Histogen and Amerimmune Announce Positive Top-Line Study Results from its Phase 1 Study of Emricasan in Mild Symptomatic COVID-19 Patients

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Emricasan Found to be Safe and Well Tolerated with No Serious Adverse Events

Patients Completing Treatment with Emricasan had a Complete Resolution of the Symptoms Most Commonly Associated in Mild COVID-19 At Day 7 Continuing to Day 45

SAN DIEGO, June 22, 2021 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), and its partner Amerimmune LLC, today announced top line results from its Phase 1 study of emricasan in mild symptomatic COVID-19 patients to assess safety, tolerability, and preliminary efficacy. The study demonstrated that emricasan was safe and well tolerated during the 14 days of dosing and at the day 45 follow-up, as compared to placebo with no reports of serious adverse events. Patients who completed treatment with emricasan had a complete resolution of the symptoms most commonly associated in mild COVID-19, such as cough, headache and fatigue at day 7 and continued through day 45. Patients in the placebo arm who completed the study did not experience COVID-19 symptom resolution at any time point out to day 45.

In addition, a number of very important observations were made related to clinical outcomes, laboratory findings and drug target related biomarkers. These improvements were seen in all subjects in the active drug group that showed decreases in caspase biomarkers, whereas patients in placebo group continued to have COVID-19 related symptoms and laboratory findings.

“The data from the Phase 1 study of emricasan administered in the outpatient setting underscores its safety and potential clinical benefit in the treatment of mild symptomatic patients,” said Raavi Gupta, M.D. Associate Professor and the Principal Investigator at SUNY Downstate Health Sciences University.

“The study data not only showed complete and early resolution of COVID-19 related symptoms in the emricasan group compared to the placebo group, which continued to have symptoms, but also provided substantial insight into disease mechanism, which will be critical in developing therapeutic options for COVID-19. We are excited to work with Histogen to bring Amerimmune’s expertise to the emricasan development program as a demonstration of how physician-owned diagnostic laboratories can be the genesis of breakthroughs in medicine and participate fully in the advancement of novel therapies,” said Dr. Oral Alpan, M.D. Chief Executive Officer of Amerimmune LLC.

“These positive results further reinforce the extensive clinical safety database of emricasan and strongly suggest that emricasan can potentially be developed as a therapeutic treatment for mild to moderate COVID-19, as well as other viral inflammatory diseases,” said Richard W. Pascoe, Histogen’s President and Chief Executive Officer. “We look forward to working with our colleagues at Amerimmune as we chart a strategic course for emricasan and its clinical development options and partnering opportunities.”

About the Emricasan Phase 1 Study
This double blinded, 1:1 randomized, placebo controlled single site study enrolled 13 symptomatic mild-COVID-19 patients in an outpatient setting using emricasan at 25mg BID dosing for 14 days versus placebo with a one-month safety follow-up. The study was designed to assess safety and tolerability and 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. A total of 13 patients were enrolled at a single site in New York City versus the initially targeted 40 patients. The decision to stop enrollment with a lesser number of patients was based solely upon the overall decline in COVID-19 cases in New York City and its negative impact on patient recruitment.

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. These and similar biomarkers are also believed to be mechanistically linked to the progression and severity of COVID-19.

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, 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.

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 joint cartilage regeneration, spinal disk repair, and dermal rejuvenation. For more information, please visit www.histogen.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 our future operations and our ability to successfully initiate and complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing; the potential that future clinical trials will establish efficacy of our product candidates, including emricasan; the potential for emricasan to be a first-in-class product; the nature, strategy and focus of our business; the sufficiency of our cash resources and ability to achieve value for our stockholders; and the development and commercial potential and potential benefits of any of our product candidates, including emricasan. We 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 our product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies of Histogen’s product candidates may not be predictive of future results, such as the data results from the emricasan Phase 1 study; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase its costs and expenses; and the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all. 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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