



Altimmune Commences Enrollment in Phase 1 Clinical Trial of AdCOVID™ -- a Needle-Free, Single-Dose Intranasal COVID-19 Vaccine Candidate

February 25, 2021

Nasal spray may offer room temperature distribution that could reduce logistical challenges for healthcare systems and providers

Intranasal administration targets the virus at its point of entry and in a preclinical study induced local nasal mucosal immunity believed to be critical for preventing further viral transmission

GAITHERSBURG, Md., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has commenced enrollment in a Phase 1 clinical trial of AdCOVID, a single-dose intranasal COVID-19 vaccine candidate. AdCOVID is an adenovirus-vector vaccine designed to stimulate a broad immune response including both systemic immunity (neutralizing antibody) and local immunity (mucosal IgA and resident memory T cells) in the nasal cavity and respiratory tract.

The Phase 1 clinical trial will evaluate the safety and immunogenicity of AdCOVID in up to 180 healthy adult volunteers between the ages of 18 and 55. Subjects will receive AdCOVID at one of three dose levels administered as a nasal spray. In addition to the primary study endpoint of safety and tolerability, the immunogenicity of AdCOVID will be evaluated by serum IgG binding and neutralizing antibody titers, mucosal IgA antibody from nasal samples, and T cell responses. Altimmune anticipates having a full data readout from this Phase 1 study in Q2 2021.

"The commencement of our Phase 1 clinical trial of AdCOVID is an important milestone for our company and the global healthcare community in our fight against the SARS-CoV-2 virus," said Dr. Scott Harris, Chief Medical Officer of Altimmune. "We believe that our expertise in intranasal vaccine development will help us bring to market a novel intranasal COVID-19 vaccine with important attributes that could potentially help prevent further transmission of the virus. Delivering vaccine directly to the nasal cavity may stimulate a specialized type of immunity called 'mucosal immunity,' which has been shown in a preclinical study to provide sterilizing immunity, that is, complete clearance of the virus from the respiratory tract. As the rise of new variants of the SARS-CoV-2 virus is particularly troubling, to stop mutations of the virus we must stop replication and transmission, and we believe AdCOVID could play an essential role in this endeavor."

While traditional vaccines delivered by an intramuscular injection can stimulate systemic immunity in the blood, they have not been shown to induce mucosal immunity in the nasal cavity, which may be critical for blocking transmission of the virus. AdCOVID is designed to deliver vaccine directly to the site of viral entry and replication to stimulate mucosal and cellular immunity in the nasal cavity and respiratory tract – potentially offering a first line of defense against the SARS-CoV-2 virus. The ability to stimulate mucosal and resident T cell immunity in the respiratory tract would be a key differentiator for AdCOVID and may play a critical role in blocking transmission of the SARS-CoV-2 virus.

"While the roll out of currently available vaccines is an important first step in our efforts to slow the pandemic, there remains a critical need for vaccines that provide mucosal immunity," said Scot Roberts, Ph.D., Chief Scientific Officer of Altimmune. "As pioneers in intranasal vaccine development, we believe AdCOVID has the potential for many advantages over currently available vaccines, including, intranasal dosing and ease of distribution and storage, if the product is shown to have extended stability at room temperature, in addition to the potential ability to block transmission of the virus."

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 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.

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.

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, and the prospects for regulatory approval, 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 Altimune, 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 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: Altimune, Inc.

AdCOVID Vaccine



A vial of AdCOVID Vaccine

Altimune Scientist



A scientist works on AdCOVID