Histogen Reports Third Quarter 2020 Earnings and Provides Business Update

November 10, 2020

Topline Data for HST-001 Phase 1b/2a Trial for Androgenic Alopecia in Men on Track for 4Q20

Received $2M Grant Award from the Department of Defense for Clinical Advancement of HST-003 for Cartilage Regeneration in the Knee

Appointed Moya Daniels as Executive Vice President and Head of Regulatory, Quality and Clinical Operations

Received IND Approval from FDA to Initiate a Phase 1 Study of Emricasan in Mild-COVID-19 Patients to Assess Safety and Tolerability and Entered into a Collaborative Development and Commercialization Agreement with Amerimmune

SAN DIEGO, Nov. 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 reported financial results for the third quarter ended September 30, 2020 and provided an update on its clinical pipeline and other corporate developments.

Key Third Quarter 2020 Highlights and Subsequent Updates

- **Received $2M Grant Award from DoD to support the HST-003 Trial for Cartilage Regeneration in the Knee**. In September, Histogen was 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. Histogen expects to start the trial in the first quarter of 2021. 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 U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702, is the awarding and administering acquisition office. The views expressed in this press release are those of Histogen and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

- **Topline Data for HST-001 Phase 1b/2a Trial for Androgenic Alopecia in Men on Track for 4Q20.** Histogen announced in October that it completed dosing for week 12, the last of three dosing timepoints, in our HST-001 trial, and we remain on track to announce top line data results in the fourth quarter of this year.

- **Appointed Moya Daniels as Head of Regulatory, Quality and Clinical Operations**. In October, Ms. Daniels joined Histogen as its Executive Vice President and Head of Regulatory, Quality and Clinical Operations. Moya brings over 30 years of experience in regulatory, quality and development in the life sciences industry to Histogen. Ms. Daniels most recently served as Senior Vice President of GMP Quality at SanBio and prior to SanBio, she held the position of Senior Vice President of Regulatory Affairs and Global Quality Assurance at Orchard Therapeutics.

- **Entered into a Collaborative Development and Commercialization Agreement with Amerimmune LLC to jointly develop emricasan, an orally active caspase inhibitor, for the treatment of COVID-19.** Under the terms of the collaboration, Histogen will retain ownership and oversight over emricasan and responsibility for all regulatory filings and maintaining its existing caspase inhibitor patent portfolio. Amerimmune, in collaboration with Histogen, will fund and lead the emricasan development efforts and maintain its own portfolio of patents for caspase inhibition and immunotherapy. Additionally, Amerimmune has been granted an option to commercialize emricasan under certain conditions for the sole purpose of supporting future third-party partnering transactions. Should any such partnering transaction emerge, Histogen and Amerimmune will share profits equally. The parties will manage the collaboration under a joint development and partnering committee governance structure.

- **Received IND Approval from FDA to Initiate a Phase 1 Study of Emricasan in Mild-COVID-19 Patients.** Histogen received IND approval from the FDA in October. Histogen's partner Amerimmune will lead the development efforts for emricasan and has selected clinical sites at two major medical centers in the New York City metropolitan area to conduct the study. Amerimmune is pursuing non-dilutive funding in order to support the clinical program and anticipates initiating the Phase 1 study as early as the end of 2020.

"With our continued successful transition into a public company during the third quarter, we believe we remain on track to achieve our key strategic

objectives in the fourth quarter of 2020, notably, the sharing of top-line results from our HST-001 Phase 1a/2b trial for androgenic alopecia in men, submitting the IND for HST-003, and supporting our partner, Amerimmune, in preparing for a Phase 1 study of emricasan as a potential therapeutic for the treatment of mild COVID-19 patients" said Richard W. Pascoe, Histogen's President and Chief Executive Officer.

Financial Highlights for the Third Quarter 2020

Revenues for the three months ended September 30, 2020 and 2019, we recognized product and service revenues of $0.5 million and $0.3 million, respectively. The year-over-year increase of $0.2 million was primarily due to the fulfillment of supply orders of CCM to Allergan.

Cost of revenues for the three months ended September 30, 2020 and 2019, we recognized cost of product revenue of $0.3 million and $0.1 million, respectively. The increase of $0.2 million for the three months ended September 30, 2020 as compared to the three months ended September 30, 2019 was commensurate with the increase in product sales to Allergan.

Research and development expenses for the three months ended September 30, 2020 and 2019 were $1.5 million and $0.7 million, respectively. The increase of $0.8 million for the three months ended September 30, 2020 as compared to the three months ended September 30, 2019 was primarily due to increases related to expanded development costs of our product candidates and increases in personnel related expenses due to changes in duties and responsibilities of existing personnel.

General and administrative expenses for the three months ended September 30, 2020 and 2019 were $2.0 million and $1.2 million, respectively. The $0.8 million increase for the three months ended September 30, 2020 as compared to the three months ended September 30, 2019 was primarily due to increases in insurance, rent and legal and accounting fees, offset by decreases in personnel related expenses due to changes in duties and responsibilities of existing personnel.

Cash and cash equivalents as of September 30, 2020 were $6.6 million. The $6.6M is exclusive of any DOD grant funding which will be received only as budgeted expenses under the grant are incurred by Histogen. Histogen believes that its existing cash and cash equivalents and cash inflow from operations will be sufficient to meet Histogen's anticipated cash needs into the second quarter of 2021.

About Histogen Inc.

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 submission of a HST-003 IND for the planned Phase 1/2 clinical trial for regeneration of cartilage in the knee, the reporting of topline data for the ongoing HST-001 Phase 1a/2b trial for androgenic alopecia in men and the planned Phase 1 study of emricasan for the treatment of COVID-19; the nature, strategy and focus of Histogen's business; the sufficiency of Histogen's cash resources and Histogen's ability to achieve value for its stockholders; the sufficiency of Amerimmune's cash resources and its ability to commence the planned Phase 1 study of emricasan and achieve value for Histogen's stockholders; and the development and commercial potential and potential benefits of any of Histogen's product candidates, such as HST-001, and HST-003, evaluating a clinical pathway for HST-002 and the Collaborative Development and Commercialization Agreement with Amerimmune and any other collaboration agreements. 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 and the reporting of topline data for the ongoing HST-001 Phase 1a/2b trial for androgenic alopecia in men and Amerimmune's ability to further develop emricasan for the treatment of COVID-19, including the complexity and length of studies required to commercialize emricasan for COVID-19 and potential delays in the commencement, enrollment, and completion of clinical trials, such as the planned emricasan Phase 1 study for the treatment of COVID-19; the uncertainties associated with Amerimmune's pursuit and receipt of non-dilutive capital for the advancement of emricasan, including any potential government grants; Histogen's dependence on its collaboration partner, Amerimmune, to carry out the development of emricasan and the potential for delays in the timing of regulatory approval; competition in the COVID-19 market and other markets in which Histogen and its collaboration partner operate; 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

HISTOGEN INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 6,649	$ 2,065
Restricted cash	10	10
Accounts receivable, net	171	110
Inventories	453	106
Prepaid and other current assets	699	167
Total current assets	7,982	2,458
Restricted cash	250	—
Property and equipment, net	295	320
Right-of-use assets	4,334	95
Other assets	1,091	69
Total assets	$ 13,952	$ 2,942
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,130	$ 808
Accrued liabilities	553	446
Current portion of Paycheck Protection Program loan	39	—
Current portion of lease liabilities	—	108
Current portion of deferred revenue	103	19
Total current liabilities	1,825	1,381
Noncurrent Paycheck Protection Program loan	428	—
Noncurrent portion of lease liabilities	4,749	—
Noncurrent portion of deferred revenue	123	138
Other liabilities	315	321
Total liabilities	7,440	1,840
Commitments and contingencies (Note 10)		
Convertible preferred stock, $0.001 par value; no shares and 73,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; no shares and 5,046,154 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively; liquidation preference of $0 and $40,294 at September 30, 2020 and December 31, 2019, respectively	—	39,070
Stockholders' Equity (Deficit)		
Preferred stock, $0.0001 par value; 10,000,000 shares and no shares authorized at September 30, 2020 and December 31, 2019, respectively; no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 200,000,000 shares and 105,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 12,487,973 shares and 3,343,356 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	—
Additional paid-in capital	66,638	6,864
Accumulated deficit	(59,194)	(43,933)
Total Histogen Inc. stockholders' equity (deficit)	7,445	(37,069)
Noncontrolling interest	(933)	(899)
Total equity (deficit)	6,512	(37,968)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 13,952	$ 2,942

HISTOGEN INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2020	2019	2020	2019
Revenues:				
License	$ 5	$ 5	$ 877	$ 7,515
Product	419	190	419	1,956
Grant	—	—	—	150
Professional services	71	119	285	272
Total revenues	495	314	1,581	9,893
Operating expenses:				
Cost of product revenue	263	81	424	873
Cost of professional services revenue	62	104	248	237
Acquired in-process research and development	—	—	7,144	2,250
Research and development	1,534	673	4,362	2,716
General and administrative	1,982	1,202	4,753	4,607
Total operating expenses	3,841	2,060	16,931	10,683
Loss from operations	(3,346)	(1,746)	(15,350)	(790)
Other income (expense):				
Change in fair value of warrant liabilities	—	30	—	77
Interest income (expense), net	(25)	18	(53)	36
Other income	108	—	108	
Total other income (expense)	83	48	55	113
Net loss	(3,263)	(1,698)	(15,295)	(677)
Net loss attributable to noncontrolling interest	14	4	34	21
Net loss attributable to common stockholders	$ (3,249)	$ (1,694)	$ (15,261)	$ (656)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (0.51)	$ (2.06)	$ (0.20)
Weighted-average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	12,169,173	3,343,356	7,425,051	3,328,549