Altimmune Begins Multinational Phase 2 Clinical Trial of HepTcellTM, a Novel Immunotherapeutic for the Treatment of Chronic Hepatitis B

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GAITHERSBURG, Md., Dec. 30, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has enrolled the first patient in its multinational Phase 2 clinical trial of HepTcell, a novel peptide-based immunotherapeutic under development for treatment of chronic hepatitis B (CHB).

The study is being conducted in the United States, Canada and Europe and is a double-blind, randomized, placebo-controlled study of 80 adult patients with HBeAg-negative inactive CHB and HBsAg ≤ 100 IU/mL. HepTcell will be administered in 6 doses at 4-week intervals for 24 weeks, and patients will be followed for one year to evaluate safety and durability of response. The primary efficacy endpoint is virological response, defined as a 1-log reduction in HBsAg levels from baseline at 24 weeks. Secondary efficacy endpoints include reactivation of anti-HBV T cell responses, HBsAg clearance, and other assessments of virologic response.

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

Acute Hepatitis B 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. Restoring T cell function 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 is to achieve a functional cure by reactivating the T cell immune response and overcoming immune tolerance.

“As one of the most common infectious diseases worldwide, there remains a significant unmet medical need for improved CHB therapies, as currently approved therapeutics prevent disease progression but rarely lead to a functional cure,” said Dr. Scott Harris, Chief Medical Officer of Altimmune. “We believe the T cell immune intolerance that characterizes the disease must be broken for the development of a functional cure. As a novel immunotherapeutic, HepTcell works by restoring dormant T cells to eliminate infection. While novel direct-acting agents under development, such as small inhibitory RNAs and capsid assembly modulators, have shown promise in reducing HBsAg load below 100 IU/mL, these agents have not resulted in the reactivation of T cell immunity and are unlikely to achieve durable virologic responses as monotherapies. Based on the encouraging preclinical and clinical data we are optimistic that HepTcell may be ideal in combination with novel direct-acting antivirals to achieve a functional cure for this disease.”

About HepTcell

HepTcell is a novel immunotherapeutic composed of nine synthetic HBV-derived peptides formulated with IC31®, a TLR9-based adjuvant from Valneva SE. The HBV peptides are designed to drive T cell responses against all HBV genotypes in patients of diverse genetic background.

In a Phase 1 clinical study of HepTcell conducted in the United Kingdom and South Korea, three monthly injections at two dose levels of HepTcell peptides were administered with and without IC31® adjuvant as add-on therapy to entecavir or tenofovir in patients with Hepatitis B e-antigen (HBeAg)-negative chronic infections. In the Phase 1 study, all doses of HepTcell 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.

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, our expectations for the potential of HepTcell as a therapy for HBV, the safety, efficacy and clinical progress of HepTcell (including, without limitation, the expected timing of the Phase 2 clinical trial), 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 September 30, 2020 filed with the SEC, which are available at www.sec.gov.

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