



Corbus Pharmaceuticals
First Quarter 2020 Earnings Conference Call and Webcast
May 11, 2020

Operator: Greetings and 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. As a reminder, this conference is being recorded. It's now my pleasure to introduce your host, Ted Jenkins, Senior Director, Investor Relations and Corporate Communications. Please go ahead, sir.

Ted Jenkins: Thank you, Kevin. 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 Pharmaceutical's First Quarter 2020 Earnings Conference Call. We had an active first quarter and are on track for an exciting year. We anticipate multiple catalysts and data readouts in the coming months.

First, topline lenabasum data from the RESOLVE-1 Phase 3 study in systemic sclerosis remains on schedule and will be available this summer. These data will be followed by topline data from our Phase 2b lenabasum study in cystic fibrosis. With these critical data readouts now closer than ever, we are focusing more and more on preparing our NDA submission and commercialization following FDA approval.

We are also on track with our CRB-4001 Phase 1 study that will start later this year, as well as the selection of our next candidate also scheduled for later this year.

I would now like to 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 program. Thank you. Barbara?

Barbara White: Thank you, Yuval. To start, we do not anticipate significant delays or impact from COVID-19 on the delivery of topline data from the ongoing Phase 3 systemic sclerosis and Phase 2b cystic fibrosis studies. Our staff and the study site staff are committed to completing these studies on time, with attention to subjects' safety and data integrity. Because of COVID-19, Corbus has put into place new ways of working remotely within the Company and with study sites, external contractors, consultants, and vendors. We have had virtual meetings with staff at all study sites about how to manage subjects' safety, efficacy evaluations, and short supply if subjects cannot have visits at sites.

We remain in frequent contact with sites about these issues, data entry, and data monitoring. We have implemented remote data monitoring procedures and are implementing central data monitoring for all ongoing clinical trials run by Corbus. Our procedures are consistent with FDA and other health authority recommendations made for the pandemic. We will resume on-site data monitoring for all ongoing clinical trials when safe to do so and travel and site restrictions are lifted.

I'm pleased to inform you that, as of Friday, as a result of these efforts, about 99% of enrolled Phase 3 systemic sclerosis study subjects and about 96% of enrolled Phase 2b cystic fibrosis study subjects have completed double-blind, randomized, placebo-controlled dosing. Each study has a 28-day safety follow-up period after dosing is complete. Just note, participation in the systemic sclerosis Phase 3 open label extension remains high. About 97% of eligible subjects to-date have enrolled in the open-label extension, with a few more patients waiting to enter the open-label extension after COVID-19 associated travel restrictions are lifted.

Only about 1% of subjects have dropped out of the OLE to-date, and some subjects have participated in the open-label extension for more than a year. Based on current study progress, we remain on schedule for topline data for the Phase 3 systemic sclerosis study in summer 2020. The cystic fibrosis data will follow.

Our Phase 3 DETERMINE study in dermatomyositis is about 80% enrolled. Enrollment in this study has slowed during COVID-19 but is still active. We anticipate enrollment will be complete in the third quarter of this year, assuming travel restrictions will ease this summer in countries where we have study sites. Topline data are therefore on schedule for 2021. The open-label extension of this study is also already active.

Our second drug candidate, CRB-4001, is a cannabinoid receptor type 1 inverse agonist. CRB-4001 is designed to have limited access to the brain to minimize risk of psychiatric side effects

with the type that were seen with rimonabant. CRB-4001 has demonstrated potent effects on glucose tolerance, influence sensitivity, lipid metabolism, body fat, and hepatic fat in animal models of disease. We have identified additional potential beneficial effects and inflammation in fibrosis assays. The Phase 1 study of CRB-4001 remains on schedule to start in the third quarter of this year. The single ascending and multiple ascending dose study will evaluate the safety, tolerability, and pharmacokinetics of CRB-4001 in healthy, normal weight, and obese volunteers.

Additional work to expand our pipeline is being done by our internal research team of medicinal chemists, DMPK specialists, toxicologists, modelers, and biologists working in concert with external collaborators and vendors. We anticipate selection of our first organically developed CB2 agonist candidate compounds within the next few months. I will now turn the call over to Craig Millian to discuss our commercial program update.

Craig Millian: Thank you, Barbara, and good morning, everyone. We continue to execute on our commercial strategy to be launch-ready ahead of a potential lenabasum regulatory approval. As we advance our pre-launch preparations, we're building our commercial capabilities, establishing a deep understanding of the market and needs of the patient, and communicating relevant scientific information in the appropriate manner. Importantly, we have established a talented group of capable leaders to drive a successful launch and have most recently filled key roles on the Marketing and Medical Affairs teams.

On the last call, I highlighted the robust market access landscape and payer research we completed at the end of last year. In the first quarter of this year, we conducted additional market research in the form of a baseline awareness and perception survey with 100 U.S.-based rheumatologists who treat systemic sclerosis. These physicians reported that nearly half of their systemic sclerosis patients suffer from the diffuse cutaneous form of disease. These are the same type of patients who are in our clinic trials and so are of specific interest to us. Importantly, a vast majority of respondents strongly agreed that there is a high burden of disease, diminished quality of life, and the high mortality rate associated with systemic sclerosis. This recognition of the unmet need is entirely consistent with other market research and KOL insights that we've gathered to date.

Through this research, we also established a baseline for awareness and perception of current treatment approaches, as well as potential medicines and development. For example, on an aided basis, about 50% of respondents were familiar with the cannabinoid receptor type 2 as a potential mechanism for treating systemic sclerosis, and about 30% were familiar with lenabasum as a potential future treatment. At this stage, these numbers are encouraging while also leaving room for growth. On a promising note, of those who are familiar with lenabasum at the time of the survey, about 75% have a positive opinion of lenabasum, while the remainder have a neutral opinion. No respondents indicated a negative opinion. We'll continue to track

these metrics over time and plan to conduct the survey again after we have topline clinical data later in the year.

In addition to the awareness and perception study, we also recently engaged ClearView Consulting to conduct a robust and independent commercial assessment for lenabasum. The results from this exercise further validate the considerable opportunity that exists across the three rare diseases that lenabasum is being studied in late stage trials.

Finally, before turning the call back over to Yuval, I'd like to provide a brief update on how our disease education campaign is progressing. On our last call, I introduced this key initiative which is providing rheumatologists with relevant scientific information on systemic sclerosis. As a reminder, the insight behind the "Totality of systemic sclerosis" campaign is that SSc is a complex, devastating disease driven by both inflammation and fibrosis. The total burden of systemic sclerosis on patients is considerable, including increased mortality risk and disability. There remains a significant, unmet need as current approaches using immunosuppressive or anti-fibrotic agents, primarily address symptoms or specific organ complications. And importantly, the campaign highlights that cannabinoid receptor type 2 agonism shows promise as a novel approach to address both the inflammation and fibrosis that drives the disease.

We are currently attracting viewers to the website, totalssc.com, which launched in March. There have been early, encouraging signs of engagement with the content. For example, approximately 40% of visitors are consuming more than half of the content on the website. This is an encouraging indicator relative to benchmarks, suggesting that typically between only 10% to 20% of visitors consume more than half of the content on a pharmaceutical website. Additionally, we've seen strong earned media interest in the campaign, and multiple outlets have published articles or podcasts in recent weeks. These pieces highlight the unmet need and systemic sclerosis and point to the website as a resource.

We plan to leverage the campaign throughout the Scleroderma Awareness Month in June and upcoming virtual medical meetings, including the ACR's State-of-the-Art Clinical Symposium this month and the Systemic Sclerosis World Congress in July.

We are building a solid foundation with these disease education efforts and plans to further scale investment later this year. And of course, with our commercial leadership team now largely in place, we are purposefully proceeding with all other key elements of launch readiness, which I look forward to updating you on in future calls. I will now turn the call back over to Yuval.

Yuval Cohen: Thank you, Craig. Thank you, Barbara. I will now provide a brief update on our financial position. The Company ended the quarter with \$46.6 million in cash and cash equivalents. We maintain our guidance and expect the cash on hand and the remaining \$7.5

million in milestone payments from the Cystic Fibrosis Foundation Award to fund our operations into the fourth quarter of 2020.

In closing, I want to reiterate how excited we are for the second part of this year. With multiple data readouts and catalysts ahead, including two topline data readouts for systemic sclerosis and cystic fibrosis respectively, this will be the most important several months since Corbus was founded six years ago.

Let me also take a moment to thank our staff, our collaborators, and the participants in our studies, especially in these very challenging times, for their continued hard work and dedication. We are immensely grateful and hopeful that we will see the end of this crisis very soon. With that, I would like to thank all of you for your time and attention this morning. I now turn the callback to the operator, and we'll open the call for questions from the audience.

Operator: Thank you. We'll now be conducting a question-and-answer session. If you'd 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'd 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 is coming from Brian Abrahams from RBC Capital Markets. Your line is now live.

Bert Kinsey: Great. Thank you. Good morning. So, you mentioned—sorry, this is Bert on for Brian this morning. Thank you for taking our questions. So, you mentioned that around 99%, I think, of the patients have been dosed in the RESOLVE-1 study. I just wonder if you could talk a little bit about what data is left to collect in the study. And then, assuming that there may be some impact of COVID-19 on the data collection, what would be the plan for imputation of any missing data, and what potential impact could that have on the powering of the study? Thank you.

Barbara White: Okay. This is Barbara. I'll take that question. A couple of things. To be clear, 99% of them have finished through the end of dosing, and there is yet another 28-day follow-up. So, we will need to collect data on the last visit or visits, as well as the 28-day safety follow-up data. So, we have some more data to be collected.

However, to-date, our data collection and the entry of what we call pages—page entry is also largely complete. It is more than 98% complete. So, we're pleased with the progress to date despite, obviously, the challenges of COVID-19. We will, when we're done, as we do for all studies, need to make sure every last page of data is entered and that has been monitored.

Because of travel restrictions, we have begun remote data monitoring. That's when sites actually give us data online. We have access to data online. We review it, and we've done central monitoring, which is where we look over the data ourselves internally, just an additional programming, make sure the data are sensible.

And we assume that, between the onsite data monitoring that we have had in place and may be able to reinstitute remote monitoring and central monitoring, we will be able to ensure data integrity. We do not anticipate a significant delay because of these challenges. There may be up to a few weeks delay, but at this point we're not expecting a lot more than that. So, we remain on target for the data in summer.

In terms of powering, we've also had our statistician look closely at powering. We—the statistical analysis programs include approaches for data imputation and, in fact, multiple projects and sensitivity analysis. Those will be applied where needed. Because many of the patients had already completed before COVID-19, this will minimize the impact of the need to impute data. And certainly, in the cystic fibrosis study, the pulmonary exacerbation data all can be collected remotely. So, again, that helps there. We remain well powered. We've enrolled in each study a few more patients than we anticipated. Dropout rate has been less than we anticipated. So, again, powering remains where we wanted it to be, which is above 90% in the SSc study.

Bert Kinsey: Excellent. Thank you so much.

Operator: Thank you. Our next question today is coming from Maury Raycroft from Jefferies. Your line is now live.

Maury Raycroft: Hi. Good morning, everyone, and thanks for taking my questions. I'm going to ask an endpoint question again. Just for the upcoming SSc pivotal data readout this summer, can you guys just talk more about the relationship between mRSS and/or CRISS scores and skin softening? And so, it said that a five point improvement is clinically meaningful on mRSS. Do you have a sense of what the bar for meaningfulness is for KOLs and FDA and the CRISS scale?

Barbara White: So, thank you for the question. We will determine what is minimal important difference, which is a change in—from baseline, which subjects say is associated with improvement and the same thing for physicians. We simply ask the patients if they think they've improved and determined the median score of patients who believe they have improved, and the same thing for physicians who say the patients have improved. So, we will have direct data on what that will be at the end of the study. So, I don't really want to speculate on what that answer is at this point. But I think we'll be able to drive that with data when we we're there, and we'll in fact do the same thing for the mRSS, we'll determine the same kind of

minimal important difference within the study for the mRSS. And we'll provide those data both in publications, as well as to the regulators.

Maury Raycroft: Got it. Okay. And so, for—as a follow-up, I guess for mRSS then, with that being a secondary endpoint, do you guys have a sense of what different scenarios look like for the data on that endpoint and how the FDA would interpret the data during the review? Or is it kind of the same answers as what you just said?

Barbara White: So, I think the most important thing is to reiterate that the FDA has clearly said that they will look at the totality of the data when they assess things. Certainly, we have our primary, and we hope—we are quite optimistic that we will see a p-value on this outcome that reflects the totality of the disease, as Craig has said. That's super important when treating these patients, and that's what the ACR CRISS does.

The mRSS is the best existing outcome to look at skin thickening, which is a measure of skin fibrosis. It's also important to patients. The FDA said to look at the totality of the disease—of the totality of the data, and we believe that there have been no stipulated requirements that we get a p-value on mRSS or that we show a certain difference. At the same time, we certainly expect there to be a treatment effect on mRSS. And we expect to be able to say what the minimal important differences and normal important changes from baseline. And we would expect, actually, to reach that in the patients who have been treated will show all this data to the regulators.

Maury Raycroft: Okay, that's helpful. And then just a quick question on that total SSc website. Just wondering, there's a lot of information on there. Just wondering, if you're collecting information from potential patients that could use lenabasum? And can you comment at all on that? I guess it was mentioned that you're getting a lot of hits through the website, and there's a lot of information being consumed. But do you have a sense of—are you collecting patient information and building a patient database from the website?

Craig Millian: Yeah, thanks. Thanks for the question, Maury. Actually, the website is directed to rheumatologists. So, specifically, rheumatologists who are treating systemic sclerosis but aren't necessarily kind of the opinion leaders. The opinion leaders are very much aware of the unmet need and are aware of Corbus in the clinical program and the potential for CB2 agonism. So, what we really wanted to do was reach out to the broader community of treating physicians who treat systemic sclerosis, not patients. So, it's not a patient-directed website. And what we wanted to do is make sure they're aware of the unmet need within the disease and what were the science is leading in terms of potential treatments including CB2 agonism.

As part of the evolution of the campaign, there'll be more, more dynamic content added to the site, and we will begin to collect information, start to build a database and begin to have a

conversation with those physicians—the appropriate types of conversations in a pre-approval context. So, this is unbranded. It's non-promotional. It's purely disease education but obviously a great opportunity to begin to identify physicians who have an active interest in learning more about systemic sclerosis. So, we are intending to sort of build that database and then continue that communication as we head into potentially a launch of lenabasum. But not—no patient information is on the website.

Maury Raycroft: Got it. That's helpful. Thanks for taking my questions.

Operator: Thank you. Our next question today is coming from Leland Gershell from Oppenheimer. Your line is now live.

Leland Gershell: Hey. Good morning. Thanks for taking my questions. Just one for me. I joined the call a few minutes after the start. Yuval, have you mentioned the number of patients who had completed dosing in the RESOLVE-1 study before COVID-19 crisis really began?

Yuval Cohen: I'll hand it over to Barbara.

Barbara White: Hi, Leland. I actually don't know the absolute number. The majority of them had. And so, we will be missing a few patients who have efficacy assessments at the very end, but we can impute those. Those subjects have actually had partial assessments, what could be done offsite. We will impute the data that we need to impute. And, again, when we looked at—look at the power calculations and that impact on the study, we've not seen a significant impact, negated in part as I said by a bit of over enrollment and a lower dropout rates than we expected. So, we do believe will remain on target for both delivery and adequate powering.

Leland Gershell: Okay. And then, just one follow-up. Since your initial disclosure of the switch from mRSS to CRISS for the primary endpoint that you intend to have for that Phase 3, have you had any further interactions with the agency on that endpoint? Any further color you could provide on their willingness to use that as a primary endpoint for the trial? Thanks.

Barbara White: So, we've not had further interaction. Again, I want to say that, they clearly said that the primary efficacy endpoint—that choice was up to Corbus, okay? They didn't say we'll think about or reassess it later. They clearly said at the meeting, that choice is up to Corbus, and that they would look at the totality of the data. So, I just wanted to emphasize that. They've had the revised protocol for quite some time that has that changed an efficacy endpoint. And we've had no further inputs on them about that change.

Leland Gershell: Okay. That's very helpful. Thanks very much.

Operator: Thank you. As a reminder, that's star one to be placed in the question queue. Our next question today is coming from Christopher Marai from Nomura Instinet. Your line is now live.

Christopher Marai: Hey. Good morning and thank you for taking the question. And congratulations, Barbara, on all your hard work to get these studies enrolled and in the right direction with the situation. Anyway, I wanted to first touch upon just a little more clarity regarding how many patients are enrolling in the open-label extension? You highlighted on the call that 97% of eligible patients were enrolled in the OLE. And could you just remind us the qualifier there on eligible, what does it mean—what does it mean for a patient to be eligible? Then I have a follow-up. Thank you.

Barbara White: Sure, Chris. First of all, I wanted to say thank you for the kind comment. I do think our staff deserve a shout out. They have gone through extraordinary efforts during this challenging time to keep the studies ongoing as seamlessly as possible, and they've just done a fantastic job. I'm so proud of them. The next question—and I lost it, because I was so focused.

Christopher Marai: Long day in this busy week. So, yeah, I know, it was just understanding—if you qualify the OLE in patients, 97% of eligible patients. Could you just remind us what it means for patients to be eligible?

Barbara White: The original definition of “eligible” was you had to complete the dosing in the double-blind placebo control part of the study. And now, because we know some subjects can't have that very last visit on site, we've extended that. So, if they're—for any reason, they couldn't get the last visit on site, we will still allow them to be eligible. They might have a bit of a pause, but we'll allow them to be eligible. We don't want the patients to suffer that consequences of COVID-19, as well. So, to date, it's all of those patients that fall in that category, and we have over, at this point—don't know the exact number, but I do know, it's more than 300 patients enrolled.

Christopher Marai: Okay, great. That's very helpful. And then, just thinking about the timelines with respect to data collection and analysis and presenting topline results from the SSc study. May that—and I guess, the timing of that is on track from our understanding, but relative to the CF data that you expect to present, is there any chance to see if data could come before that the SSc data? And then, finally, on the SSc topline, I was just curious what you're expecting to share with the street and how you're expecting to share that with the street. Thank you, Barbara.

Barbara White: So, will the CF data results topline come before the SSc? The answer to that is no. The study is behind the SSc study in terms of where it stands. We have slightly more patients to come through. The last—the time that their last dose will be later. So, we expect the

topline CF data to be out more or less a month, give or take a few weeks, later than the SSc data. Can't say precisely at this point, but it will be later by about that amount of time. When we present topline results, we would certainly expect to present topline efficacy results, results—most, if not all of the secondaries and safety information, of course, because of the importance of safety. That's what you should expect.

Christopher Marai: Great. Very helpful. Thank you, and congrats again.

Barbara White: Thank you.

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