Histogen and Amerimmune Enter into a Collaborative Development and Commercialization Agreement for Emricasan in the Treatment of COVID-19

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Histogen Receives IND Approval from FDA to Initiate a Phase 1 Study of Emricasan in Mild-COVID-19 Patients to Assess Safety and Tolerability

Amerimmune to Lead Development Efforts of Emricasan in a Phase 1 Study in Mild-COVID-19 Patients Expected to Commence as Early as the End of 2020

SAN DIEGO, Oct. 27, 2020 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing potential first-in-class therapeutics that ignite the body's natural process to repair and maintain healthy biological function, today announced entering into a Collaborative Development and Commercialization Agreement with Amerimmune LLC to jointly develop emricasan, an orally active caspase inhibitor, for the treatment of COVID-19. Additionally, Histogen has received Investigational New Drug (IND) approval from the United States Food and Drug Administration (FDA) to initiate a Phase 1 study of emricasan in mild-COVID-19 patients to assess safety and tolerability. Amerimmune, which will lead the development efforts of emricasan, has selected clinical sites at two major medical centers in the New York City metropolitan area to conduct the study. Amerimmune is pursuing non-dilutive funding in order to support the clinical program and anticipates initiating the Phase 1 study as early as the end of 2020.

Under the terms of the collaboration, Histogen will retain ownership and oversight over emricasan and responsibility for all regulatory filings and maintaining its existing caspase inhibitor patent portfolio. Amerimmune, in collaboration with Histogen, will fund and lead the emricasan development efforts and maintain its own portfolio of patents for caspase inhibition and immunotherapy. Additionally, Amerimmune has been granted an option to commercialize emricasan under certain conditions for the sole purpose of supporting future third-party partnering transactions. Should any such partnering transaction emerge, Histogen and Amerimmune will share profits equally. The parties will manage the collaboration under a joint development and partnering committee governance structure.

"Since completing the merger with Conatus Pharmaceuticals in the second quarter, we have been evaluating opportunities to create value from the emricasan asset, which we believe can be best accomplished in partnership with Amerimmune in the potential treatment of COVID-19. The Amerimmune team brings both a strong caspase inhibitor scientific background and relevant technologies for the treatment of COVID-19 using caspase inhibitors to this collaboration," said Richard Pascoe, President and CEO of Histogen. "With Amerimmune leading the development efforts related to emricasan, Histogen will remain focused on delivering the top line data results in the fourth quarter of 2020 for its HST-001 Phase 1b/2a trial for androgenic alopecia in men, evaluating a clinical pathway for HST-002 as a dermal filler, and continuing to progress our HST-003 program for regeneration of cartilage in the knee," concluded Pascoe.

"We are delighted to work in collaboration with Histogen to explore the potential role of caspase inhibition as a therapy for reducing disease severity and progression of COVID-19," said Dr. Oral Alpan, CEO of Amerimmune. "We believe our research and development efforts over the last decade have enabled us to make important advancements in our understanding of how SARS-CoV-2 compromises the immune system. We are encouraged by our progress and look forward to advancing emricasan into the clinic as early as the end of 2020," concluded Dr. Alpan.

About Emricasan
Emricasan is a first-in-class, orally active, pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. 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 our future operations and our

ability to successfully initiate and complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing, including those related to the planned Phase 1 study of emricasan for the treatment of COVID-19; the nature, strategy and focus of our business; the sufficiency of our and Amerimmune's cash resources and ability to commence the planned Phase 1 study of emricasan and achieve value for our stockholders; and the development and commercial potential and potential benefits of any of our product candidates and the Collaborative Development and Commercialization Agreement with Amerimmune or any other collaboration agreements. 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 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 commencement, enrollment, and completion of clinical trials, such as the planned 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 our respective financial conditions and increase our 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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