Positive Phase 1 Results in Covid-19 Patients for Histogen, Inc. (NASDAQ: HSTO) Regenerative Medicine as well

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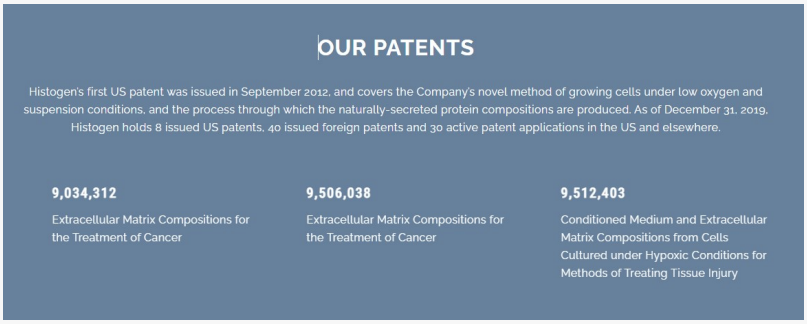
$HSTO Logo



$HSTO Patents

SAN DIEGO, CALIFORNIA, UNITED STATES, June 22, 2021 /EINPresswire.com/ -- Positive Phase 1 Results in Covid-19 Patients for Histogen, Inc. (NASDAQ: HSTO)Regenerative Medicine also

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

Regenerative Medicine Technology Platform Developing Orthopedic Product Candidates.

Trial for Cartilage Regeneration in the Knee On-Track with Anticipated Phase 1/2 Study Initiation in June 2021.

Product Candidate for Spinal Disc Repair with IND Enabling Activities.

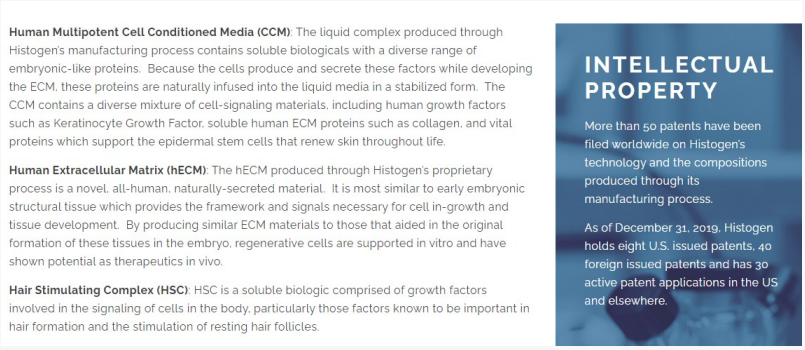
Top-line Data for Phase 1 Study of Emricasan Product in Mild-Symptomatic COVID-19 Patients Anticipated in June 2021.

Research Paper on Emricasan Published in Allergy, the Journal of the European Academy of Allergy and Clinical Immunology.

Histogen Inc. (NASDAQ HSTO) 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. HSTO has an innovative technology platform that utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells. The HSTO proprietary, reproducible manufacturing process provides targeted solutions across a broad range of therapeutic indications including joint cartilage regeneration, spinal disk repair, hair growth and dermal rejuvenation.

HSTO is NASDAQ listed and has an attractive share structure with only 35,751,957 shares outstanding as of May 6, 2021.

$HSTO Pipeline



$HSTO Intelectual Property

$HSTO Regeneration

Update on Development Programs and Pipeline Focus

On June 3rdHSTO announced an update on its pipeline focus following a strategic evaluation of its regenerative medicine platform technology development programs with the goal of focusing on high value orthopedic indications, creating pipeline synergies and maximizing resources in an effort to further drive long-term shareholder value.

Development Program Updates

-- HST 003 – HSTO is on track to initiate its Phase 1/2 clinical study of HST 003 in June 2021. The upcoming study is designed to evaluate the safety and efficacy of human extracellular matrix (hECM) implanted within microfracture interstices and the cartilage defect in the knee to regenerate hyaline cartilage in combination with a microfracture procedure. Patients will be enrolled at three sites: Oasis MD in San Diego, CA, The Steadman Clinic in Vail, CO, and Walter Reed Medical Center in Bethesda, MD.

-- HST 004 - HSTO recently initiated an investigational new drug application (IND) enabling activities for HST 004, a CCM solution intended to be administered through an intradiscal injection for spinal disc repair. The HSTO initial preclinical research has shown that HST 004 stimulates stem cells from the spinal disc to proliferate and secrete aggrecan and collagen II,

> 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"
>
> *Raavi Gupta, M.D. Associate Professor*

regenerate normal matrix and cell tissue structure, and restore disc height. HST 004 was also shown to both reduce inflammation and protease activity and upregulate aggrecan production in an ex vivo spinal disc model. HSTO anticipates filing an IND in the second half of 2022.

-- Emricasan - In May, HSTO, along with its partner Amerimmune, completed enrollment of the Phase 1 study of Emricasan for the treatment of mild-symptomatic COVID-19 patients. A total of 13 patients have been 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. To date, there have been no reports of serious adverse events, and HSTO anticipates top-line safety, biomarker and patient reported outcomes data to be available in June 2021.

Emricasan is a potential first-in-class, orally active, pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. HSTO acquired certain rights to Emricasan and other caspase inhibitor compounds as a part of its merger with Conatus Pharmaceuticals Inc. in 2020. HSTO believes that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases.

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.

On May 19th HSTO and its partner, Amerimmune, LLC, reported the publication of the potential utility of Emricasan in COVID-19 in Allergy, the official Journal of the European Academy of Allergy and Clinical Immunology. The research paper entitled "Caspases in Moderate-Severe, Long COVID-19 Disease and the Therapeutic Potential of Caspase Inhibitors" has been published in Allergy, the Journal of the European Academy of Allergy and Clinical Immunology, and is currently available electronically at https://onlinelibrary.wiley.com/doi/10.1111/all.14907

As a result of the recent HSTO product evaluation, management has charted a new course with a focus on orthopedic indications that they believe sit at the crossroads of pre-clinical and clinical proof of concept, significant commercial opportunity, and unmet medical needs. HSTO management feels that by developing products that are therapeutically synergistic, the company can be more efficient with its resources and create a strategic pipeline of novel therapeutics that

has the potential to create long-term value for the benefit of HSTO shareholders.

For more information on Histogen Inc. (NASDAQ HSTO) visit http://www.histogen.com.

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