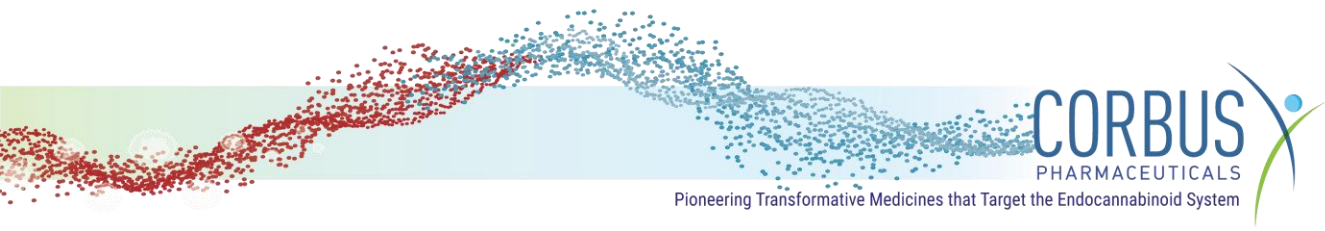


**Corbus Pharmaceuticals Holdings**  
**Fourth Quarter and Year End December 31, 2019 Earnings Conference Call**  
**March 12, 2020**

---



**Operator:** Good morning, and welcome to the Corbus Pharmaceuticals Fourth Quarter and Year End December 31, 2019 Earnings Conference Call. 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. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Ted Jenkins, Senior Director, Investor Relations and Corporate Communications. Please go ahead, sir.

**Ted Jenkins:** Thank you. Good morning, everyone. 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 and 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.

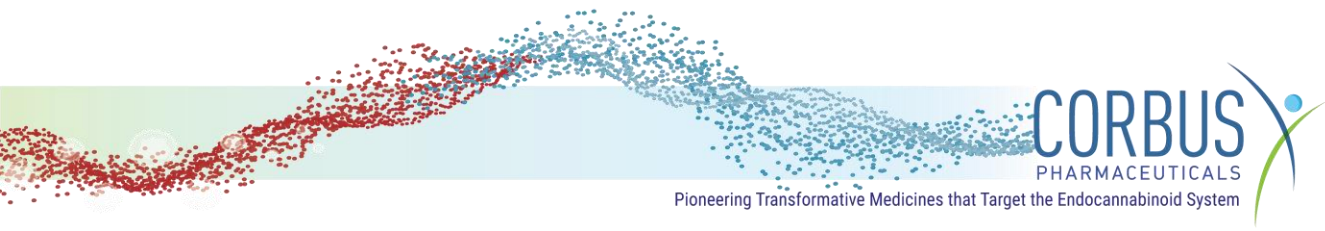
Some of the factors that could cause actual results to differ materially from those contemplated by such forward-looking statements are discussed in the periodic reports Corbus files with the Securities and Exchange Commission. These documents are available in the [Investor](#) section of the Company's [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 and Head of Research, 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 on this call this morning. Overall, 2019 was marked by multiple clinical and corporate achievements, an important progress towards realizing our vision to become the leader in drug development targeting the endocannabinoid system.

We presented new data, including all presentations at the American College of Rheumatology 2019 Annual Meeting, where we introduced the two-year Phase 2 open label extension data that showed continued favorable safety and durable outcomes in our study of lenabasum for systemic sclerosis and our study for dermatomyositis. In addition, we completed enrollment in



both RESOLVE-1, our Phase 3 systemic sclerosis study, and in our Phase 2b cystic fibrosis study, positioning us well for topline data this coming summer.

I'd like to remind you all of our vision as a company. We believe that targeting the body's endocannabinoid system, also known as the ECS, holds the potential to provide new therapies to treat inflammatory, fibrotic, and metabolic diseases. We are focused on developing potential novel medicines that modulate this powerful biological system.

We have deep expertise in medicinal chemistry, endocannabinoid system biology, regulatory and patent strategy, as well as a proven track record of executing on our clinical development plan. This past year, we've also been focusing on laying the important groundwork for having the commercial expertise necessary to execute a successful product launch.

As we look ahead to this year, we are on track for lenabasum topline data from our Phase 3 study in systemic sclerosis this summer, to be followed by our Phase 2b study in cystic fibrosis. We also expect topline data from our 100-patient Phase 2 study of lenabasum in systemic lupus erythematosus in the latter part of this year. That study is funded and run by the National Institutes of Health. Finally, we expect to launch our Phase 1 study of CRB-4001 this year and look forward to the key safety data the study will generate.

Before Dr. White provides comment on our clinical programs, I do want to say a few words on the coronavirus, or COVID-19, situation and how we're dealing with this rapidly evolving situation. At present, we are not experiencing significant impact or delays from the coronavirus on our business or operations. Like many of our peers, we have put in place a robust risk mitigation plan to ensure the safety of our workforce and to deal with possible effects to short clinical trials, supply chain, and research studies. We are monitoring the situation carefully and are following guidance from local and federal health authorities.

With that, I'd like to turn the call over to our Chief Medical Officer and Head of Research, Dr. Barbara White, to provide you with a quick update on our clinical and research program.

**Barbara White:** Thank you, Yuval. Lenabasum is an oral, small molecule CB2 agonist that has been shown to reduce inflammation and fibrosis in a variety of preclinical and human models. Promising safety, efficacy, and biomarker data have been demonstrated in our initial Phase 2 studies in systemic sclerosis, cystic fibrosis, and dermatomyositis patients.

At the American College of Rheumatology, or ACR, Annual Meeting in November 2019, we presented Phase 2 OLE data that showed chronic dosing with lenabasum continued to have an acceptable safety and efficacy profile after 25 months of treatment. The median ACR combined response index in diffuse cutaneous system sclerosis, or ACR CRISS score, remained at or above

0.95 out of a maximum score of 1. Improvement from baseline in the modified Rodnan Skin Score reached about minus 9 points at the time the data were presented.

Our 12-month global Phase 3 RESOLVE-1 study of lenabasum for the treatment of systemic sclerosis is fully enrolled with 365 subjects dosed. Topline data are on schedule and expected this summer. You will be pleased to learn that 98 percent of the eligible subjects who completed the double-blind, randomized, placebo control part of the RESOLVE-1 study to date have enrolled in the Phase 3 open label extension.

We remain optimistic that the upcoming Phase 3 topline data will show favorable safety and positive treatment benefits for lenabasum in this rare, life-threatening disease. This optimism is based on consistency between the biologic activities of lenabasum and the underlying disease mechanisms in systemic sclerosis, our encouraging Phase 2 safety, efficacy, and biomarker data, the similarities in baseline disease characteristics between Phase 2 and Phase 3 subjects, and use of the same primary efficacy endpoint, the ACR CRISS score in the Phase 2 and 3 studies.

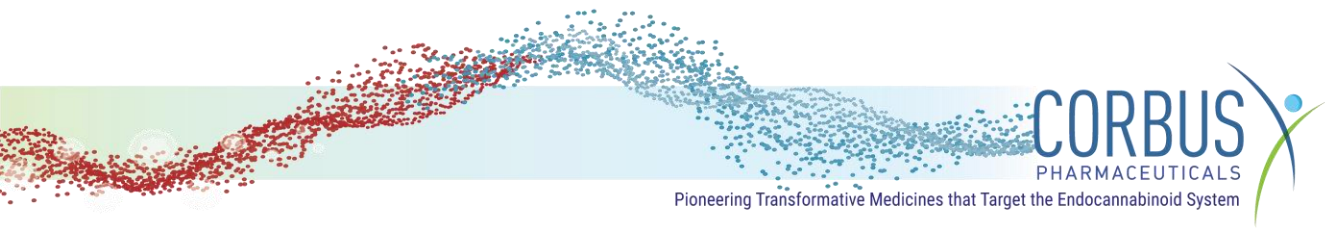
If the RESOLVE-1 efficacy data are positive and the safety profile remains acceptable, we plan to hold discussions with regulatory authorities in the U.S., Europe, and Asia, about filing for marketing authorizations.

Our second global Phase 3 study is the DETERMINE study of lenabasum for treatment of dermatomyositis. We are very pleased with the rate of enrollment, expecting to be fully enrolled later this year, with study completion in 2021. The open label extension of this study is already active. We are optimistic that the DETERMINE Phase 3 study will show positive efficacy in support of safety data for similar reasons as systemic sclerosis.

Data in an oral presentation at the ACR Annual Meeting in November 2019 highlighted continued acceptable safety of lenabasum in subjects with dermatomyositis with chronic dosing through 23 months. Continued improvement was seen in active skin disease in this open label extension with a mean improvement from baseline of minus 20.9 points in the Cutaneous Dermatomyositis Activity and Severity Index, or CDASI, activity score at 23 months. Eighteen of the 20 subjects remained enrolled in the Phase 2 OLE study at that time.

Turning to cystic fibrosis, our 28-week Phase 2b study of lenabasum in 426 CF patients at high risk for recurrent pulmonary exacerbations completed enrollment last November. Pulmonary exacerbations in CF are acute events of increased lung inflammation with clinical manifestations of worsening respiratory signs and symptoms, often including a significant worsening in lung function.

We believe lenabasum represents a potential new anti-inflammatory option for reducing rates of pulmonary exacerbations in people with cystic fibrosis without regard to CFTR mutation or



current background therapy. Topline data from our CF study are expected following the RESOLVE-1 study.

Our second asset, CRB-4001, is a CB1 inverse agonist, designed to have minimal access to the brain in order to avoid psychiatric effects seen with rimonabant. CRB-4001 has demonstrated potent, potentially beneficial effects on glucose tolerance, insulin sensitivity, lipid metabolism, body fat, and hepatic fat in animal models of disease with robust literature supporting these metabolic effects. We have identified additional potential beneficial effects on inflammation and in fibrosis assays.

Dr. Tam and colleagues reported last month that CRB-4001 blocked liver fibrosis. We are considering CRB-4001 as a potential treatment for NASH with fibrosis, with potential to be used in other diseases such as diabetic nephropathy. We plan to start a CRB-4001 Phase 1 study in Q3 to evaluate the safety, tolerability, and pharmacokinetics of CRB-4001. We plan that the Phase 1 testing will also include a PET scan study to test whether therapeutic exposures to CRB-4001 will lead to significant binding of CRB-4001 to CB1 in the brain.

Lastly, our research team anticipates selection of our next candidate compound this year, representing the output of our growing research team of medicinal chemists, DMPK specialists, toxicologists, modelers, and biologists.

I will now turn the call back to Yuval.

**Yuval Cohen:** Thank you, Barbara. In 2019, we began to prepare for the potential approval of lenabasum and subsequently its commercial launch. We are making very good progress with our initiatives, including the initiation of our disease educational campaign in systemic sclerosis last week.

I would now like to turn the call over to our Chief Commercial Officer, Craig Millian, who will provide you an update on our commercial activities.

**Craig Millian:** Thank you, Yuval, and good morning, everyone. On our last call, I highlighted that at this point in pre-launch planning, we're focused on three critical elements to ensure success: first, building our commercial leadership team in capabilities; second, establishing a strong foundation of deep market insights; and third, communicating a compelling narrative that provides an appropriate scientific context ahead of a potential regulatory approval.

Starting with building out our team, we have established a talented group of capable leaders to drive a successful launch, including leads for marketing, market access, medical affairs, commercial analytics and operations, supply chain, public relations, and patient advocacy.

We continue to develop a strong foundation of market insights in both systemic sclerosis and cystic fibrosis and have conducted market research with patients, physicians, and payers in both the U.S. and in Europe. Many of these insights have been incorporated into our most recent investor deck available on the Corbus [website](#).

Now, I'd like to take a moment to highlight some of our key learnings specific to systemic sclerosis. The greatest unmet need is in patients with early or active diffuse systemic sclerosis. These patients, once diagnosed, often have considerable challenges managing their disease, and the impact of scleroderma on their lives is profound.

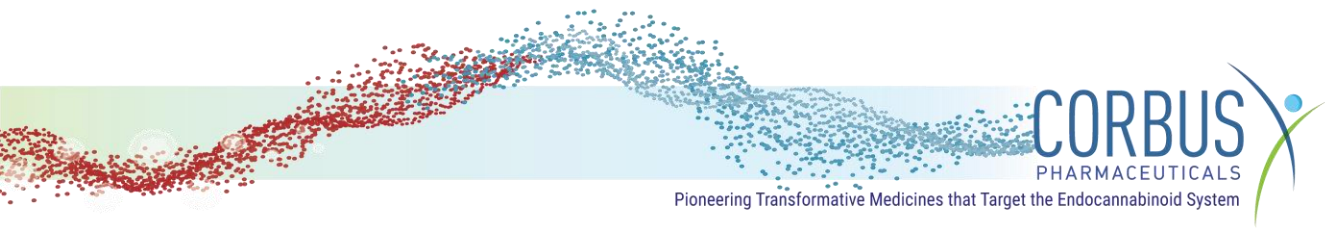
From a go-to-market perspective, there are roughly 50 scleroderma centers of excellence, and we estimate that fewer than 2,000 rheumatologists at these centers and also in the community treat the majority of scleroderma patients. Upon FDA approval, we believe we can efficiently reach potential prescribers with a small customer-facing team augmented by targeted multichannel outreach.

The rheumatologists who manage scleroderma patients do the best they can with available treatments, but they have no single approved treatment to address the totality of disease. Currently used therapies address symptoms or specific organ complications but not the underlying disease progression and generally come with the added burden of immunosuppression.

In our market research, we've also tested a blinded target product profile for lenabasum based on our Phase 2 data as well as our Phase 3 study design. This profile was met with positive interest by patients, rheumatologists, and payers. Most recently, we completed market access research with payers in both the U.S. and in Europe. Payers appreciate that systemic sclerosis is a rare disease with a substantial unmet need. Recognizing the limitations of current treatments, payers are highly receptive to the need for and potential value of new treatment options.

After presenting a potential product profile for lenabasum, we explored how payers might approach access and reimbursement decisions. Based on disease burden and lack of approved treatments, payers acknowledge the overall potential value of lenabasum as being consistent with treatments for other serious rare diseases. Of course, more work will be done post-data to establish our value platform before finalizing pricing strategy.

Finally, before turning the call back to Yuval, I'd like to update you on our recently launched systemic sclerosis disease education campaign that targets rheumatologists. This campaign is based on our market insights, conversations with KOL advisers, and of course the scientific literature.



The campaign calls for healthcare professionals to evaluate the totality of systemic sclerosis. The insight behind the campaign is that systemic sclerosis is a complex, devastating disease, driven by both inflammation and fibrosis. However, current approaches using immunosuppressive or anti-fibrotic agents address only symptoms or specific organ complications.

This campaign also emphasizes the total burden of systemic sclerosis on the patient, including increased mortality risk and disability. A central feature of the campaign is a website that unravels the complexity of systemic sclerosis and also considers the potential of targeting novel mechanisms, including the CB2 receptor.

This website was launched last week, and I encourage you to visit [totalssc.com](http://totalssc.com) to learn more. In the coming weeks, we will launch the full campaign, including paid search and ads on social media and relevant medical websites, all aimed at reaching the rheumatology audience. In addition, the campaign will be highlighted at upcoming medical congresses.

This is our initial step, and throughout 2020, we plan to increase our investment to add content and expand reach. In summary, we are focused on ensuring strong execution around pre-launch fundamentals. We look forward to providing future updates as we advance our commercial capabilities and progress toward launch.

Let me turn the call back to Yuval for the financial discussion.

**Yuval Cohen:** Thank you, Craig. I'd like to provide a brief update on our financial position. Corbus has strengthened its balance sheet. In February, last month, we raised \$46 million in gross proceeds from a public offering, bringing the total capital raised over the past 12 months to \$86 million. We expect the cash on hand of \$31 million as of December 31, 2019, together with the \$43 million in net proceeds from the public offering we just did, and the remaining \$7.5 million in milestone payments from the Cystic Fibrosis Foundation award, to fund operations into the fourth quarter of 2020.

In closing, I want to highlight again that our vision of focusing on novel compounds that target the endocannabinoid system has the potential to yield transformative medicines that could improve the treatment of inflammatory and fibrotic diseases. This year, with our key multiple data readouts, will be our most important year to date. We look forward to what it brings.

With that, I'd like to thank you all for your time and attention and turn it over to the operator for any questions from our listeners today.

**Operator:** Thank you. At this time, we'll now be conducting a question-and-answer session. If you would like to ask a question, please press star, one from your telephone keypad, and 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 that are using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

One moment, please, while we poll for questions. Thank you. Our first question is from the line of Brian Abrahams with RBC Capital Markets. Please proceed with your questions.

**Brian Abrahams:** Hi there. Thanks so much for taking my questions. First off, on the Phase 3 systemic sclerosis trial, how are you guys feeling about the overall conduct as we get closer to the potential readout? It sounds like a lot of patients are rolling into the open label extension. What's the retention look there? Is it as high as in the Phase 2? And what's your sense as to the key CRISS subcomponents that might also be important from both the clinical and regulatory perspective? Then I had a follow-up.

**Dr. Barbara White:** Thanks, Brian. I'll try and remember all of those. First, how is the trial going? Great. We're near the end. Most of the subjects are reaching Month 11 out of 12. Two-thirds of the subjects are out of the study now. So, we're really closing in on the finish of this study. So far, we've been pleased with the conduct.

And we've been especially pleased with the enthusiasm of the patients and the subjects. And as part of that, I think you can see that if we have 98, 99 percent of the eligible people rolling over into the open label, we could not be more delighted. And in terms of retention in the open label, I think we've got over 200 in it now, and we've had, I think, maybe 1 percent drop out. And some of them have been in for a year or so.

So again, the retention rate to date is really quite good. The enrollment rate is great, the retention rate is great. And this is important because it's going to give us additional safety data. It's important to provide long-term safety data. To date, it's been quite acceptable in the other OLEs, and we're going to have even more patients in this one. And we think that will help support the study approvability based on a single trial, to have that much additional information, not only on safety but also on outcomes.

We think that the regulators across the globe will look at all of the components of the ACR CRISS. The ACR CRISS gives us a tool to address the totality of the disease, just what Craig pointed out was so important. It is a measure of, is the patient overall better or not. And it is a regulatory outcome.

In terms of what's important to the patients, we think each of the individual components are, and we think the regulators will be interested in all of them: the improvement in mRSS or skin thickening, change in lung function, change in patient global, change in patient function, as well



as what the physician thinks. Do they think the patient has improved or not. So, we expect them to pay attention to all, and we will certainly do a variety of analyses to support that.

**Brian Abrahams:** Thanks so much, Barbara. And then maybe a question for Craig. You talked about some of the interesting findings from the initial market research that you've done in systemic sclerosis. And I guess obviously it's before the data and the label, it is premature to talk about pricing specifically, but you did mention that some of the payers in your access work were expressing receptivity for the potential value of lenabasum and viewing it as consistent with certain other treatments for rare diseases.

I was wondering if you would just be maybe a little bit more specific and help us understand sort of the types of treatments that payers are viewing the value as being consistent with, just to provide some framework for how they're thinking about value. And I'll jump back in the queue. Thanks.

**Craig Millian:** Yeah. So thanks for the question, Brian. We are obviously very much engaged with the pricing strategy, and it is early, so I appreciate that you know I'm not going to get into specific numbers. But I'd be happy to share some general thoughts in terms of the research we've conducted.

First, we're focusing on optimizing our value proposition in systemic sclerosis, and the emphasis is on patients with diffuse disease, which, as you're aware, is the most serious form of scleroderma as well as the population in which our drug has been studied.

So, the prevalence of diffuse disease is about 9 diffuse systemic sclerosis patients per 100,000 in the U.S., and that patient population clearly falls within the rare disease category and obviously not the ultra-rare but kind of this new concept of the medium rare disease category. And this is a term that I've heard used.

Our market research was conducted independently by Clearview Consulting, and the payers agreed that systemic sclerosis is a serious, rare disease with limited treatment options. They're aware that there are not specific treatments indicated for systemic sclerosis overall.

And I'll leave you with this thought. Based on the reaction to the blinded lenabasum product profile, payers suggested that there would be quite a bit of flexibility when considering levels of access throughout a broad pricing range. And, again, I'd say their thought is it would be consistent with treatment analogs from other serious diseases with prevalence rates similar to SSc. And again, diffuse is 9 per 100,000, overall SSc is about 30 per 100,000.

So, at this point and of course, as you're aware, it's not cut-and-dried in terms of access levels. So depending on pricing strategy, different levels of access and reimbursement are achieved, so

a lot of that depends on the goals we set. But certainly, we plan to leverage these insights from the payer research.

We're just beginning our work in terms of health economic modeling. As you mentioned, until we have our data and a final label, we really can't determine our final value proposition, but we'll certainly combine those insights with our health economic modeling and further down the road, we'll determine an optimal pricing value strategy.

**Brian Abrahams:** Great. Thank you so much.

**Operator:** The next question is coming from the line of Maury Raycroft with Jefferies. Please proceed with your questions.

**Maury Raycroft:** Hi. Good morning, everyone, and thanks for taking my questions. To start, for systemic sclerosis or any of your other late stage trials, are you taking regular blood samples from patients and assessing those for inflammatory or possibly fibrosis biomarkers in the blood on a blinded basis? And can you comment on what you're seeing qualitatively?

**Dr. Barbara White:** So first of all, we are taking samples, but we're actually taking them from involved tissue. So, we think that that's probably a little more relevant. We found in the Phase 2 study--it was quite informative--that, in fact, many of the biomarkers are not elevated because our patients are on background immunosuppressants, about 80 percent of them or so on at least some background immunosuppressant. And in that group of subjects, it's less common to find these markers elevated in the blood. That's why we're looking in involved tissue. So, we will look at histology and gene expression in the skin of patients with systemic sclerosis and dermatomyositis, and we are certainly looking at cells and markers of inflammation in the sputum of patients with CF.

As you may recall, Maury, we certainly saw very encouraging data in the Phase 2 study, and we've seen samples with the reduction of inflammation and fibrosis in the scleroderma skin, a reduction of cells in inflammatory mediators in the DM skin, and a reduction in cells and inflammatory mediators in CF sputum.

**Maury Raycroft:** Got it. And are you taking those on a serial basis over time? I guess, are there different time points that you're getting the samples?

**Dr. Barbara White:** We're doing that, Maury, because they are biopsies, we're doing them at baseline and at 12 months. We're not doing them more often than that except in the DM study. I think some patients may volunteer for three, but mostly it's just beginning and end of the study. The CF sputa are easier to come by, so they're being done a little more frequently.

**Maury Raycroft:** Got it, okay. And then, for 4001, just clarifying, will you include some obese individuals in your initial SAD, MAD, safety and PK study? And--okay.

**Dr. Barbara White:** Go ahead, sorry.

**Maury Raycroft:** And then, will you just do one PET scan or multiple PET scans on those individuals, and have you established a threshold for how much receptor occupancy would be acceptable at different time points to move to the next step, to test during a larger study?

**Dr. Barbara White:** Great questions. First, the question about testing safety, tolerability, pharmacokinetics in obese individuals, that is a part of the Phase 1 study. There was a potential that those parameters might be different than they would be in a normal or overweight individual. So, we will test that because if we're targeting NASH, we're going to be dealing with a lot of obese people, so that's a straightforward early safety and PK understanding that we need. We will move from there. After we've got those studies done, we will move into doing the PET scan at the NIH. We've been working quite closely with Dr. George Kunos and his colleagues there.

The way the study is done is the patients will get multiple doses of 4001 first. They will be loaded with it. And these will be obese individuals. And then, they will be injected with a specific CB1 ligand that is for PET scanning and will light up their brain. They will first have a study at baseline before they receive anything--we know that to see how much of the ligand binds in their brain. They will get the drug, and then they'll have another study, and we'll see if there's any displacement of the binding of the ligand.

So, the results will be compared in a cohort that gets placebo for seven days and a cohort that gets 4001 for seven days. And we will look for whether or not 4001 displaces ligand binding better than placebo--more than placebo.

The data that are available in the literature suggests that we're less likely to see the CNS adverse event if the levels of displacement that would be specific binding are probably in the 10 percent or less range. Of course, there will be some variability around that. Certainly, we would be less comfortable if we saw specific binding in the 30, 40 range--or 40 percent range. That would certainly be room for caution. Somewhere in between I think would be--we would need to interpret and really think about but a little bit, we would move forward, I think, and a lot, no, and in between we'll think about it.

**Maury Raycroft:** Got it. Very good. And will you announce when you start dosing individuals in that study?

**Dr. Barbara White:** Sure. We'll announce it. And as I said, we're on target, and we expect it to start in Q3. So, so far, so good.

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

**Operator:** Our next question is from the line of Leland Gershell with Oppenheimer. Please proceed with your questions.

**Leland Gershell:** Hi. Good morning, everyone. I have a two-part question, which is--it relates to the variety of mechanisms and drugs that are used as anti-inflammatories, anti-fibrotics, versus lenabasum. And I'm wondering, Barbara, if you could comment on which of those other therapeutics that are often used for the kinds of conditions that you are looking at could either work very well with, and pairing with lenabasum or potentially interfere with its function, given that some of these agents can actually go against resolution. And then, I have a second part. Thanks.

**Dr. Barbara White:** So, I think, if I may repeat that question, it is, what's the potential to use lenabasum in combination with other therapies? What might be synergistic efficacy or antagonistic effects, and might there be drug-drug interactions that would be a safety signal?

**Leland Gershell:** Right.

**Dr. Barbara White:** So, as you know, we are studying patients on their background treatment, whatever it is. That's always been the approach. And we have felt comfortable doing that because expression of CB2 really just on activated immune cells goes away when they are not. That increases the safety profile--and the fact to date we've not seen significant clinical evidence of drug-drug interactions or abnormalities in the lab tests, etc.

Mechanistically, I think it's possible that we could see even better efficacy in some of the patients who might be on background immunosuppressives such as MMF. We'll know obviously when the trial is over and the subset analyses are done. But for example, the approach that we have of activating resolution of inflammation is absolutely novel. Nobody else is doing that. This is brand-new. This provides a whole new approach to treating these chronic inflammatory and fibrotic diseases.

So, if you view the disease mechanisms sort of as a mountain--you have a climb up the hill and a climb down the hill--lenabasum activates the going down the hill, the turning of things off, although there certainly are some effects on the activation phases. But the potential--if you pair things, you might even see better efficacy.

However, we don't know that. We'll find out. And I have no belief that it needs to be that way. By itself, and we tested lenabasum by itself, and we're testing it in the current studies without concomitant suppressives, we have every expectation that we will see really substantial clinical benefit.

So, I think that the way that we think it will be used will be either as monotherapy in early patients who have early active disease, to bring it under early control--I can talk about that more--as well as in combination therapy, depending upon certain organ involvements and preferences of the patients and the physicians.

Drug-drug interaction studies--we have done some significant modeling of that, consistent with what the FDA likes to see. And while there are some potential drug-drug interactions with some types of compounds, they are not the compounds that the patients usually use, so we're not expecting significant issues there.

Craig, I didn't know if you wanted to comment about your views of commercially, use alone or in combination?

**Craig Millian:** Yeah, and obviously, as Barbara said, it will come down to the data. Certainly, I think there is significant opportunity for both. Certainly, most patients are on some sort of background immunosuppression, and certainly adding--the opportunity to add lenabasum without adding to the overall--based on the safety and tolerability profile that we expect, that we've seen to date. Not adding significant treatment burden while adding significant incremental efficacy will be very compelling.

Certainly, there are also patients who experience problematic side effects on immunosuppressants. They and their health care provider may want to try to titrate down to some degree the amount of immunosuppression. And obviously the opportunity there, even for patients further along in their disease and have more stable disease--certainly there could be a nice opportunity for lenabasum there as well.

And certainly the de novo patient, who is first diagnosed--we would love to be top of mind in terms of the first drug that they consider for a newly diagnosed patient as well. And certainly as we think about how we construct a go-to-market strategy and the insights that these patients are being diagnosed and treated often by the community rheumatologist, and when you think about the profile of lenabasum being oral, again safety and tolerability to date looking quite reasonable, and obviously the efficacy, it's going to--we would consider to be very attractive potentially as a first-line agent. So, we think it really covers multiple bases.

**Leland Gershell:** Thanks. That's very helpful. Just a quick follow-up, as we look toward the RESOLVE-1 readout in systemic sclerosis, can you give indication at this point if we're going to

see in the topline a breakdown of the CRISS components, the secondary endpoint, or if you will be limited more to just through the topline? Or is it just too early to give that indication--I mean, the data? Thanks.

**Dr. Barbara White:** Definitely, you'll see the primary. You will see the CRISS. And I think it would be reasonable to expect most if not all of the secondaries. It's the components of the CRISS you'll--because each individually address how lenabasum could provide benefit to the totality of the illness that we're treating. So, I would at this point--I can't promise—but I think it would be our intent to show you what the overall score and the components look like, and that covers the secondaries.

**Leland Gershell:** Great. Thanks very much for taking the questions.

**Operator:** Our next question is from the line of Liisa Bayko with JMP Securities. Please proceed with your questions.

**John:** All right, John on for Liisa. Thanks for taking the questions. I guess, following up on a previous question, in RESOLVE-1, when you're looking at these biopsies and biomarkers, can you discuss how you think the importance of seeing a correlation between the biomarker changes and what you're seeing clinically in patients?

**Dr. Barbara White:** I think there will be a--certainly, I would expect it to correlate. I'm not sure I would expect to see a fabulously strong correlation because that's the difference between skin and clinical outcomes. And as we've had many discussions, there's variability in the clinical outcomes and so forth and so on, but I would certainly expect to see some correlation. That's why we do it, so that we can support that the efficacy outcomes we have are very sensible when you look at impact of this drug on the underlying disease pathogenesis.

**John:** Thanks. And I guess just one more for Craig. You discussed targeting about 2,000 rheumatologists. Can you discuss how you're tiering those docs and then kind of your thoughts on the size of your sales force. Thanks.

**Craig Millian:** Sure. Yeah, so just to take a step back. I mean, at launch our goal is going to be clearly to build awareness and understanding with both the academic and community-based rheumatologists who are treating scleroderma patients. And we talked about the product profile--we think lending itself well for both those who treat at the centers of excellence as well as those community rheumatologists who often are diagnosing and getting patients. Our goal would be to get patients started on treatment immediately upon diagnosis.

So, let me caveat this by saying we haven't done a formal sales force sizing exercise yet, but we would envision a national footprint, ensuring coverage first and foremost of the roughly 50

scleroderma centers of excellence. And we would envision that being dually covered by a commercial-facing team as well as a field medical team.

We would also want to have the capacity to call on those community-based rheumatologists who are treating a sizeable number of scleroderma patients in their practice. And right now, we estimate that number to be between 1,500 and 2,000 rheumatologists. And the cutoff we're using preliminarily is if they have roughly 10 scleroderma patients or more in their practice.

But again, this is quite preliminary, and there's going to be additional work done to validate that number. So, I would expect a fairly modestly sized specialty sales team of no more than 50, but with national reach. And then, as I mentioned, we'd want to augment that with innovative, multichannel marketing approaches and obviously also have a strong field base medical team.

**John:** Right. Thanks for taking the questions, and congrats on the progress.

**Dr. Barbara White:** Thank you.

**Dr. Yuval Cohen:** Thank you.

**Operator:** Thank you, everyone. This concludes our question-and-answer session and our conference for today. Thank you for your participation, and you may now disconnect your lines at this time and have a wonderful day.

**Dr. Yuval Cohen:** Thank you, everyone. Take care, stay safe.