



Redefining Regenerative Medicine

## **Histogen Announces \$2M Grant Award from the Department of Defense for Clinical Advancement of HST-003 for Cartilage Regeneration in the Knee**

September 16, 2020

### **Investigational New Drug (IND) Filing Expected in the Fourth Quarter of 2020**

SAN DIEGO, Sept. 16, 2020 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), 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, has been awarded a \$2 million grant by the Peer Reviewed Orthopedic Research Program (PRORP) of the U.S. Department of Defense (DoD) to help fund a Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702, is the awarding and administering acquisition office.

The Phase 1/2 clinical trial is designed to evaluate HST-003 in combination with a microfracture procedure in 15 civilian and military patients with recent focal cartilage defects in the knee caused by injury. Patients will be enrolled at three clinical sites: OasisMD in San Diego, CA, The Steadman Clinic in Vail, CO and Walter Reed Medical Center in Bethesda, MD. In addition to safety parameters, endpoints will include traditional scores for pain and joint function from The Knee Injury and Osteoarthritis Outcome Scores (KOOS) and The International Knee Documentation Committee (IKDC), as well as an MRI to quantify cartilage regeneration.

"The Steadman Clinic is world renowned for our dedication to excellence in treating orthopedic defects and we are excited about being a clinical center for studying Histogen's human extracellular matrix, or hECM, for focal lesions of the knee," said Matthew Provencher MD, CAPT, MC, USNR. "Regenerating uniform functional hyaline cartilage is critical to restoring normal function for military personnel and civilians alike."

"Lesions in articular knee cartilage can cause considerable morbidity and current surgical options may result in uneven repair and a scar-like fibrous cartilage instead of the normal hyaline cartilage that provides the greatest long-term function," said Dr. Gail K. Naughton, Histogen Founder and CSO. "Histogen's HST-003 has demonstrated hyaline cartilage regeneration in three different in vivo animal models conducted by orthopedic experts. It is an honor to have been granted an award from the DoD to support our HST-003 Phase 1/2 trial," concluded Dr. Naughton.

There is a significant need for improved acute knee injury treatments in both military and civilian populations. Approximately 900,000 Americans are affected by knee cartilage injuries annually, with 200,000 requiring surgical intervention<sup>i</sup>. Further, among US military personnel, musculoskeletal injuries are a leading cause of morbidity, lost training time and reduced operational readiness, resulting in as many as 2.4 million health visits and 25 million limited-duty days per year<sup>ii</sup>.

"These non-dilutive funds will support our efforts to clinically evaluate the safety and efficacy of our novel cartilage repair treatment which has applicability in both the military and civilian populations," said Richard W. Pascoe, Histogen's President and CEO. "As a former soldier, I understand that the health and readiness of our servicemembers is essential to our national defense. We are pleased to partner with the DoD and these prestigious clinical sites to advance HST-003 into the clinic in support of that effort."

The views expressed in this press release are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

### **About HST-003**

Histogen's human extracellular matrix, or hECM, is intended for regenerating hyaline cartilage for the treatment of articular cartilage defects with a novel malleable scaffold that stimulates the body's own stem cells. In multiple preclinical models, HST-003 has been shown to regenerate mature cartilage and well vascularized bone, indicating great therapeutic potential in the sports medicine, spinal disc repair, orthopedic, and dental areas. Studies conducted by outside experts have demonstrated that HST-003 is anti-inflammatory, angiogenic, and can stimulate the growth of stem cells in damaged areas to induce tissue regeneration. The most extensive in vivo work in animals has focused on the regeneration of new hyaline cartilage and bone in full thickness knee injuries.

### **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](http://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 Histogen's future operations and its ability to successfully initiate and complete clinical trials and achieve regulatory milestones and related timing, including those related to the planned Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee; the nature, strategy and focus of Histogen's business; and the development and commercial potential and potential benefits of any of Histogen's product candidates. 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 Histogen's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Histogen 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, including potential delays in the commencement, enrollment and completion of clinical trials such as the planned

Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee; the potential that earlier clinical trials and studies of Histogen's product candidates may not be predictive of future results; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm Histogen's 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 Histogen's filings with the Securities and Exchange Commission. Except as otherwise required by law, Histogen disclaims 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.

<sup>i</sup> Merkely, G., Ackermann, J. & Lattermann, C. Articular Cartilage Defects: Incidence, Diagnosis, and Natural History. *Oper. Tech. Sports Med.* 26, 156–161 (2018).

<sup>ii</sup> Teyhen, D. S., Goffar, S. L., Shaffer, S. W., Kiesel, K., Butler, R. J., Tedaldi, A.-M., Prye, J. C., Rhon, D. I. & Plisky, P. J. Incidence of Musculoskeletal Injury in US Army Unit Types: A Prospective Cohort Study. *J. Orthop. Sports Phys. Ther.* 48, 749–757 (2018).

**CONTACT:**

Susan A. Knudson  
Executive Vice President & CFO  
Histogen, Inc.  
[ir@histogen.com](mailto:ir@histogen.com)