Altimmune Announces FDA Clearance of AdCOVID™ IND Application

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Enrollment in Phase 1 clinical trial of single-dose, needle-free, intranasal COVID-19 vaccine candidate set to begin in the coming week

GAITHERSBURG, Md., Feb. 17, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for its Phase 1 clinical trial of AdCOVID, a novel, single-dose, intranasal COVID-19 vaccine candidate. Altimmune expects to commence patient enrollment in the Phase 1 clinical trial in the coming week.

"We believe deployment of intranasal vaccines like AdCOVID will be essential to a successful global response to the pandemic," said Vipin K. Garg, President and Chief Executive Officer of Altimmune. "FDA clearance of the IND marks an important step in developing a safe and effective vaccine designed to stimulate mucosal as well as systemic immunity following intranasal administration. Developing vaccines that can effectively prevent transmission is a growing imperative to block the spread of disease and combat the emergence of new variants. We look forward to the data from this trial in the coming weeks."

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. Volunteers 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.

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 initiation and timing of the AdCOVID Phase 1 clinical trial in the coming week, the timing of the data readout for the AdCOVID Phase 1 clinical trial, 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 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 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, 2019 and quarterly report on Form 10-Q for the quarter ended September 30, 2020 filed with the SEC, which are available at www.sec.gov.

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