So, is that one of the goals, as well?

**Barbara White:** Let me start, George, with a bit of background information then address the question. Diffuse cutaneous systemic sclerosis--patients who carry that diagnosis have more widespread body involvement, skin involvement. Patients with limited cutaneous systemic sclerosis also can have significant skin involvement, it just doesn't extend above the elbows, knees around the trunk. Both groups have significant internal organ involvement. Internal organ involvement is a major cause of death. Skin involvement is a major cause of morbidity, lots and lots of signs of symptoms and effects on quality of life.



I believe that the use of the ACR CRISS score better reflects again, the totality of what happens to the patients. It will provide the physicians and the people with scleroderma with information on a number of outcomes that will be important to them. Yes, skin, it's very important, but also function, global assessment of health, and lung function. I believe that having these data available will be useful in allowing physicians to best estimate its usefulness--the usefulness of lenabasum in the patients with scleroderma. So, yes, it provides more opportunity for them to have data that they'll want to see.

**George Zavoico:** Okay, thank you for that. And I have a question CRB-4001. So, this is an inverse agonist, and it appears that you've designed it to be an inverse agonist rather than as an antagonist, and you probably did that for a reason. Is there some level constituent of activity that an inverse agonist you think would be more effective than a simple antagonist?

**Barbara White:** George--Yuval, is it okay. If I go ahead? Sorry.

**Yuval Cohen:** By all means, please do.

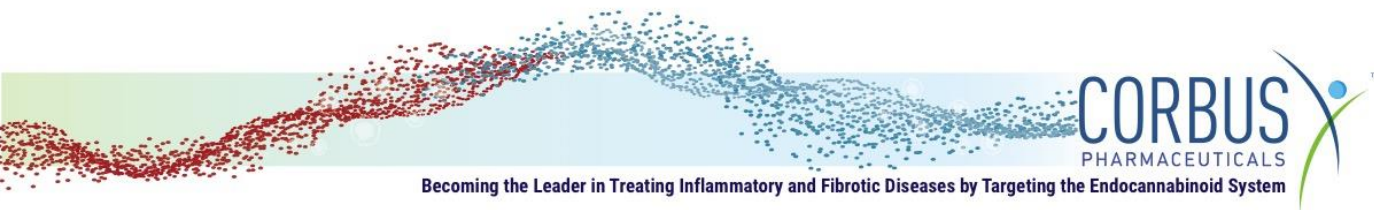
**Barbara White:** Yes, so, George, again, thank you for that, and I agree with what you're implying. There would be reason to theoretically think that an inverse agonist might have more activity than a neutral antagonist. And these compounds came to us from our acquisition of the Jenrin library, and, indeed, that's what the medicinal chemist there had in mind. And we're delighted that it is an inverse agonist, and we look forward to taking it into the clinic at the end of the year, quickly moving through our Phase 1 testing and then moving on to Phase 2 testing in collaboration with the NIH.

**George Zavoico:** Thanks for that. It puts in for NASH an entirely new approach, which certainly makes that feel a lot more interesting. So, thank you for that, and good luck with 4001.

**Barbara White:** Thank you, George.

**Yuval Cohen:** And George, if I can just butt in, on your very last comment here, I couldn't agree more, except I do want to remind everyone that there is, in fact, a competitor or peer that is placing a bet in NASH, on the same mechanism of action but using a different way of achieving the same results. This will be Jansen, with their collaboration with Bird Rock Bio that, just like CRB-4001, are out to neutralize or reverse the CB1 receptor in the liver. But there are some very important differences between our compound and their compound.

CRB-4001 is a daily oral small molecule. Their compound is an injectable, once a month, monoclonal antibody that acts as an antagonist. What we share in common, is a very, very different approach, but a common goal of keeping our respective drugs out of the brain. Again,



we achieved this by chemical modification to a small molecule. They achieved this by having a monoclonal antibody.

So, I think what's interesting, and George, going back to your comment,, this is a completely novel approach to targeting inflammation and fibrosis in the liver, but so far, it's an N equals 2, and one of those, of course, is one of the world's largest and probably one of the most innovative pharmaceutical companies. So, we look at that as a very, very interesting endorsement of the potential for this pathway.

**George Zavoico:** Thanks for that added information. Yeah, interesting.

**Operator:** There are no further questions at this time, so this will conclude today's conference. You may disconnect your lines. Thank you for your participation.

**Yuval Cohen:** Thank you, everyone. Take care. Have a wonderful day.