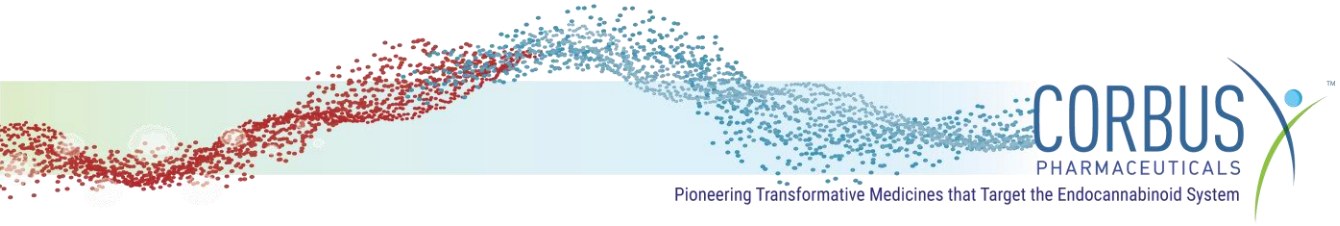

Corbus Pharmaceuticals Holdings
Second Quarter Earnings Conference Call
August 6, 2020

Operator: Hello and welcome to the Corbus Pharmaceuticals Second Quarter August 6, 2020 Earnings Conference Call. As a reminder, all participants are in a listen-only mode. If anyone should require operator assistance during the conference, please press star zero on your telephone keypad. Following the formal presentation, there will be a question-and-answer session. This conference is being recorded at the company's request and will be available on the company's website following the end of the call.

I will now turn the conference over to your host, Ted Jenkins, Senior Director, Investor Relations and Corporate Communications. Please go ahead, sir.

Ted Jenkins: Thank you, Brock. 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 for 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 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 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. It is my pleasure to welcome everyone to Corbus Pharmaceuticals' Second Quarter of 2020 Earnings Conference Call. Our team has had a very busy second quarter. We are on track for what we believe could be a transformative year with multiple anticipated catalysts in the coming months. First, we look forward to top-line data from our recently concluded Phase 3 systemic sclerosis study this summer. Next, these results will be followed by our recently concluded cystic fibrosis Phase 2b study results in the third quarter. With these critical data readouts now closer than ever, we are focusing more and more on preparing the groundwork for NDA submission and then commercialization following potential FDA approval.

At this time, our finances are stronger than ever having just announced that we've raised additional capital of up to $121 million from a combination of our ATM strategy and a debt

financing deal from K2 HealthVentures. This significant capital investment, ahead of data, gives us the ability to have strategic flexibility following data without the pressure of a financing overhang. We are also very pleased to have Dr. George Golumbeski join us as a new board member on our Board of Directors. George's experience growing companies and advancing innovation will be a significant asset to Corbus as we transition from an R&D-only organization to a commercial-stage company with a deep pipeline of novel drug candidates targeting the endocannabinoid system. I will now turn the call over to our Chief Medical Officer and Head of Research, Dr. Barbara White, to provide us with an update on our clinical and research programs to be followed by comments from Craig Millian, our Chief Commercial Officer. Thank you, Barbara.

Barbara White: Thank you, Yuval. I would like to start by reviewing the impact of COVID-19 on our clinical programs. COVID-19 did not substantially delay last patient, last visit in the RESOLVE-1 study or the Phase 2b CF study. However, it has slowed time to database lock. For the RESOLVE-1 Phase 3 and the CF-002 Phase 2b studies anticipating and responding to the potential negative consequences of COVID-19 on study integrity took priority over other activities that are usually done near the end of a study. In-person access to study staff and data at study sites was essentially shut down for about three months and remains limited.

Similarly, physical access of study site staff to their own sites was restricted, and some sites even closed temporarily. These restrictions limited the ability of study site staff to do in-person assessments of subjects and slowed data entry and responses to questions about data. To adjust for these changes and access to sites and data, we set up and continue to use alternative ways to monitor study data, that is remote data monitoring and central data monitoring. Combined, these COVID-19-associated limitations have slowed completion of data entry and data cleaning, and hence, database lock for the systemic sclerosis Phase 3 and CF Phase 2b studies. Nonetheless, we are expecting top-line data from the Phase 3 SSc study soon, to be followed by the CF-002 top-line data. In addition, although COVID-19-associated limitations at some vendors slowed the start of supported Phase 1 study, those studies are now ongoing.

Last subject visit in the RESOLVE 1 Phase 3 study was reported on May 27th. We dosed 365 subjects in the double-blind placebo-controlled part of the study. Of subjects dosed, 328, or 90%, completed the study and 37, or 10%, discontinued the study early, which is lower than the discontinuation rate we assumed at the start of the study. We estimate that SSc-002 study remains greater than 90% powered at less than or equal 0.05 for the primary efficacy endpoint ACR CRISS score at week 52.

Data entry for the RESOLVE-1 study is complete, and data cleaning is expected to be completed in the very near-term. We are on schedule to report top-line data this summer following database lock and data analyses. The open-label extension of the RESOLVE-1 Phase 3 study, which is separate from the open-label extension of the Phase 2 SSc study, is ongoing. 98% of

eligible subjects or, 320 of 328 subjects, entered the open-label extension, and 33 subjects have already completed at least the first year in the OLE. Only six subjects, or 2%, have dropped out of the SSc-002 open-label extension to-date, which we find encouraging given the extra burden of coming for study visits during COVID-19. Of note, at the 3.5 year mark in the Phase 2 SSc-001 open-label extension, 25 of 36, or 69% of the subjects, were still in the study.

This quarter, new analysis showing ACR CRISS score correlates with improvements from baseline and how patients feel and function from the lenabasum SSc Phase 2 study were presented at the 6th Systemic Sclerosis World E-Congress. In addition, data showing the biologic effects of lenabasum may include inhibition of inflammasome activation were presented at the EULAR Annual Conference. We are also pleased to announce that Kaken Pharmaceuticals, our partner in Japan, recently obtained Orphan Drug Designation for lenabasum for the treatment of systemic sclerosis from Japan's Pharmaceutical and Medical Devices Agency, or PMDA.

Turning to the CF-002 Phase 2b study, last subject visit was reported on June 22nd. We had 425 subjects dosed from this study. Of those, 387, or 91%, completed the study, and 36, or 9%, discontinued the study early, which again is a lower discontinuation rate than we had assumed at the start of the study. Power for the CF-002 study remains unchanged at about 80% for event rate of pulmonary exacerbations at 28 weeks with P less than or equal to 0.05. Data entry for the CF-002 study is nearly complete, and we are actively cleaning data.

Yesterday, we reported that last patient first visit in our DETERMINE Phase 3 study of lenabasum in dermatomyositis occurred. This study dosed 176 subjects, which exceeds the enrollment target of 150 subjects. To-date, only 4, or 2% of subjects, have discontinued from this study early. The open-label extension of this study is active, and all eligible subjects have enrolled to-date. Of note, at the three-year mark in the Phase 2 DM-001 open-label extension, 16 of 20, or 80% of subjects, were still in the study.

The NIH-sponsored 100 patient Phase 2 study of lenabasum in systemic lupus erythematosus is ongoing. Study enrollment was temporarily halted by the NIH because of COVID-19 but has recently resumed at several sites. 87 subjects have been enrolled to-date, and we are optimistic that enrollment may be complete by the end of the year.

I am going to speak briefly about several preclinical programs now. CRB-4001 is a CB1 inverse agonist, which improves metabolic abnormalities and reduces inflammation in fibrosis in non-clinical models of disease. CRB-4001 is undergoing chronic pharmacokinetic studies and primates to measure brain exposure. Results of these studies are expected this year. Our pipeline is growing. As you may remember from our last R&D Day, CRB-317 is one of our promising CB2 agonist that Corbus has developed in-house. We are pleased to announce that CRB-317 has been selected as our next candidate for development based on its significant

potency and selectivity for CB2, and biologic activity and animal models of inflammation and fibrosis. Non-clinical studies and formulation work to enable IND submission are underway. We expect CRB-317 to be in Phase 1 safety testing in 2021. We will share information with you at our next R&D Day. I will now turn the call over to Craig Millian, who will provide the commercial program update.

Craig Millian: Thanks, Barbara. Good morning. We are very excited to be moving closer toward top-line data and the anticipated commercialization of lenabasum. Over the second quarter, we continued to effectively execute on our key prelaunch activities, and today I am going to provide brief updates on the progress we're making to build out our launch team, as well as on our disease education efforts. With leadership in place in the key areas of marketing, market access, commercial operations, and medical affairs, we are advancing plans for scaling up our teams to support a successful launch. The first area of focus is implementing our field medical go-to-market model.

We are executing a phased approach that will ensure a robust and appropriate field medical presence ahead of launch with the initial hiring of a small number of medical science liaisons, or MSLs, which would follow positive clinical data. The MSLs are part of the medical affairs team reporting up to Barbara. They will be experts in scientific and medical information related to the disease states we are studying, as well as our clinical programs. MSLs will be responsible for building strong relationships with external clinical and scientific leaders at both the national and regional level. We also plan to begin scaling up other key launch-related areas, including national payer accounts, patient services and reimbursement, commercial technology, marketing, and market analytics. I look forward to providing additional details in future calls as we further build these capabilities following data.

Turning briefly to disease education. On our previous call, I highlighted the progress we're making on the rollout of the "Total SSc" campaign. Earlier this year, we launched this disease education campaign targeted to rheumatologists, and we are continuing to build out and fully leverage this program. The totalssc.com website has seen traffic steadily increased month-over-month. And to-date, the website has received more than 19,000 unique visitors. More recently, we expanded our disease education outreach with an email campaign directed to the majority of physicians who treat systemic sclerosis as identified by Acclaim Data. We are actively collaborating with systemic sclerosis Key Opinion Leaders to further expand educational subject matter, including videos and other dynamic content, and we plan to have this available on the Total SSc website later in the year.

As Barbara mentioned, Corbus had a strong presence at the Virtual Systemic Sclerosis World E-Congress. We fully leveraged the Total SSc campaign at the Corbus Virtual booth to drive engagement and to educate on the total burden of systemic sclerosis, the unmet need, and the promise of CB2 agonism. We were pleased to learn from conference organizers that there were

1,300 meeting registrants and the large portion visited our booth and engaged with key content. In summary, we continue to make substantial progress ensuring we will be in a position to successfully commercialize lenabasum, following FDA approval, and to providing important treatment option to patients suffering with this debilitating disease. I look forward to continuing to update you on our expanding efforts in the coming months and will now turn the call back over to Yuval.

Yuval Cohen: Thank you, Barbara and Craig. I will now provide an update on our financial position. We head towards our data announcements with a strong balance sheet. We recently announced up to $121 million in new capital, comprised of approximately 71 million from our existing ATM and $50 million debt financing facility with K2 HealthVentures, of which 20 million is in the first tranche. We've also received a $5 million milestone payment from the Cystic Fibrosis Foundation, to whom we are very grateful. We reported $101 million of cash on hand as of July 28, 2020, putting us in a strong financial position and giving us valuable strategic flexibility heading into data.

In closing, I would like to reiterate how excited we are for these upcoming milestones. We are on the verge of an inflection point. We believe that these upcoming data will change our company, and we are poised to make the transition from an R&D-only organization to a commercial-stage company. Thank you all for your time and attention this morning. I now turn the call back to the operator, and we'll open the call for questions from our audience.

Operator: Thank you. We will now be conducting a question-and-answer session. If you would like to be placed in the question queue, 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 star one. One moment, please, while we pull for questions.

Our first question today comes from Brian Abrahams of RBC Capital Markets. Please proceed with your question.

***Brian Abrahams*:** Hi there. Good morning. Thanks for taking my questions. Congrats on the progress and really appreciate all the details on timelines and enrollment across the clinical trials. I guess my first one is on the patient reported outcome components of CRISS. I guess I am wondering, coming out of the recent presentation, any sense as to how the FDA or KOLs, as well, are viewing CRISS overall and regulatory amenability to, I guess, to approval on CRISS if the benefits are predicated primarily on the PROs versus trends in mRSS?

Dr. Barbara White: Hi, Brian. This is Barbara. Thanks very much for your question. I think as we've discussed before, based on what has happened in past clinical trials, KOL opinion, in my

belief, has swung towards thinking that change in modified Rodnan skin score or mRSS, while a valuable assessment of skin thickening, perhaps is not performing especially well, or it hasn't performed especially well as a primary efficacy outcome in trials in systemic sclerosis and they have moved towards thinking about a more holistic approach at looking at the impact of treatment on the overall disease. And with that in mind, the ACR CRISS score is the best composite outcome that we have at this time. It uses five clinical measures that are sought by experts around the world to be those most important to assess in clinical trials in systemic sclerosis. So, we do think that, at this time, KOL opinion in general is supportive of this holistic approach at looking at improvement in patients on study drugs.

In terms of the regulatory agency views, as I think we've said before, the FDA has been quite clear that–to us that the choice of primary efficacy endpoint was up to us. We told you we have chosen the ACR CRISS and reasons why, and they have also stressed that they want to look at the totality of the data. We believe that the ACR CRISS score, with its five components that are considered by the experts to be most essential in evaluating the overall status of the patients, will speak to treatment benefits. They include not just patient reported outcomes, but, as I said, effect on skin, effect on lung, and the physician global assessment. The way the score works is all will contribute. That's certainly a reasonable expectation. All will contribute. So, we expect to be able to show that the score does correlate with how the patient feels and function, which will be important to regulators.

***Brian Abrahams*:** Got it. That's really helpful, Barbara. Thanks. And then, what additional work do all you need to do to file the NDA in systemic sclerosis following the data? I think you mentioned some additional supportive Phase 1 work. And I am curious if you could talk a little bit more about the potential timelines between data and filing and how COVID could potentially impact that?

Dr. Barbara White: Well, I think that, we–as I mentioned, there are some Phase 1 studies that are underway and that we will complete, and we do not believe will delay the filing of the NDA. They have to do with the TQT study and studies and books with hepatic and renal impairments, and they are all underway. Most important step or the next step to getting to NDA filing is actually to have the pre-NDA meeting. And we are, at this point, anticipating that that will happen at the end of the year. And we will then, based on what we hear, move forward with NDA filing. So, again, I think, we're anticipating the NDA filing, of course, happening next year, but I think in terms of timelines, we'd really rather prefer to wait until we have input from the FDA itself.

***Brian Abrahams*:** It makes sense. One last one from me if I could. You spoke a lot about managing through some of the potential COVID-related headwinds when it comes to the data cleaning and analysis over the past few weeks. Now that the–through last patient, last visit as well can you also talk about the overall impact of the pandemic on data collection expectations

for missing data relative to, I guess, what you had anticipated going in, and how you guys are managing through that from a statistical analysis and imputation standpoint? Thanks so much.

Dr. Barbara White: Sure. Thanks, Brian, for that one, too. First of all, we were able to assess safety on essentially all the patients, because that can be done remotely, and that held true for all the studies across the board that we are doing, and that's really the most critical thing. When it came in the SSc Phase 3 study, we were nearly at the end and most of the patients were out. There were some patients in the last two visits who did not have efficacy assessments. The FDA has issued some guidance on how to handle these, and what we've done and are doing in our statistical analysis plan is consistent with that. And, because we enrolled more patients than we had anticipated, we had less dropouts than we thought we would have, and we were very well powered to start with. As I say, we still remain more than 90% powered for ACR CRISS at week 52. So, yes, we lost a few assessments at the end, but it's not enough to make a substantial difference in our powering. And the other thing is the way the statistical analyses are done, variability is assessed across the study with using a mixed model repeated measures. So, that also helps with our powering.

In terms of the CF study, again, safety was done on all the patients. In this case, the primary efficacy endpoint was actually done on all patients despite COVID-19, because that was set up so it could be done remotely from the very beginning of an assessment on the occurrence of pulmonary exacerbation. So, we didn't lose any efficacy data at all in it from the primary endpoint in the CF study. So, again, that remains well powered. Dermatomyositis study was largely in the early phases, and we again don't expect a substantial impact on the data or the powering there, the bigger impact with some delay in the start of the Phase 1 studies, which have all started at this point.

***Brian Abrahams*:** Got it. That's super helpful. Thanks again and looking forward to the data.

Dr. Barbara White: Thanks. We are, too.

Operator: The next question is from Maury Raycroft of Jefferies. Please proceed with your question.

Maury Raycroft: Hi. Good morning, everyone. Congrats on the progress and thanks for taking my questions. So, I had one on SSc. So, you guys have previously mentioned that FDA has indicated that you don't need to hit stat sig on mRSS. I'm wondering if there is any specific guidance regarding percent FVC in lung function, and what your thoughts are in a commercial or real world setting for patients who are worsening FVC. I guess, are there any natural combo strategies in mind that you guys have?

Dr. Barbara White: Maury, this is Barbara. I think I didn't quite hear the very last part of the question. So, would you mind repeating that before we go ahead? I want to make sure I do.

Maury Raycroft: Sure. Just wondering if you guys have thoughts on commercial or the real world setting for treating patients with worsening FVC, and are there natural combo strategies in mind for that?

Dr. Barbara White: Okay. So, I'll take the first part, and Craig will take the second. So, in terms of FVC, that's our third secondary endpoint. What we anticipate seeing is less decline from baseline in the lenabasum-treated patients than in the placebo-treated patients. The natural history is that, over the course of the year, we would expect in the placebo group several percentage points, 2.5% to 4%, reduction in FVC percent predicted, and we anticipate seeing less than that in the lenabasum-treated patients. The study is not powered to see a statistical difference in the FVC. That requires a much larger study and probably particular selection of patients who may be at greater risk for decline in FVC over time. Nonetheless, I want to point out that the baseline FVC percent predicted in our Phase 3 study is just about 80%, which is right at the border line. If you have less than 80% predicted as an individual, you could be considered to be have restrictive lung disease. So, the patients in our study do indeed have substantial lung involvement. And we do expect to see an impact, and we expect that that will address a very significant unmet need. Craig?

Craig Millian: Yeah. And just a few comments. So, about 40% to 50% of patients with the diffuse form of systemic sclerosis have some clinically meaningful interstitial lung disease. And so, we know that's a priority of treating physicians to treat that component of system sclerosis. We would expect, based on the--as Barbara described--the patients that are in our trial, many of whom are already on stable immunosuppression in part to treat their lung decline that we would be used in a complementary fashion for all the other elements of systemic sclerosis that are problematic. So, again, in terms of what we think about patient segmentation, we view this certainly as potentially a population of patients who will be on polypharmacy, and certainly we view--we'll see what the data tell us that lenabasum, if the data are favorable, should be a helpful addition to the armamentarium for these patients for the other troubling components of diffused systemic sclerosis.

Maury Raycroft: Got it. That's very helpful. And then as a follow-up question, just given the skin involvement in SSc, I'm wondering if you can comment on overlap of sites and investigators between the SSc and in that dermatomyositis studies. And is the over-enrollment dermatomyositis say anything about investigator enthusiasm and whether this was impacted by what the investigators are seeing in SSc?

Dr. Barbara White: This is Barbara. Thank you, Maury, again, for the question. There is overlap. The diseases themselves have some substantial clinical overlap and disease manifestations, and

certainly both are characterized by chronic inflammation and some degree of tissue damage. We're at academic sites. We're at top sites around the world, and we're looking at rare diseases in rheumatology. So, that certainly lends towards overlap. In addition, we've had experience with these sites and investigators and SSc. So, that allows us to feel more comfortable and then to feel more comfortable with the DM study. So, we think there is actually real operational pluses by using some of the same sites.

I think that, in terms of the over-enrollment in the DM study, it really has been, to us, quite rewarding. We didn't know what the enrollment was going to be like. Others have had trouble enrolling much smaller studies. Our KOLs told us, our advisors told us upfront, 'hey, you're going to have a tough time getting 150 in.' But we wanted to get at least that many in for powering purposes. But when the study started, it started enrolling much more quickly than we thought. It kept on going even during COVID-19. Certainly, it slowed. I mean, we are still in COVID-19, but it slowed during the early throes of COVID-19. And when sites began to reopen and enroll more patients, they just came in very quickly. We could have easily enrolled more. And I think that that does speak to, first and foremost the unmet need.

This is a disease in which people have significant skin and lung and muscle and joint involvement, as well as that of other organs and they also are pretty much left to immunosuppressants, immunomodulating agents. The patients in our DM study–we've again presented the baseline characteristics in part--are very sick. They have got more skin involvement than we thought. They've got significant weakness. Their patients' physician, global assessments are all in the mid-range and at mean. And most of them are on background immunosuppressive. So, these are a group of patients with very substantial unmet need, and I think that speaks in part to the enthusiasm over enrollment. Of course, we'd like to think that experience that the investigators have had already and experience they had with the first subjects in had something to do with the speed and our ability to over enroll but, we're also optimistic. I'll stop with that.

Maury Raycroft: Great. Great perspective. I guess, do you know the exact number of overlap in sites between the two studies?

Dr. Barbara White: I don't have that at my dispose–at my fingertips. So, I wouldn't want to give you incorrect information. But there is a fair number of them.

Maury Raycroft: Understood. Okay. Thanks again for taking my questions.

Operator: The next question is from Leland Gershell of Oppenheimer & Company. Please proceed with your question.

Leland Gershell: Good morning. Thank you very much for that comprehensive update and for taking my questions. Just a regulatory question for me. You said that that the Phase 2 in CF serve as a registrational study pending the data, with that coming sometime after the RESOLVE data, how should we think about the regulatory approach there? Would that be kind of a dual NDA approach? How should we think about timelines? Presumably, do you want to include CF along with RESOLVE when you go to the FDA, given the division? Will there be modules shared in the application? How should we think about that and the mechanics in the timeline? Thank you.

Dr. Barbara White: Leland, this is Barbara. Thank you, again, for that question. Very insightful. Our current thinking is that, indeed, we would want to submit one application rather than two, should both of those studies be positive. There is certainly room in a number of sections for the NDA application to use the same information, particularly in the non-clinical module four and the CMC module three, certainly module one, and some aspects of the safety review in module two. So, there is lots of room for overlap to help be efficient.

Leland Gershell: Great. So, we would–I guess, my question would be, would CF at all meaningfully delay the process or would it be negligible?

Dr. Barbara White: We think it's quite manageable. Certainly, we are expecting the CF data, as we said, approximately a month after the SSc data come out the top-line. There are other things that need to be done in terms of getting the NDA ready, and waiting for the CF data is not going to substantially delay the overall submission.

Leland Gershell: Okay. Great. Thank you very much for taking the questions.

Operator: The next question is from Dae Gon Ha of BTIG. Please proceed with your question.

Dae Gon Ha: Great. Thanks for taking our questions and congrats from my end, as well, on all the progress despite COVID-19. Hope you guys are all staying well. So, just a couple from me. Maybe, Barbara, just wondering what your latest thoughts are on how much disclosure or how much data you will be presenting for both RESOLVE-1 and the CF data expected this quarter. Specifically, I guess, for RESOLVE-1, what component scores can we expect, and, as well as--since you talked about OLE, can we expect any of that OLE data to also materialize when you report the top-line data? And then, just following up on an earlier question, just looking at ACR CRISS once again, not to beat a dead horse here, but recognizing that mRSS plays a critical role also in ACR CRISS calculation, just wondering if you can speak to what strategy or strategies you had implemented to minimize variability and how that has kind of evolved given the COVID-19 restrictions of monitoring, if you will. And then I've got a follow-up.

Dr. Barbara White: Okay. Let me see. Thanks for only doing them two at a time. I am going to try and remember them both. I think I've lost one already. So, let me start with the one about data variability with mRSS. Certainly, mRSS is a major driver of the ACR CRISS score. We've talked about that. The other components augment and increase the score, decrease the score to make it more clear whether the patient improved or did not improve from the baseline. But the mRSS is very important, and we certainly expect that mRSS changes will be directionally correct, if not statistically significant, in this study. And to reduce variability, we did--first of all, we selected investigators who, for the large part, I think nearly all of them, had extensive experience in the care of systemic sclerosis patients and the assessment of the skin thickening involving mRSS and in the conduct of clinical studies. The next thing we did was we trained them uniformly.

There is a Scleroderma Clinical Trials Consortium, an international group of experts, and they–with them, we developed a course and the approach to actually train all the investigators in the same way to do the score with live patients, and they had to pass certificates. Next, we monitored the data. There was a significant variability. We queried it, and, if we needed to, we actually retrained the investigators. So, looking over blinded data, I am not anticipating undue variability in the mRSS scores are lot of unexpected kind of data. So, I think that's where we are with that. Now, the first question, again, Dae Gon, about the ACR CRISS, what was it, again?

Dae Gon Ha: First question was just looking at what can we expect when you report top-line data for both RESOLVE-1 and CF?

Dr. Barbara White: Yeah. So, for both of them, of course, you will get safety information. That's always critical. You will get the disposition. So, you'll know how many patients did what. You will get the primary efficacy endpoints, and you will get for the SSc study, the secondary efficacy endpoints, and for the CF study, you will get, perhaps the few of the secondaries. There is a longer with the secondaries, and I think most–if they are not quite as relevant, as the actual event rate of pulmonary exacerbations. So, by the time we're done with top-line of the systemic sclerosis Phase 3, you will know ACR CRISS. You'll know mRSS. You'll know HAC. You'll know FVC. You'll know safety. And by the time we're done with the CF, you'll know that rate of pulmonary exacerbations using our primary definition and at least our secondary definition.

Dae Gon Ha: Got it. Thanks very much. And then, my last question is, given that you've now fully enrolled DM, and there is quite a bit of significant overlap in terms of skin manifestations, as well as some underlying attributes, I was wondering if you could speak to perhaps what we can glean from your SSc data to that DM data, recognizing that the endpoints are different. And maybe if you can also just give us a little bit of a primer on total improvement score, how that may be different from CDASI? Thank you.

Dr. Barbara White: Thank you, Dae Gon. Yes, we do think that there will be read through from the systemic sclerosis to the dermatomyositis study. The total improvement score is also a composite score that looks wholistically at improvement from baseline in these patients, and, again, it is the best composite that is there for assessing overall improvement in dermatomyositis. It is developed by experts. The components of it are the ones the experts think best reflects the overall nature of the disease and a way to assess treatment effects. And a number of those components are very similar to the components in the CRISS. There are physician global assessments, patient global assessments, and overall assessment of, in this case, extracellular manifestations, which would include skin and lung. There are assessments of muscle weakness, which, if you could, is equivalent of the mRSS assessment in scleroderma, picking a key organ and assessing its degree of involvement. And these are assessed for a degree of improvement from baseline and then put into a weighted algorithm to determine improvements. So, we think that, given that the nature of the actual components of at score are quite similar, that's the way it is. You look at patient physician global some measure of key organ involvement that there should be any disability, there should be a read through.

Dae Gon Ha: Great. Thanks for taking the questions and look forward to the data.

Dr. Barbara White: Thank you.

Operator: We have time for one more question from Elemer Piros of Roth Capital. Please proceed with your question.

Elemer Piros: Yes. Good morning. Thank you for taking my questions. Just a couple, Barbara. So, I don't think I asked this question before, but is there a particular reason why there is no open-label extension in the CF trial?

Dr. Barbara White: Hi, Elemer. This is Barbara. Yes, there is at this point. First of all, we worked very extensively with the Cystic Fibrosis Foundation and their leadership and their experience. And their feeling was that, perhaps that was not be an appropriate thing to do at that time. And so, we really followed their guidance on that one. That's the reason. Pretty much that's it.

***Elemer Piros*:** Okay. Thank you. And I can imagine that the missing data in the Scleroderma trial versus the CF trial would be treated differently, different methodologies since one of them is at 52-week observation and the other is a collection of events over 26-weeks. Could you please tell us how they would be handled differently?

Dr. Barbara White: Sure. So, first of all, let me start with CF. So, the primary outcome there is, as you know, pulmonary exacerbations, and that's also the first secondary outcome, event rate of pulmonary exacerbations. And we have very little missing data on that. That's collected even remotely. So, first of all, there was essentially no COVID-19 impact on that one. So, there isn't

anything special we're going to need to do for that primary endpoint. For the primary in SSc, as I said, it wasn't a lot of patients, and it was at the end. Wasn't a lot of patients, and our approach will be to handle the missing data in COVID-19-only patients by LOCF. I mean, that's our initial intent at this point. And handling other missing data throughout the study will be handled in standard ways, and there will be a number sensitivity analysis done handling missing data in this, that, or the other way as is ordinarily done. So, I don't think, Elemer that there is anything particularly unusual except for the few patients that are missing because of COVID-19. We'll pull that in with LOCF and do a sensitivity analysis without that.

Elemer Piros: Great. Well, thank you so much, Barbara.

Operator: Thank you. We have reached the end of our question-and-answer session. Ladies and gentlemen, that concludes today's teleconference and webcast. You may disconnect your lines at this time and have a wonderful day. Thank you for your participation.