Histogen Announces Update for its HST-002 Dermal Filler Program

September 29, 2020

HST-002 Designated as Drug-Biologic-Device Combination Product

HST-001 1b/2a Trial for Androgenic Alopecia in Men on Track for Top Line Data Results in 4Q20

HST-003 IND Submission for Regeneration of Cartilage in the Knee Expected 4Q20

SAN DIEGO, Sept. 29, 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 that it received communications from the Office of Combination Products (OCM), a division of the United States Food and Drug Administration (FDA), that HST-002 is a drug-biologic-device combination product and will be assigned to the Center for Biologics Evaluation Research (CBER) Office of Tissues and Advanced Therapies (OTAT) as the agency lead for premarket review and regulation. In April of 2020, Histogen had submitted an IDE (Investigational Device Exemption) application for HST-002 based upon its primary mechanism of action and historical regulatory precedence for approved dermal fillers.

"Assuming the IDE had been granted by FDA, we planned to initiate a Phase 1 clinical trial designed to assess the safety and tolerability of HST-002, as well as look for early indications of efficacy versus Restylane-L in moderate to severe nasolabial folds, in the fourth quarter of 2020," said Richard W. Pascoe, Histogen's President and CEO. "Based upon FDA's communications that HST-002 will be regulated as a drug-biologic-device combination product, we are evaluating the impact to our clinical timeline and expect to provide an update in the fourth quarter of 2020."

"We remain on track to announce top line data results in the fourth quarter of this year for our HST-001 phase 1b/2a trial for androgenic alopecia in men," 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. In addition, we continue to make progress on our HST-003 program for regeneration of cartilage in the knee and anticipate filing an IND in the fourth quarter of 2020."

About HST-002
HST-002 is a human-derived collagen and extracellular matrix dermal filler intended to be injected into the dermis for the treatment of facial folds and wrinkles. Human Extracellular Matrix, or hECM is an insoluble hECM for applications such as orthopedics and soft tissue augmentation, which can be fabricated into a variety of structural or functional forms for tissue engineering and clinical applications. The hECM produced through Histogen's proprietary process is a novel, all-human, naturally secreted material. It is most similar to early embryonic structural tissue which provides the framework and signals necessary for cell in-growth and tissue development. By producing similar ECM materials to those that aided in the original formation of these tissues in the embryo, regenerative cells are supported in vitro and have shown potential as therapeutics in vivo.

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 our future operations and our ability to successfully initiate and complete clinical trials, obtain clinical trial data, and achieve regulatory milestones and related timing, including those related to the submission of a HST-003 IND for regeneration of cartilage in the knee, any initiation of a HST-002 Phase 1 trial for the treatment of moderate to severe nasolabial folds and the reporting of topline data for the ongoing HST-001 Phase 1a/2b trial for androgenic alopecia in men; the nature, strategy and focus of our business; the sufficiency of our cash resources and ability to achieve value for our stockholders; and the development and commercial potential and potential benefits of any of our product candidates, such as HST-001, HST-002 and HST-003. We 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 our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of ours 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 our product candidates, including potential delays in the commencement, enrollment and completion of clinical trials,; the potential that earlier clinical trials and studies of our 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 our 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 our 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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