Histogen Announces Completion of Patient Enrollment for its HST 001 Phase 1b/2a Trial for Androgenic Alopecia in Men

July 14, 2020

Top Line Results Expected Q4'2020

SAN DIEGO, July 14, 2020 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), a regenerative medicine company with a novel biological platform that replaces and regenerates tissues in the body, today announced completion of patient enrollment ahead of schedule 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 this clinical milestone with HST 001 and we look forward to completing the treatment phase of the study and releasing top-line data in the fourth quarter of this year," said Richard W. Pascoe, Histogen's President and CEO. "The on-time achievement of this milestone demonstrates our ability to execute on the clinical development plans for HST 001, which has the 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 divided between the temporal recession and vertex scalp areas, the most common regions of hair loss in men with androgenic alopecia. Primary endpoints will be assessed at Week 18 and secondary endpoints at both Week 18 and Week 26. 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. We expect HSC to be a relatively safe, minimally invasive treatment that promotes new hair growth where existing treatments only reduce hair loss. HSC is designed 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 is a regenerative medicine company developing patented technologies that replace and regenerates tissues in the body. The company's innovative technology platform utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells, developing therapeutic products that address underserved, multi-billion US dollar global markets. 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 and achieve regulatory milestones and related timing, including those related to the planned Phase 1a/2b clinical trial of HST 001 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 completion of the Phase 1a/2b clinical trial of HST 001 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.

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