Histogen Announces Week 26 HST-001 Study Results for the Treatment of Androgenic Alopecia in Men

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HST-001 Found to be Safe and Well Tolerated with No Serious Adverse Events

Planning Underway for Next Clinical Study in U.S.

SAN DIEGO, Feb. 16, 2021 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO) today announced week 26 results from its Phase 1b/2a clinical trial of HST-001 in male patients with androgenic alopecia. At the week 26 timepoint, patients treated with HST-001 demonstrated statistically significant change from baseline in total hairs (terminal and vellus) in the target area (TAHC) in the vertex as measured by Canfield's Hairmetrix macrophotography system. HST-001 was also shown to be safe and well tolerated at week 26 as compared to placebo with no reports of serious adverse events. Similar to the week 18 primary endpoint results we reported in December of 2020, HST-001 did not achieve statistical significance at week 26 when compared to placebo.

"The recently completed study demonstrated that HST-001 was safe, well tolerated, and exhibited signals of efficacy. This data will inform future development, and I look forward to working with Histogen and our other expert advisors as we plan and execute the next study in men with androgenetic alopecia," said Dr. Stacy Smith, M.D., founder of the California Dermatology and Clinical Research Institution and principal investigator for the HST-001 trial.

"We are encouraged that these results demonstrated that patients treated with HST-001 grow both terminal and vellus hairs in men with androgenic alopecia," said Richard W. Pascoe, Histogen's President and CEO. "Moreover, 84% of the subjects who received HST-001 responded to treatment over the 26-week period and the study drug was found to be safe and well-tolerated across all subjects. With this data in hand, we have begun planning for a more substantive clinical trial in men with androgenic alopecia with the goal of determining the best clinical pathway for future registration trials. We anticipate the trial will commence in the second half of 2021."

About the HST-001 Phase 1a/2b Study
This 2:1 randomized, blinded, placebo controlled, single site study enrolled 36 male patients with androgenic alopecia with mild to moderate hair loss on a Norwood-Hamilton (N-H) Scale (3V, 4, 5), with a total of 30 evaluable patients at week 26. It was designed to assess the safety and tolerability of HST-001, as well as indicators of efficacy at weeks 18 and 26. The primary study endpoint is absolute change from baseline versus week 18 in total hairs (terminal and vellus) in the (TAHC) of the vertex as measured by Canfield's Hairmetrix macrophotography system. Secondary endpoints include absolute change from baseline in total hairs (terminal and vellus) new terminal and vellus hair count, hair thickness density and percent change from baseline in TAHC, terminal and vellus hair counts in the vertex and right temporal regions at weeks 18 and 26, all as measured by Canfield's Hairmetrix macrophotography system. At each treatment timepoint (Weeks 0, 6 and 12), patients received a total of 20 injections, 10 in the vertex scalp region and 5 in each temporal region for a total dose of 2mL.

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.

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 commencement of Histogen's next clinical trial for HST-001 for androgenic alopecia in men; the potential that future clinical trials will establish efficacy of Histogen's product candidates, including HST-001; the potential for HST-001 to be a first in class product; the nature, strategy and focus of Histogen's business; the sufficiency of Histogen's cash resources and ability to achieve value for its stockholders; 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 it 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 commencement of its next clinical trial for HST-001 for androgenic alopecia in men; the potential that earlier clinical trials and studies of Histogen's product candidates may not be predictive of future results, such as the week 18 and week 26 results from the HST-001 Phase 1a/2b clinical trial; 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, 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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