Altimmune Announces Update on AdCOVID™ Phase 1 Clinical Trial

June 29, 2021

- AdCOVID was well tolerated but did not stimulate an adequate immune response in healthy volunteers
- Altimmune will discontinue further development of AdCOVID and focus its resources on its ongoing obesity and liver programs
- Altimmune also provides an update on its T-COVID™ Phase 1/2 Clinical Trial


AdCOVID Update

The Phase 1 AdCOVID clinical trial is evaluating the safety and immunogenicity of the intranasally administered vaccine candidate in approximately 80 healthy adult volunteers between the ages of 18 and 55. Subjects received either 1 or 2 doses of AdCOVID as a nasal spray at 3 dose levels. In addition to the primary study endpoint of safety and tolerability, the immunogenicity evaluation of AdCOVID included serum binding and neutralizing antibody titers and mucosal IgA antibody from nasopharyngeal swabs post-vaccination.

AdCOVID appeared to be well tolerated with an overall adverse event profile similar to intranasal saline placebo. The immunogenicity data demonstrated lower than expected immune responses for each of the immune parameters tested. Although antibodies were detected that bound the SARS-CoV-2 Spike protein and neutralized the virus in a subset of subjects, the magnitude of the response and the percent of subjects responding to AdCOVID were substantially lower than what had been demonstrated for other vaccines already authorized for emergency use. Based on these data, and in view of the highly competitive COVID-19 vaccine landscape, Altimmune is discontinuing further development of AdCOVID beyond the completion of this Phase 1 trial.

"The immune response to AdCOVID was inferior to that seen in our NasoVAX influenza vaccine trial," commented Scot Roberts, PhD, Chief Scientific Officer at Altimmune. “Unlike the NasoVAX study, the AdCOVID study population lacked immunity from prior infection or vaccination. We believe that prior immunity in humans may be important for a robust immune response to intranasal dosing with AdCOVID.”

“The top-line Phase 1 clinical data are disappointing given the encouraging preclinical data and our substantial efforts in advancing a differentiated, intranasal vaccine candidate in the fight against COVID-19,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimmune. “However, we are fortunate to have a strong pipeline with highly differentiated product candidates targeting indications of significant unmet need. Moving forward, Altimmune will focus its resources on the development of ALT-801 and HepTcell, its novel peptide-based therapeutics for obesity and liver diseases.”

Dr. Garg continued, “Encouraging 6-week interim data were recently demonstrated in our ongoing ALT-801 12-week Phase 1 clinical trial in overweight and obese volunteers, demonstrating significant weight loss without the need for dose titration and only transient nausea with no reports of vomiting, diarrhea or constipation. With our strong balance sheet providing a cash runway into 2023, we look forward to advancing our obesity and liver disease programs in the second half of 2021 and beyond.”

T-COVID Update

The Phase 1/2 trial completed dosing in 2 of the 3 planned dose cohorts. The first 2 cohorts were designed to assess the safety of T-COVID treatment and were comprised of COVID-19 infected patients 49 years or younger with a low risk of progression to serious disease. In these cohorts, T-COVID was well tolerated without any serious adverse events observed. The 3rd cohort was intended to evaluate the efficacy of treatment and enroll patients over the age of 65 or with increased risk of serious sequelae by virtue of pre-existing comorbidities. However, the effective rollout in the United States of authorized COVID-19 vaccines and decreasing incidence of disease significantly reduced the number of patients meeting these criteria, and Altimmune has been unable to enroll subjects in the final cohort.

As a result of these enrollment challenges, the Company has decided to terminate further enrollment and evaluate options for future T-COVID development following an assessment of the available data and discussions with its partners, the U.S. Army Medical Research & Development Command (USAMRDC) and the Medical Technology Enterprise Consortium (MTEC).

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver disease and intranasal vaccines. Our pipeline includes next generation peptide therapeutics for obesity, NASH (ALT-801), and chronic hepatitis B (HepTcell™); proprietary intranasal vaccines; and an immune modulating therapeutic for COVID-19 (T-COVID™). For more information on Altimmune, please visit www.altimmune.com.

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