Histogen Announces Completion of Dosing Milestone in its 1b/2a Trial for Androgenic Alopecia in Men

September 10, 2020

Top Line Results Remain on Track for Q4'2020

SAN DIEGO, Sept. 10, 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, today announced completion of patient dosing for the week 6 treatment timepoint in its Phase 1b/2a clinical trial of HST-001, designed to assess the safety, tolerability and indicators of efficacy of HST-001 for the treatment of androgenic alopecia in men.

"We are pleased to have accomplished the second of three treatment timepoints in our HST-001 trial and we remain on track to announce top line data results in the fourth quarter of this year," said Richard W. Pascoe, Histogen's President and CEO. "HST-001, if approved, could be a first-in-class product given its potential to stimulate new long-lasting hair growth in contrast to existing therapies that focus on reducing hair loss."

About the HST-001 Phase 1a/2b Trial
This blinded, randomized, placebo controlled, single site study has enrolled 36 subjects with male pattern hair loss using a 2:1 randomization of HST-001 to placebo. It is designed to assess the safety and tolerability of HST-001, as well as indicators of efficacy including non-vellus hair count, total hair count, and hair thickness density as measured by Canfield macrophotography. At each treatment timepoint (Weeks 0, 6 and 12), subjects will receive a total of 20 injections, 10 in the temporal recession region and 5 in each vertex scalp region, the most common areas of hair loss in men with androgenic alopecia. Primary and secondary endpoints will be assessed at Week 18. Top-line data is anticipated to be available in the fourth quarter of 2020.

About HST-001
HST-001, or Hair Stimulating Complex (HSC), is intended to be a physician-administered therapeutic for hair loss. HSC is anticipated to be a relatively safe, minimally invasive treatment that promotes new hair growth where existing treatments only reduce hair loss. HSC is manufactured to enrich for growth factors including KGF, VEGF and follistatin, which are involved in signaling stem cells in the body and have been shown to be important in hair formation and the stimulation of resting hair follicles.

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. 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 Histogen's future operations and its ability to successfully initiate and complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing, including those related to the reporting of topline data for the ongoing HST-001 Phase 1a/2b clinical trial for the treatment of androgenic alopecia in men; 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, including HST-001. 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 reporting of the topline data for the ongoing HST-001 Phase 1a/2b clinical trial for the treatment of androgenic alopecia in men; 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.

CONTACT:

Susan A. Knudson
Executive Vice President & CFO
Histogen Inc.
ir@histogen.com