Altimmune Provides an Update on its Investigational New Drug Application for a Phase 1 AdCOVID™ Clinical Trial

December 23, 2020

GAITHERSBURG, Md., Dec. 23, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has issued a clinical hold on the Company's Investigational New Drug (IND) application for AdCOVID, a single-dose intranasal COVID-19 vaccine candidate. The Agency requested certain protocol modifications and the submission of additional Chemistry, Manufacturing and Controls (CMC) data. Altimmune has responded to the Agency's clinical hold letter received on December 22, 2020 and, at this time, does not anticipate a significant impact on the overall clinical development timeline as the Company has agreed to each of the FDA's requests.

"We appreciate the FDA's support and guidance as we seek to bring a novel, single-dose intranasal COVID-19 vaccine candidate into the clinic," said Vipin K. Garg, President and Chief Executive Officer of Altimmune. "We look forward to working with the FDA and will continue preparing to commence our planned Phase 1 clinical trial of AdCOVID."

About AdCOVID

AdCOVID is a single-dose intranasal COVID-19 vaccine candidate developed by Altimmune based on the Company's significant experience in the development of intranasal vaccines for respiratory pathogens. 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, AdCOVID induced potent serum neutralizing antibody and T cell responses in mice as well as a robust induction in mucosal immunity against the spike protein of the virus that causes COVID-19. Importantly, the 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 transmission.

Data from Altimmune's other intranasal platform vaccines (NasoVAX ™ and NasoShield ™) suggest that AdCOVID likely will have extended stability at room temperature, which would allow for cold chain-free shipment of the vaccine. If such stability is demonstrated, AdCOVID could be stored in the common refrigerators found in community-based doctors' offices and pharmacies for two years or more. The simple and convenient handling requirements may greatly increase the accessibility of the vaccine, if approved for use.

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 and data readout, the potential immunization effects or safety of AdCOVID, the shipping and storage requirements for AdCOVID, our ability to manufacture AdCOVID, our ability to achieve commercial-readiness for AdCOVID in 2021 and the prospects for regulatory emergency use authorization or 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 likelihood or timing of the U.S. Food and Drug Administration allowing the Company's AdCOVID investigational new drug application to go into effect; 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.

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

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