Altimmune Announces IND Clearance for a Phase 2 Trial of HepTcell™ Immunotherapeutic for the Treatment of Chronic Hepatitis B

June 22, 2020

GAITHERSBURG, Md., June 22, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to conduct a Phase 2 trial of HepTcell, a peptide-based immunotherapeutic for the treatment of chronic hepatitis B. The Company is also filing clinical trial applications in Canada, Spain, Germany and the United Kingdom. Altimmune plans to initiate a multinational trial in Q4 of this year, subject to an ongoing assessment of the impact of COVID-19 on study conduct.

"We are pleased to have obtained IND clearance for the evaluation of HepTcell in a Phase 2 trial. HepTcell is the only investigational immunotherapeutic designed specifically to restore antiviral T cell responses against the most conserved antigenic domains of the Hepatitis B virus (HBV)," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "We believe that HepTcell could also be the key immunotherapy component of a future anti-HBV combination regimen to help break immune tolerance and achieve a functional cure."

According to World Health Organization estimates, chronic HBV affects 292 million worldwide, and nearly 900,000 people die annually of complications of the disease. There is no cure for chronic HBV, and currently available antiviral medications only control the disease and require life-long treatment. These treatments represent a significant burden for chronic hepatitis B patients, considering life-long commitment to medication and monitoring costs. If left untreated, chronic HBV infection can lead to serious health issues including cirrhosis, liver failure and liver cancer.

HepTcell is an immunotherapeutic product candidate composed of nine synthetic HBV-derived peptides formulated with IC31®, a TLR9-based adjuvant from Valneva SE. The HBV peptides were designed to drive T cell responses against all HBV genotypes in patients of diverse genetic background. In the Phase 1 clinical study conducted in the United Kingdom and South Korea, three monthly injections at two dose levels of HepTcell peptides were given with and without IC31® adjuvant as add-on therapy to entecavir or tenofovir in patients with Hepatitis B e-antigen (HBeAg)-negative chronic infections. All arms were generally well-tolerated and both high and low doses of HepTcell given in combination with IC31® resulted in potent T cell responses against HBV antigens – representing a break in immune tolerance with no evidence of immune-mediated adverse events.

Acute HBV infections are cleared through a T cell-dependent immune response. However, in chronically infected patients, high viral antigen load can induce a state of immune tolerance that prevents T cells from clearing the infection. Breaking immune tolerance is considered essential to achieving a functional cure, defined as the loss of hepatitis B surface antigen (HBsAg) in the blood. Ultimately, the goal of all HBV therapeutics in current development is to achieve a functional cure by reactivating the T cell immune response and overcoming immune tolerance, either indirectly by further lowering HBV antigen load or directly, as is the goal of HepTcell.

The double-blind, randomized, placebo-controlled Phase 2 study of HepTcell plans to recruit 80 adult subjects with HBeAg-negative chronic HBV infection and low HBsAg levels. This patient population was selected as it is envisioned to mimic the HBV status of the patient population when HepTcell is combined with a novel direct-acting antiviral in subsequent trials. HepTcell will be administered intramuscularly at intervals of 4 weeks for 6 doses. The primary endpoint will be the virological response, defined as a 1-log reduction in HBsAg levels; secondary endpoints will incorporate safety, immunologic criteria, and other assessments of virologic response.

"HepTcell is a novel immunotherapeutic in development that holds potential for the treatment of patients with chronic hepatitis B," said Dr. Mark Thursz, Professor of Hepatology and Head, Department of Metabolism, Digestion and Reproduction, Imperial College London and Lead Investigator of the multinational trial. "Immune tolerance is a considerable problem in chronic HBV patients, and I see the potential for HepTcell to be combined with the newer direct acting agents in development. HepTcell, if approved, could offer an additional agent in our efforts to achieve functional cure".

About Altimmune
Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for liver disease, immune modulating therapies and intranasal vaccines. Our diverse pipeline includes next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™), an intranasal immune modulating treatment for COVID-19 (T-COVID™) and intranasal vaccines (AdCOVID™, NasoShield™ and NasoVAX™). For mo 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, our expectations for the potential of HepTcell as a therapy for HBV, the further development of HepTcell, the initiation and timing of clinical trials for HepTcell, 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, adverse effects on healthcare systems and disruption of the global economy 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 Company's ability to obtain potential regulatory approvals on the timelines anticipated, or at all; and 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. 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.

Contacts

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

Ashley R. Robinson
Managing Director LifeSci Advisors
Phone: 617-430-7577
Email: arr@lifesciadvisors.com

Source: Altimmune, Inc.