Histogen and Amerimmune Announce First Patient Dosed in Phase 1 Study of Emricasan in Symptomatic COVID-19 Patients

March 16, 2021

Topline Results Expected in the Second Quarter of 2021

SAN DIEGO, March 16, 2021 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO) and Amerimmune LLC today announced dosing the first patient in a Phase 1 study of emricasan in mild symptomatic -COVID-19 patients to assess safety, tolerability, and preliminary efficacy. SUNY Downstate Medical Center in Brooklyn, New York, has been selected as the single site for the study conduct.

This double blinded, 1:1 randomized, placebo controlled single site study is expected to enroll 40 symptomatic mild-COVID-19 patients in an outpatient setting using emricasan at 25mg BID dosing for 14 days versus placebo. The study is designed to assess safety and tolerability and will also include various clinical and laboratory measures and patient reported outcomes (PROs) using the FDA COVID-19 Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment Assessment tool.

“This study of emricasan in symptomatic COVID-19 patients marks a significant milestone for Histogen and our partner Amerimmune as we enter the fight against this unprecedented pandemic,” said Richard W. Pascoe, President and Chief Executive Officer of Histogen. “Moreover, we believe emricasan is potentially an ideal candidate to treat symptomatic patients in the acute phase, as well as addressing the long-term complications in later phases of COVID-19, due to its anti-inflammatory properties.”

“Our first treatment in this clinical trial is an important step toward potentially bringing new and promising treatments to patients with mild COVID-19. SUNY is honored to be involved in this effort to address this medical need,” said Raavi Gupta, M.D. Associate Professor and the Principal Investigator at SUNY Downstate Health Sciences University.

“In early 2020, at the beginning of the pandemic, Amerimmune carried out a pioneering study showing that caspases are over-stimulated in the cells of patients with COVID-19, during both acute, late and chronic phases of the disease, potentially resulting in uncontrolled inflammation,” said Oral Alpan, M.D., President and CEO of Amerimmune. “Amerimmune will support the Phase 1 study of emricasan in mild COVID-19 patients by carefully evaluating biomarkers of antibody, T cell and caspase related immunity in patients receiving the pan-caspase inhibitor.”

About Emricasan
Emricasan is a potential first-in-class, orally active, pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Histogen acquired certain rights to emricasan and other caspase inhibitor compounds as a part of its merger with Conatus Pharmaceuticals Inc. in 2020. Histogen believes that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases. To date, emricasan has been studied in over 950 patients in 19 completed clinical trials across a broad range of liver diseases. In NASH cirrhosis patients in multiple clinical Phase II trials conducted by Conatus, emricasan demonstrated rapid and sustained reductions in elevated levels of key biomarkers of inflammation and cell death. Similarly, elevated biomarkers are also believed to play a role in the severity and progression of COVID-19.

About Histogen
Histogen Inc. is a clinical-stage therapeutics company focused on developing potential first-in-class restorative therapeutics that ignite the body’s natural process to repair and maintain healthy biological function. Histogen’s innovative technology platform utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells. Histogen’s proprietary, reproducible manufacturing process provides targeted solutions across a broad range of therapeutic indications including hair growth, dermal rejuvenation, joint cartilage regeneration and spinal disk repair. For more information, please visit www.histogen.com.

About Amerimmune
Amerimmune LLC is a research center and immunology laboratory with a strong focus on identifying underlying mechanisms of immune disorders. Amerimmune’s mission is to bring relevant science, data, and diagnostic and therapeutic solutions to diseases that involve the immune system **.** Amerimmune LLC is a spinoff of Amerimmune Diagnostics LLC, which is focused on establishing a network of physician-owned immunology labs across the United States. Amerimmune Diagnostics’ clinical approach led to the development of the innovative therapeutics technology upon which Amerimmune was founded. When the COVID-19 pandemic emerged early this year, Amerimmune brought its expertise to bear against this devastating disease. Amerimmune is a privately held development-stage company based in Fairfax, VA. For more information and to explore partnering opportunities, please visit www.amerimmune.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. For example, we are using forward-looking statements when we discuss Histogen’s future operations and its ability to successfully complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing, including those related to the Phase 1 study of emricasan for the treatment of COVID-19 and the reporting of topline results for the study; the nature, strategy and focus of Histogen’s business; the sufficiency of Histogen and Amerimmune’s cash resources and ability to complete the Phase 1 study of emricasan and achieve value for its stockholders; and the development and commercial potential and potential benefits of any of its product candidates and the Collaborative Development and Commercialization Agreement with Amerimmune or any other collaboration agreements. Histogen may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of ours that could differ materially

from those described in or implied by the statements in this press release, including: the uncertainties associated with the clinical development and regulatory approval of Histogen's product candidates and Amerimmune's ability to further develop emricasan for the treatment of COVID-19, including the complexity and length of studies required to commercialize emricasan for COVID-19 and potential delays in the enrollment and completion of clinical trials, such as the emricasan Phase 1 study for the treatment of COVID-19; the uncertainties associated with Amerimmune's pursuit and receipt of non-dilutive capital for the advancement of emricasan, including any potential government grants; Histogen's dependence on its collaboration partner, Amerimmune, to carry out the development of emricasan and the potential for delays in the timing of regulatory approval; competition in the COVID-19 market and other markets in which Histogen and its collaboration partner operate; risks related to business interruptions to Histogen and/or Amerimmune, including the outbreak of COVID-19 coronavirus, which could seriously harm their respective financial conditions and increase their respective costs and expenses; the potential for adverse reactions to emricasan; and market conditions. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including those risks discussed in our filings with the Securities and Exchange Commission. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events, or circumstances or otherwise.

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