



**Altimune, Inc.**

**T-COVID Conference Call**

**June 1, 2020**

## C O R P O R A T E P A R T I C I P A N T S

**Monique Kosse**, *Investor Relations, LifeSci Advisors*

**Vipin K. Garg, Ph.D.**, *President and Chief Executive Officer*

**Scot Roberts, Ph.D.**, *Chief Scientific Officer*

**M. Scott Harris, M.D.**, *Chief Medical Officer*

**Will Brown**, *Chief Financial Officer*

## C O N F E R E N C E C A L L P A R T I C I P A N T S

**Yasmeen Rahimi**, *ROTH Capital Partners*

**Jonathan Wolleben**, *JMP Securities*

## P R E S E N T A T I O N

### Operator

Greetings. Welcome to Altimmune Inc. T-COVID Conference Call.

At this time, all participants are in a listen only mode. A brief 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 call is being recorded.

It's now my pleasure to introduce your host, Ms. Monique Kosse with LifeSci Advisors. Thank you. You may begin.

### Monique Kosse

Thank you Operator, and thank you everyone for participating in today's T-COVID conference call.

Leading the way today will be Vipin Garg, Chief Executive Officer of Altimmune. Also participating on the call today is Scot Roberts, Chief Scientific Officer, Scott Harris, Chief Medical Officer, and Will Brown, Chief Financial Officer. After their prepared remarks, we will open up the call for a question-and-answer session.

A press release announcing the launch of the T-COVID program was issued this morning and can be found on the Investors page of the Company's website.

Before we begin, I would like to remind everyone that remarks about future expectations, plans and prospects constitute forward-looking statements for the purposes of the Safe Harbor provisions under the

Private Securities Litigation Reform Act of 1995. Altimmune cautions that these forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those indicated, including those related to COVID-19 and its impact on our business operations, clinical trials, and results of operations. For a discussion of some of the risk factors that could affect the Company's future results, please see the Risk Factors and other cautionary statements contained in the Company's filings with the Securities and Exchange Commission. I would also direct you to read the forward-looking statement disclaimer in our press release issued this morning and now available on our website. Any statements made on this conference call speak only as of today's date, Monday, June 1, 2020, and the Company does not undertake any obligation to update any of these forward-looking statements to reflect events or circumstances that occur on or after today's date.

As a reminder, this conference call is being recorded and will be available for audio rebroadcast on Altimmune's website at [www.altimmune.com](http://www.altimmune.com).

With that, I will now turn the call over to Vipin Garg, Chief Executive Officer of Altimmune. Vipin, please go ahead.

**Dr. Vipin K. Garg**

Thank you, Monique.

Good morning everyone, and thank for joining us as we discuss the initiation of our clinical program T-COVID, our intranasal therapeutic product candidate for COVID-19.

Before I begin, I would like to clarify the difference between the T-COVID program, which is the subject of this morning's discussion, and AdCOVID vaccine development program, which we have discussed in the past.

In February, we announced the development of AdCOVID, our single-dose, intranasal vaccine candidate to protect against COVID-19. AdCOVID is based on our replication-deficient adenovirus platform technology, RD-Ad5. It is also used in our NasoVAX vaccine for influenza, and our NasoShield for anthrax. The development of AdCOVID is progressing well with our collaborators at the University of Alabama at Birmingham currently performing preclinical testing of our candidate vaccines. We expect to begin sharing the results of this testing near the end of June, and are hopeful that the next step will be initiation of human clinical trials in Q4 2020. Based on the proposed product profile of AdCOVID, we're very excited about the prospects of this vaccine program.

In addition to developing our AdCOVID vaccine, we also recognize the need for additional therapeutic options for those with COVID-19. We have known for sometime that our RD-Ad5 vectors can modulate the innate immune system of the respiratory tract in a way that protected animals against the effects of severe respiratory virus infection. This effect is unrelated to a vaccine effect or the stimulation of specific immunity against the pathogen, and instead relates to an alteration of the host innate immune response, lessening the exaggerated information that can be associated with pandemic respiratory infections, such as SARS-CoV-2. As this pandemic unfolded, we realized we had an opportunity to test this novel immunomodulatory activity of our vaccine technology in a clinical setting, and the team has been working diligently to design a clinical trial to evaluate this therapeutic application of our vector technology. We call this T-COVID.

Immunomodulatory is one of the important therapeutic approaches that is currently being evaluated for COVID-19. However, most of these efforts have been directed to treating hospitalized patients with a focus on ARDS or cytokine storm. By contrast, T-COVID is targeting individuals who have recently been infected and are showing early symptoms with the goal of modulating the severity of lung inflammation and potentially stop the progression of the disease before hospitalization is required. The T-COVID approach

therefore is highly differentiated from other current applications of immunomodulatory agents targeted at advanced lung disease.

We began discussing this approach with the FDA in late March and the agency has been very responsive and involved with our program. As had been widely reported, the FDA has been inundated with COVID-19 related programs, and despite their heavy workload, they did an incredible job with the review of our submission throughout the pre-IND meeting and IND process. We requested and expedited review from the FDA and received clearance 43 days following our submission. I would like to publicly thank the FDA review team for their prompt attention and thoughtful comments which were very helpful to our regulatory filing process and helped us design a study protocol that we feel very good about.

One of the key aspects of our ability to undertake the T-COVID development program is that we will be using our existing supply of NasoVAX influenza vaccine to perform the T-COVID therapeutic trial. This allows us to start the clinical trial immediately.

I will now turn the call over to Scot Roberts, our Chief Scientific Officer, who will discuss in more detail the preclinical studies that led us to this new clinical approach, the mechanism of action of T-COVID and the use of NasoVAX drug product for the trial. Scot?

**Dr. Scot Roberts**

Thank you, Vipin, and good morning, everyone.

As Vipin indicated, T-COVID is a application of our replication-deficient adenovirus type 5, or RD-Ad5, vaccine technology as a potential therapeutic for COVID-19. The scientific basis for this approach stem from the studies we conducted with the National Institute of Allergy and Infectious diseases. In those studies, we observed that intranasal administration of our Ad5 protected mice from death following lethal challenge with a respiratory virus. The protection occurred within days and was not associated with any type of vaccine effect that one normally thinks about, such as antibodies, T-cells, mucosal IgA directed against the challenge virus. Instead, we found that treatment with our RD-Ad5 vectors affected an immunomodulatory response that culminated in significantly decreased levels of inflammatory cytokines and inflammation in the lung that occurs following challenge with a respiratory virus.

The inflammatory cytokines that were suppressed in the treated animals included IL-1 alpha, IL-12 and IL-6. It's important to note that for the protection to occur the RD-Ad5 vector had to be administered by the intranasal route, as intramuscular injection was ineffective in providing protection. The suppression of IL-6 levels is especially relevant to COVID-19, as IL-6 is believed to be involved in ARDS and death associated with severe COVID-19.

Now, earlier, they indicated that the protective effect of T-COVID was mediated by our RD-Ad5 vector technology and not associated with a specific vector. In fact, much of the preclinical work was performed with an RD-Ad5 vector that did not express any vaccine antigen at all. Importantly, essentially identical protective results were obtained with a NasoVAX influenza vector. Considering we have remaining NasoVAX drug product from our Phase 2 clinical study available, the FDA has agreed that we may use NasoVAX as the therapeutic vector in the upcoming T-COVID clinical trial, allowing us to launch this trial in June.

With that, I'll turn the call over to Scott Harris, Altimmune's Chief Medical Officer, who will discuss our clinical trial plans. Scott?

**Dr. Scott Harris**

Thank you, Scot, and good morning, everyone.

As Vipin noted, we held a pre-IND meeting with FDA in late March and filed the IND in early May. The agency was gracious in granting Altimmune a pre-IND meeting and expediting review of the IND in a shorter timeframe than the usual PDUFA guidance. We want to thank the agency for its wholehearted support in moving products for COVID-19 forward as quickly as possible in the face of this pandemic. Their efforts on our behalf were particularly remarkable in view of the number of applications they have received since the start of the pandemic.

The clinical trial which Altimmune is initiating is a placebo-controlled, Phase 1/2 study to evaluate the potential of T-COVID to prevent clinical worsening in outpatients with early COVID-19. The trial design is in line with the recent FDA guidance for the conduct of clinical trials during the COVID-19 pandemic and is based on the concept that T-COVID administered as a single intranasal dose to patients with recent diagnosis of COVID-19 in early symptoms could prevent the progression to severe lung inflammation and decrease the development of advanced COVID-19 and the need for hospitalization.

The trial was expected to enrol approximately 100 patients with a recent diagnosis of COVID-19 and early symptoms, who will be randomized one-to-one to receive either intranasal T-COVID or intranasal placebo administered in the outpatient setting. Patients will be followed at home for the next 14 days. These patients will be provided (inaudible) symmetry devices and tablets recording their symptoms over this 14-day time period. This will be supplemented with daily phone calls from the investigative site. Patients will be followed out to 42 days for hospitalization and medical status. No clinic visits will be required once the patient is determined to need medical attention. The primary endpoint for the study is the proportion of patients with clinical worsening, which is defined as a 4% decrease in pulse oxygen saturation or the need for hospitalization. Secondly endpoints include change in pulse oxygen saturation, heart rate, the need for oxygenation and the need for mechanism ventilation.

As a further background, I'd like to spend a few moments on the underlying safety profile of T-COVID, which builds on the safety profile of our intranasal RD-Ad5 vector vaccines, which include NasoVAX, our intranasal influenza vaccine, and NasoShield, our intranasal vaccine for anthrax. To date, 176 subjects have been dosed across five clinical studies with an adverse event profile similar to placebo. To further ensure the safety of study participants, we are announcing patients will be enrolled in three cohorts of increasing risk or deterioration of COVID-19 based on age and clinical risk factors for more severe disease, with safety reviews at the completion of each cohort.

From a timing perspective, the clinical trial is expected to commence in June and readout rapidly with study results anticipated as early as the fourth quarter of 2020. We have already engaged clinical investigators and thought leaders and these individuals have experienced enthusiasm for the concept of T-COVID and the design of the clinical trial. Clinical trial sites have already been recruited.

I want to finish by saying that there is a serious unmet need for therapeutics for COVID-19, and while multiple other investigative efforts are underway, they have mainly been focused on patients who are hospitalized with established pulmonary deterioration. In contrast, T-COVID is squarely focused on outpatients and the prevention of hospitalization and deterioration in this population. Pending a successful readout, we also anticipate discussions with FDA about future clinical trials and emergency use authorization.

And with that, I'll turn it back over to Vipin Garg. Vipin?

**Dr. Vipin K. Garg**

Thank you, Scott.

I would like to add that looking forward we envision other important usage of T-COVID. For example, we believe it could be studied not only for the treatment of early COVID-19, but for pre- and post- exposure prophylaxis for higher risk individuals, such as frontline healthcare workers. Based on the underlying activity of T-COVID, we believe it would also be attractive as a first-line defense for other viral respiratory pathogens for which vaccines are not yet available, such as an influenza pandemic or if a new strain of coronavirus emerges.

As a public health initiative, treatment consisting of a single intranasal dose not requiring the use of needles or infusion with the potential for self-administration would be extremely attractive in the setting of a pandemic. From international health perspective, the current stability profile at ambient or room temperature may allow T-COVID to be widely distributed worldwide without the need for refrigeration. These are important concepts that go well beyond the immediate readout of the clinical trial that we are now initiating.

Finally, I would like to say that everyone in the Company has worked extremely hard over the last few months to launch two new programs, in addition to advancing our existing and very exciting portfolio of drug and vaccine candidates in other therapeutic areas. We continue to be dedicated and committed to increasing value to our shareholders and very much look forward to generating data across our portfolio.

Before we open the call for Q&A, I would like to turn the call over to Will Brown, our Chief Financial Officer, who will provide some financial updates. Will?

**Will Brown**

Thank you, Vipin, and good morning, everyone.

As we reported on our Q1 earnings call, we ended Q1 with \$33 million of cash and investments on hand. Since that call, we have seen \$4.6 million warrants exercises for proceeds of approximately \$16 million. This additional cash along with the anticipated cash tax refund of \$2.9 million related to our NOL carryback, puts Altimmune in a strong financial position to execute the T-COVID trial.

As the team has discussed, we will be using existing NasoVAX drug product in the T-COVID trial, which saves considerable manufacturing related cost in addition allowing us to commence the trial quickly. Accordingly, our costs are primarily related to conducting the clinical trial and are expected to be approximately \$5 million.

Finally, today, we amended our prospectus supplement related to our previously announced equity distribution agreement with JMP Securities, which increases the offering amount from \$18.9 million to \$50 million. We made this amendment considering we are no longer subject to baby shelf rules given the recent appreciation of our stock price.

Now, I would like to open the call for Q&A. Operator?

**Operator**

Thank you. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you'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 the star keys.

Our first question is from Yasmeen Rahimi with ROTH Capital Partners. Please proceed.

**Yasmeen Rahimi**

Hi team. Thank you for taking our questions, and congratulations on the great progress. I have a number of questions for you, so let's start off one by one.

Can you shed light to us the common element between T-COVID and AdCOVID? Is that they have the same vector, the replication-deficient adenovirus? Can you shed light if the doses of the vector are the same between T-COVID and AdCOVID, and then provide a little bit more color on how much read through we will have between the two, the T-COVID and AdCOVID?

And then the second question is, can you help us with or shed light into the SARS-CoV-2 viral load reduction that you saw with T-COVID in your preclinical data set that was recently generated? And then I have a few more.

**Dr. Vipin K. Garg**

Good morning Yasmeen. Thank you for your questions. I think we're going to tag team here to answer your questions. Let me first turn it over to Dr. Scott Harris to handle the front part of your question and the Scot Roberts can walk you through some of the additional points that you're asking for clarification. Scott?

**Dr. M. Scott Harris**

Hi Yasmeen. So in the current trial we're going to be using 10 to the 11 viral particles. The actual dose of viral particles in the AdCOVID test vaccine will be the subject of clinical testing. Based on the NasoVAX profile, lower levels of viral particles could be effective as a vaccine but we elected to choose the 10th to the 11th lot that we currently have available for NasoVAX, for the current clinical trial.

And in terms of the read through to the COVID vaccine, I would say that the vaccine has tremendous attributes by itself, especially the induction of mucosal immunity. If this additional property were demonstrated in the current clinical trial, it would add to the current AdCOVID profile. Like I say that that's not an assumption that we're making at this point. We think AdCOVID by itself has tremendous attributes but if this additional property were demonstrated in the T-COVID trial would be only an upside.

I'll turn the second question over to Scot Roberts.

**Dr. Scot Roberts**

Yes. Hi Yasmeen. Could you restate the second part of your question there for me?

**Yasmeen Rahimi**

Yes, of course. Scot, my question was, can you shed light on the preclinical data that was generated for T-COVID? What type of viral load reductions was seen with T-COVID preclinical model?

**Dr. Scot Roberts**

Sure. Yes. So what we saw was effects on viral replication and those were consistent but they were relatively modest and the way that we think about how T-COVID works is rather than being a direct antiviral type of mechanism, it's modulating the host immune response so that it's not exaggerated and not pathological in its response. And by that I mean the exaggerated production of IL-6 leading to (inaudible) lack of oxygenation and failure of critical organs. So we're really modulating the host immune response to the infection rather than the infection itself.

**Yasmeen Rahimi**

Thank you Scot for the clarity. Another question we have for you is, so the study is going to be in patients that are not hospitalized with onset of symptoms, can you shed light with how you define onset of symptom, and then why did you select to go into patients over the age of 35? What was the reason for that age group? And then are there any exclusions of patients that are at high risk in the study?

**Dr. Vipin K. Garg**

Scott Harris?

**Dr. M. Scott Harris**

Sure. Thank you for the question Yasmeen. So, the onset of symptoms is defined in the protocol of symptoms within two days or 48 hours of entry into the trial. The reason that we chose patients over the age of 35 in this initial clinical trial were we're trying to pick up efficiency and we felt that we wanted to be able to get a readout on the endpoint and if we enrolled lower risk patients it would dampen the signal. Now as drug development ensues, if the initial trial is successful, we will also target that population. In agreement with the FDA we agreed to conduct a study much like a Phase 1 trial with ascending risk. The initial population will have lower risk than the second cohort, and then the final cohort will be opened up.

So, in many ways the beginning of the trial will be a safety part of the trial, and as we progress there's greater opportunity to get readout on efficacy.

**Yasmeen Rahimi**

Thank you. And then last question for the team. Can you shed light into where you are in regard to timelines with AdCOVID program?

**Dr. Vipin K. Garg**

Yes, Yasmeen. As we announced, I think it was middle of May, that we have actually started preclinical work, our collaborators at University of Alabama, and we are expecting results during June and we will be sharing them as those results become available. As you know, what we are doing here is looking at multiple arms of the immune system, so we'd be looking at antibody response, T-cell response, and more importantly the mucosal response, in particular, the nasal mucosal immunity that we think could also be very, very important for this particular pathogen.

So we hope to have all of that data by the end of June, and that would set us up for initiation of our clinical trials in the fourth quarter of this year. So, we're pretty much on that timeline right now.

**Yasmeen Rahimi**

Excellent. Thank you so much team and congrats on the amazing progress.

**Operator**

Our next question is from Jonathan Wolleben with JMP Securities. Please proceed.

**Jonathan Wolleben**



Hi, good morning. Congrats on the progress and thanks for taking the questions. Just more on the trial design. Can you tell us what risk factors are being considered in these different cohorts and how those change as the trial progresses? And is that a change in specific inclusion criteria? So any details there.

**Dr. Vipin K. Garg**

Scott Harris?

**Dr. M. Scott Harris**

Sure. Hey, thank you Jonathan for the question. So, the first cohort will be patients between the ages of 35 and 49 with no CDC defined risk factors for worsening COVID-19. That'll be 20 patients. At the end of that cohort there'll be a safety review and if the safety profile meets out then we'll progress to the second cohort, which will be a total of 28 patients who are unrestricted in their age over the age of 35. That'll be 28 patients and will be a safety review after those patients are fully enrolled and observed. And then the final 48 patients or 50% of the trial, there'll be no restrictions so long as the patient is over the age of 35. We will allow all comorbidities, such as diabetes, obesity, hypertension, cardiovascular disease and the life that had been defined as risk factors for severe COVID-19 that will be allowed in the trial.

So, as I said before in response to Yasmeen's question, you can see the early part of the study we'll be looking at safety, and as we move through the three cohorts, we'll be increasing the opportunity to examine efficacy whereby the final cohort will really have the whole population.

**Jonathan Wolleben**

Great. And with these non-hospitalized patients, how are you thinking about the placebo response and how that might change between these cohorts?

**Dr. M. Scott Harris**

Well, it's a hard endpoint, Jonathan. We specifically avoided endpoints such as symptom scales. A 4% drop in oxygenation is not something that you would see normally. So, it's something that will happen in patients who are untreated. We have estimates of what those rates will be and we're not fearful that this trial will be consumed by placebo effect.

Okay. And then final question for me, can you comment on manufacturing, is this something you're going to start scaling up during the study or wait to see results?

**Dr. Vipin K. Garg**

Scot Roberts, do you want to take that?

**Dr. Scot Roberts**

Sure. So, we've been fortunate with respect to the NasoVAX availability. Not only do we have a drug product available for the initiation of the trial here in June, but we also have additional drug substance which can be quickly formulated into a drug product, and that's to drive a second trial. Beyond that, I think that the negotiations with regulatory agencies and the path toward any UA will really dictate our next steps.

**Jonathan Wolleben**

Great. Thanks for taking the questions and congrats again on the progress.

**Operator**

As a reminder, it is star, one on your telephone keypad if you would like to ask a question. We will pause for a brief moment.

Okay, we have reached the end of our question-and-answer session. I would like to turn the conference back over to Management for closing remarks.

**Dr. Vipin K. Garg**

Thank you everyone for listening in today. We look forward to speaking to you again. Thank you.

**Operator**

Thank you. This does conclude today's conference. You may disconnect your lines at this time and thank you for your participation.