Altimmune Announces New Preclinical Data for AdCOVID™ Demonstrating Sterilizing Immunity After a Single Intranasal Dose

May 10, 2021

Data Show No Detectable Levels of Infectious Virus in Lungs of Vaccinated Mice Following Challenge with SARS-CoV-2

Sterilizing Immunity Believed to be Critical for Blocking Viral Transmission

Phase I Clinical Trial of AdCOVID Expected to Report Data in June 2021

GAITHERSBURG, Md., May 10, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced positive results from a preclinical study of AdCOVID in a SARS-CoV-2 challenge model of infection. In this study, a single intranasal dose of AdCOVID provided sterilizing immunity in the lungs of vaccinated mice, in contrast to the development of dense pulmonary infection and disease in the lungs of non-vaccinated mice following infection with SARS-CoV-2. AdCOVID is a novel, single-dose intranasal vaccine candidate for COVID-19.

“These latest data are very exciting, as they confirm and expand upon the numerous potential advantages of our differentiated intranasal vaccine approach,” said Scot Roberts, Ph.D., Chief Scientific Officer at Altimmune. “In the current study, we found a heavy burden of infectious SARS-CoV-2 virus in the lungs of non-vaccinated mice following challenge with the virus. Importantly, no detectable levels of infectious virus were observed in the lungs of AdCOVID-vaccinated animals.”

Dr. Roberts continued, “These data suggest that a single intranasal vaccination with AdCOVID may provide sterilizing immunity that neutralizes infectious virus, which is believed to be the best way to block viral transmission. Blocking transmission is critical for preventing spread of the virus and preventing the emergence of new variants of concern, both of which have the potential to prolong the pandemic. We continue to be encouraged by the accumulating preclinical data for AdCOVID and look forward to reporting the results of our ongoing Phase 1 clinical trial later this quarter.”

“Growing vaccine hesitancy, which is emerging as a real problem in the fight against SARS-CoV-2, underscores the importance of developing novel vaccine approaches like AdCOVID, which is a needle-free, thermostable vaccine that may be delivered in a single-dose and has the potential to prevent SARS-CoV-2 transmission. These attributes could foster vaccine acceptance, both nationally and globally. In addition, intranasally delivered AdCOVID could play a critical role in re-vaccination campaigns to control future spread of the virus, and ultimately to help bring an end to this devastating global pandemic,” said collaborator Frances Lund, Ph.D., Charles H. McCauley Professor and Chair for the Department of Microbiology at the University of Alabama at Birmingham (UAB).

In the current study, performed in collaboration with UAB, K18-hACE2 transgenic mice, which are highly permissive for SARS-CoV-2 replication and considered one of the best models for COVID-19, were vaccinated with a single intranasal dose of AdCOVID and challenged one month later with live SARS-CoV-2 virus.

When the lungs of the mice were evaluated for infectious SARS-CoV-2 virus, no detectable levels of infectious virus were observed in the lungs of vaccinated mice, representing a greater than one million-fold reduction of infectious virus compared to the non-vaccinated controls. This demonstration of sterilizing immunity is consistent with the stimulation of local and systemic immunity by AdCOVID shown in previous animal studies, including high serum neutralizing antibody and T cell responses, and most importantly, mucosal IgA responses in the respiratory tract.

In previously reported preclinical studies, AdCOVID was associated with a 29-fold induction of spike-specific IgA and resident memory T cell responses in the lungs of experimental animals, as well as robust systemic serum neutralizing antibody titers and T cell responses in the lung and spleen.

The ongoing AdCOVID Phase 1 clinical trial is evaluating the safety and immunogenicity of AdCOVID following a single dose or two intranasal doses administered one month apart and is expected to report topline data in June 2021. The trial is evaluating three different dose levels of AdCOVID and will measure local mucosal IgA responses in the nasaopharyngeal cavity, systemic serum immune responses, including serum neutralizing antibody relative to COVID-19 convalescent serum, and T cell responses directed against the spike protein receptor binding domain.

About AdCOVID

AdCOVID is a single-dose intranasal vaccine candidate for COVID-19. It is designed to stimulate a broad immune response including both systemic immunity (neutralizing antibody) and local immunity (mucosal IgA, resident memory T cells) in the nasal cavity and respiratory tract.

In published preclinical studies (www.biorxiv.org/content/10.1101/2020.10.10.331348v1) conducted in collaboration with the University of Alabama at Birmingham, potent serum neutralizing antibody responses, T cell responses, and a robust induction in mucosal immunity were observed in mice following a single intranasal dose of AdCOVID. Mucosal immunity was characterized by IgA antibody and resident memory T cell responses in the respiratory tract, both of which are believed to be important in fighting infection, and importantly, transmission. In other preclinical studies, AdCOVID provided 100% protection against lethal SARS-CoV-2 challenge.

Based on data from Altimmune’s other intranasal platform vaccine candidates, AdCOVID is expected to have extended stability at room temperature that would allow for cold chain-free shipment of the vaccine. If demonstrated, AdCOVID could be stored in the common refrigerators found in community-based doctors’ offices and pharmacies for two years or more. The Company believes that these simple and convenient handling requirements, together with the potential ability to block SARS-CoV-2 transmission, could position AdCOVID as a leading intranasal COVID-19 vaccine.

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing intranasal vaccines, immune modulating therapies and treatments for

liver disease. Our diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID™), anthrax (NasoShield™) and influenza (NasoVAX™); an intranasal immune modulating therapeutic for COVID-19 (T-COVID™); and next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™). For more information on Altimmune, please visit www.altimmune.com.

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Forward-Looking Statement

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the timing of key milestones for our clinical assets, the timing of the data readout from the AdCOVID Phase 1 clinical trial in Q2 2021, the potential immunization effects of AdCOVID, the potential of AdCOVID to block SARS-CoV-2 transmission, the shipping and storage requirements for AdCOVID, the prospects for regulatory approval, our ability to manufacture AdCOVID for our clinical trials and commercial needs, and commercializing or selling any product or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Altimmune, Inc. (the "Company") may identify forward-looking statements. The Company cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward looking statements or historical experience include risks and uncertainties, including risks relating to: potential impacts due to the COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, access to clinical sites, enrollment, adverse effects on healthcare systems and disruption of the global economy; the reliability of the results of studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; the Company's ability to manufacture clinical trial materials and commercial supply on the timelines anticipated; the Company's ability to secure manufacturing approval from its SARS-CoV-2 cell licensor on the timelines anticipated; and the success of future product advancements, including the success of future clinical trials. Further information on the factors and risks that could affect the Company's business, financial conditions and results of operations are contained in the Company's filings with the U.S. Securities and Exchange Commission, including under the heading "Risk Factors" in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC, which is available at www.sec.gov.

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Source: Altimmune, Inc.