Altimmune Announces Submission of Investigational New Drug Application for AdCOVID™ a Single-dose Intranasal COVID-19 Vaccine; On Track to Commence Phase 1 Clinical Study in December

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Simple, single-dose nasal spray offers greater ease and comfort of administration; positioning AdCOVID as a differentiated vaccine candidate for adults and children

AdCOVID is capable of stimulating an additional and specialized type of immunity – local nasal mucosal immunity – believed to be critical for preventing further transmission of the virus

GAITHERSBURG, Md., Nov. 25, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company advancing proprietary intranasal vaccines and peptide therapeutics, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to commence a Phase 1 clinical study of its single-dose intranasal COVID-19 vaccine candidate, AdCOVID. AdCOVID is 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.

"We've made exceptional progress advancing AdCOVID and are on track to begin a Phase 1 clinical study this year, with a data readout anticipated in the first quarter of 2021," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "While the progress being reported with current vaccines is very encouraging, many in the scientific and medical communities agree that there is continued need for next-generation vaccines that offer significant enhancements. AdCOVID has the potential to provide many benefits not offered by current vaccines, including simple intranasal administration (particularly well-suited for use in children), the ability to be transported at room temperature and conveniently stored in refrigerators for years, and the stimulation of nasal mucosal immunity with the potential to provide sterilizing immunity and block transmission of the SARS-CoV-2 virus. In addition to testing in adults, our IND included a preliminary proposal for evaluation of children as young as 2 years of age, and we look forward to further discussions around our pediatric program with the FDA in the near future."

"It's not widely known or appreciated that nasal mucosal immunity may be essential in preventing the spread of the SARS-CoV-2 virus to other individuals by stopping replication and transmission of the virus at the site of infection – the nose and respiratory tract," said Frances E. Lund, the Charles H. McCauley Professor and Chair for the University of Alabama at Birmingham, Department of Microbiology. "Several recent studies have shown that in the absence of mucosal immunity, the nasal cavity may become a reservoir for the coronavirus, particularly in children, potentially allowing for disease transmission even after an intramuscular vaccination. A vaccine that prevents transmission by children would allow them to return to school and their parents to return to work. We are excited to collaborate with Altimmune on the advancement of this important next-generation vaccine and look forward to seeing data from the upcoming clinical study."

In a recent pre-IND meeting, the FDA agreed to the overall Phase 1 study design and patient population, as well as plans for manufacturing and product testing of AdCOVID. The FDA also confirmed that additional nonclinical studies were not required and that the toxicology data previously submitted and reviewed for Altimmune's NasoShield™ and NasoVAX™ intranasal vaccine candidates support the clinical development of AdCOVID, with no additional toxicology studies required before initiation of the Phase 1 trial.

About AdCOVID

In recently 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 and T cell responses were induced in mice in addition to a robust induction in mucosal immunity against the spike protein of the virus. Importantly, the mucosal immunity was characterized by IgA antibody and resident memory T cell responses in the respiratory tract, both are believed to be important in fighting infection.

Based on data from Altimmune's other intranasal platform vaccines (NasoVAX ™ and NasoShield ™) AdCOVID is expected to have extended stability at room temperature allowing for cold chain-free shipment of the vaccine, where it can then be stored in common refrigerators found in community-based doctor's offices and pharmacies for two years or more. The simple and convenient handling requirements may greatly increase the number of people willing to take the vaccine.

Altimmune anticipates commencing a Phase 1 safety and immunogenicity trial of AdCOVID in the fourth quarter of 2020 with a data readout in the first quarter of 2021.

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.

About UAB

Known for its innovative and interdisciplinary approach to education at both the graduate and undergraduate levels, the University of Alabama at Birmingham is an internationally renowned research university and academic medical center, as well as Alabama's largest employer, with some 23,000 employees, and has an annual economic impact exceeding $7 billion on the state. The pillars of UAB's mission include education, research, innovation and economic development, community engagement, and patient care. Learn more at www.uab.edu.

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 Q4 2020 and data readout in Q1 2021, the potential immunization effects of AdCOVID, the shipping and storage requirements for AdCOVID, the willingness of the general public to use 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 secure regulatory approval for its AdCOVID investigational new drug application submission to the U.S. Food and Drug Administration, 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 March 31, 2020 filed with the SEC, which are available at www.sec.gov.

Investor Contacts:

Will Brown
Chief Financial Officer
Phone: 240-654-1450
wbrown@altimmune.com

Ashley R. Robinson
LifeSci Advisors, LLC
617-430-7577
arr@lifesciadvisors.com

Stacey Jurchison
Sr. Director, Investor Relations
Phone: 410-474-8200
sjurchison@altimmune.com

Media Contact:

Warren Rizzi
Sard Verbinnen & Co.
Phone: 212-687-8080
altimmune-svc@sardverb.com

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