Altimmune Announces Successful Pre-IND Meeting with FDA

June 10, 2019 at 8:00 AM EDT

Meeting on HepTcell Phase 2 program for treatment of chronic hepatitis B (HBV)

GAITHERSBURG, Md., June 10, 2019 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it successfully completed a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding its Phase 2 trial design and manufacturing plans for HepTcell. The FDA did not object to the planned study design and patient populations, as well as plans for manufacturing and product testing, and did not recommend any additional studies in preparation for an IND submission and initiation of Phase 2 trials. A recently completed Phase 1 study in chronically infected subjects was performed in the United Kingdom and South Korea. Altimmune intends to conduct a Phase 2 study in the United States and the pre-IND meeting was held to obtain feedback from the FDA on our intended development path.

"We are pleased to have completed the pre-IND meeting with the FDA and will move forward with our plans to file the IND and initiate a Phase 2 trial of HepTcell," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "We appreciate the FDA's guidance as we endeavor to find a cure for chronic hepatitis B."

HepTcell is an immunotherapeutic product candidate composed of nine synthetic peptides chosen from across the HBV proteome with a proprietary T-cell epitope identification method. In a Phase 1 clinical study conducted under clinical trial agreement in the United Kingdom and South Korea, three monthly injections at two dose levels of HepTcell peptides were given with and without IC31® adjuvant (Valneva) as add-on therapy to entecavir or tenofovir in patients with HBe antigen negative chronic infections. All arms were well tolerated, and both high and low peptide doses given in combination with IC31® resulted in increased cellular immune responses against HBV antigens.

Breaking immune tolerance against HBV antigens is the key to clearance of infection. This occurs naturally in the majority of acute HBV infections through a T-cell immune response. However, in chronically infected patients immune tolerance prevents the clearance of the virus and these patients can progress to cirrhosis and are at risk of developing liver cancer. Currently licensed treatments do not clear infection and require lifelong therapy to control the disease. The goal of all HBV therapeutics currently in development is to achieve functional cure by reactivating the T-cell immune response, either indirectly by further lowering the HBV antigen expression, or directly, as is the goal of HepTcell.

In the planned Phase 2 trial, Altimmune will evaluate immune responses after a 6-month treatment course of HepTcell in an expanded population of HBV infected patients. The Phase 2 trial is anticipated to start in 2020.

About Altimmune

Altimmune is a clinical-stage biopharmaceutical company focused on the development of products to stimulate robust and durable immune responses for the prevention and treatment of disease. HepTcell is a synthetic peptide immunotherapeutic candidate designed to break immune tolerance in chronic Hepatitis B infection. ALT-702, a TLR7/8 agonist conjugate, is a tumor immunostimulant product candidate that has the potential to safely elicit or improve immune responses in a variety of cancer indications. NasoVAX, our influenza vaccine candidate, has unique characteristics that stimulate multiple arms of the immune system and offers the potential to stop infection and the spread of flu, while being easier to administer through an intranasal rout. NasoShield is a next-generation intranasal anthrax vaccine candidate that is designed to provide more rapid and stable protection than the only approved anthrax vaccine. By leveraging the complementary attributes of its proprietary technology platforms, Altimmune is able to design and develop products tailored to address a wide range of disease indications including both acute and chronic infections and cancer. For more information on Altimmune, please visit the website 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 filing of the IND for HepTcell initiation of a Phase 2 clinical study in the U.S. in 2020, the prospects for 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: the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; the impact of the Tax Cuts and Jobs Act; delays caused by third parties challenging government contracts awarded to the Company; the receipt of future potential payments under government contracts or grants; the Company's ability to identify potential future government contracts or grant awards; the Company's ability to obtain potential regulatory approvals on the timelines anticipated, or at all; the Company's ability to obtain additional patents or extend existing patents on the timelines anticipated, or at all; the Company's ability to identify and consummate potential future strategic partnerships or business combinations; the Company's ability to expand its pipeline of products and the success of future product advancements, including the success of future clinical trials, and the Company's ability to commercialize its products; the Company's anticipated financial or operational results; the Company's ability to obtain additional capital resources; unforeseen safety and efficacy issues; breaches of data privacy, or disruptions in the Company's information technology systems; and the Company's ability to continue to satisfy the listing requirements of the NASDAQ Global Market. 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 reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, which are available at www.sec.gov.

Contacts

Vipin K. Garg, Ph.D.
President and CEO
Phone: 240-654-1450
Email: vgarg@altimmune.com

Ashley R. Robinson
Managing Director LifeSci Advisors
Phone: 617-535-7742
Email: arr@lifesciadvisors.com

Source: Altimmune, Inc.