



Histogenics and Ocugen Enter into Definitive Merger Agreement to Create Nasdaq-Listed Clinical-Stage Company Developing Novel Ocular Gene Therapies and Biotherapeutics

April 8, 2019

— Conference call to be held today at 8:30 a.m. Eastern Time —

BOSTON, Mass. and MALVERN, Penn., April 08, 2019 (GLOBE NEWSWIRE) -- Histogenics Corporation (Nasdaq: HSGX) and Ocugen, Inc., a privately held clinical-stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases, today jointly announced that they have entered into a definitive merger agreement under which the stockholders of Ocugen will become the majority owners of Histogenics' outstanding common stock upon the close of the merger. The proposed merger will result in a combined publicly-traded, clinical-stage biopharmaceutical company operating under the Ocugen name.

"Since Ocugen's founding, we have sought to develop innovative therapies to treat rare and underserved eye diseases through a combination of therapeutic approaches that utilize small molecules, biologics, and gene therapies," said Shankar Musunuri, Ph.D., M.B.A., Chairman, Chief Executive Officer and Co-Founder of Ocugen. "We have developed a broad pipeline which includes OCU300, an orphan drug candidate for ocular graft versus host disease, and OCU310 for dry eye disease; our modifier gene therapy platform and OCU400, a gene augmentation therapy for patients with inherited retinal diseases caused by mutations in the *NR2E3* gene, which recently received orphan drug designation from the FDA. We've also made pre-clinical progress toward our retinal disease programs which includes novel biologic therapies for wet- age-related macular degeneration, diabetic macular edema and diabetic retinopathy, as well as for retinitis pigmentosa."

"This transaction with Ocugen reflects the continued commitment of our management team and Board of Directors to deliver value to stockholders and make a difference in patients' lives," said Adam Gridley, President of Histogenics. "Following a thorough review of strategic alternatives for Histogenics and the NeoCart program, we have determined that a merger with Ocugen will enable Histogenics investors to participate in Ocugen's broader pipeline of ocular disease and gene therapy opportunities, including several late-stage clinical candidates, and a robust preclinical platform. In addition, we plan to continue to evaluate opportunities to realize additional value from the discontinued NeoCart program over the coming weeks."

Ocugen's broad pipeline of promising ophthalmology programs in development include:

Modifier Gene Therapy Platform

Ocugen's modifier gene therapy platform is licensed from the Schepens Eye Research Institute of Massachusetts Eye and Ear (Harvard Medical School) and involves targeted delivery and expression of one or more nuclear hormone receptor (NHR) genes in the disease tissues. NHRs are believed to play a vital role in regulating retinal cell development, maturation, metabolism, visual cycle function, survival, and maintaining the cellular and molecular homeostasis of various tissues, including the retina. Multiple animal models have shown that expression of NHRs within the retina can stabilize retinal cells and suppress/prevent the development of inherited diseases, demonstrating their modifier function. Many degenerative retinal conditions are caused by genetic mutations that are passed down within families and lead to progressive disease, severe visual impairment and blindness.

OCU400 (*NR2E3*-AAV) for the treatment of *NR2E3* mutation-associated retinal degenerative diseases consists of a functional copy of the NHR gene, *NR2E3*, delivered to target cells in the retina using an adeno-associated viral (AAV) vector. OCU400 is a novel gene therapy currently in development as a gene augmentation therapy product for the treatment of *NR2E3*-mutation associated retinal degenerative diseases, and in February 2019, received Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (the FDA). In a mouse model of *Nr2e3* mutation, *Nr2e3* delivery to retinal cells reversed disease progression and restored retinal histology. Based on preclinical studies, Ocugen plans to initiate a Phase 1/2a clinical study of OCU400. Unlike single-gene replacement approaches, which have shown tremendous promise in rare retinal diseases despite being highly specific for a single condition, OCU400 represents a powerful and remarkably broadened means of potentially treating a variety of IRDs (inherited retinal diseases) with a single therapy.

OCU410 (*RORA*-AAV) is a second in-line modifier gene therapy being developed for the treatment of dry age-related macular degeneration (AMD). OCU410 utilizes an AAV delivery platform for retinal delivery of the *RORA* gene (RAR Related Orphan Receptor A). OCU410 is currently in preclinical development.

Ocular Surface Disease Programs

OCU300 (brimonidine 0.18%, OcuNanoE™), is currently in a Phase 3 clinical trial for the treatment of ocular graft versus host disease (oGVHD), which develops in approximately 60% of patients following an allogeneic bone marrow transplant. OCU300 consists of FDA-approved brimonidine tartrate formulated in a proprietary nanoemulsion based on Ocugen's patented [OcuNanoE™ technology](#). In August 2017, OCU300 received Orphan Drug Designation (ODD) from the FDA. Currently there are no FDA-approved products for the prevention or treatment of oGVHD.

Ocugen has developed its proprietary OcuNanoE™ nanoemulsion formulation to deliver drugs more efficiently to relevant ocular tissues, provide protection to the ocular surface, and potentially increase overall efficacy compared to conventional eye drops. We recently completed our first Phase 3 clinical trial of OCU310 (brimonidine 0.2%, OcuNanoE™) for the treatment of dry eye disease. We are waiting for a full dataset from this trial and will provide an update once we complete full analysis.

Retinal Disease Programs

Ocugen has two protein biologic preclinical programs in development, focused on treating inflammatory, degenerative and neovascular diseases of the eye. OCU200 is being developed for the treatment of wet AMD and OCU100 for the treatment of retinitis pigmentosa (RP). OCU100 has received Orphan Drug Designation from both the FDA and European Medicines Agency (EMA).

OCU200 is a biologic product candidate in preclinical development for the treatment of wet AMD, a severely sight-threatening disease caused by the abnormal growth and infiltration of new, leaky blood vessels into the retina. OCU200 is a novel fusion protein consisting of two naturally occurring molecules, transferrin and tumstatin, that are present normally in retinal tissues. In preclinical studies, OCU200 demonstrated superior efficacy compared to anti-VEGF therapies in reducing choroid neovascularization (CNV) lesion areas in laser-induced rats and mice CNV models. We believe these results highlight the potential for OCU200 to deliver disease modification for wet-AMD and other high-need ocular neovascular diseases, such as diabetic macular edema (DME) and diabetic retinopathy (DR).

OCU100 is a protein-based biologic in preclinical development for the treatment of retinitis pigmentosa (RP), which is a class of diseases that leads to the progressive degeneration of the retina and blindness. There is currently no FDA approved treatment for RP.

About the Proposed Merger

The merger is structured as a stock-for-stock transaction whereby all of Ocugen's outstanding shares of common stock and securities convertible into or exercisable for Ocugen's common stock will be converted into Histogenics' common stock and securities convertible into or exercisable for Histogenics' common stock. Immediately following the closing of the transaction, the former stockholders of Ocugen will hold approximately 90% of the outstanding shares of common stock of the combined company and the current Histogenics stockholders will retain an ownership interest representing approximately 10% of the outstanding shares of common stock of the combined company, subject to certain adjustments as described in the merger agreement of up to an additional 5% ownership for the current Histogenics stockholders based on Histogenics' cash at the closing of the proposed merger, including proceeds from sale of the assets underlying Histogenics' NeoCart product in connection with the closing.

Upon closing of the transaction, Histogenics will be renamed Ocugen, Inc. and will be headquartered in Malvern, Pennsylvania under the leadership of Ocugen's current management team. Dr. Musunuri, Chairman, Chief Executive Officer and Co-Founder of Ocugen, will continue as the Chairman and CEO of the combined company. Susan L. Drexler, C.P.A., M.B.A. will be the interim Chief Financial Officer and Dan Jorgensen, M.D., M.P.H., M.B.A., will be the Chief Medical Officer. No Histogenics employees will remain employed by the combined company. The merger agreement provides that the Board of Directors of the combined company will be comprised of seven directors designated by Ocugen. The merger agreement has been unanimously approved by the Board of Directors of each company. The transaction is expected to close in late second quarter or third quarter of 2019, subject to approvals by stockholders of each company and other customary closing conditions.

Canaccord Genuity LLC is acting as exclusive financial advisor to Histogenics on the proposed transaction and Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP serves as legal counsel to Histogenics. Chardan Capital Markets LLC is acting as exclusive financial advisor to Ocugen on the proposed transaction and Morgan, Lewis & Bockius LLP serves as legal counsel to Ocugen on the proposed transaction.

Conference Call Information

Adam Gridley and Shankar Musunuri will co-host a conference call to discuss the proposed merger on April 8, 2019, at 8:30 a.m. Eastern Time.

To access the live conference call, please dial 1.877.930.8064 from the U.S. and Canada or 1.253.336.8040 internationally and provide the conference ID "6495686" five to ten minutes before the start of the call. To access a live audio webcast of the presentation on the "Investor Relations" page of the Histogenics website, please click [here](#). A replay of the webcast will be archived on Histogenics' website for approximately 45 days following the call.

About Histogenics Corporation

Histogenics (Nasdaq: HSGX) develops restorative cell therapies that may offer rapid-onset pain relief and restored function. Histogenics' technology platform has the potential to be used for a broad range of restorative cell therapy indications. For more information on Histogenics and NeoCart, please visit www.histogenics.com.

About Ocugen, Inc.

Ocugen is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing a pipeline of innovative therapies that address rare and underserved eye diseases. Ocugen offers a diversified ophthalmology portfolio that includes novel gene therapies, biologics, and small molecules and targets a broad range of high-need retinal and ocular surface diseases. For more information on Ocugen, please visit www.ocugen.com.

Additional Information about the Proposed Merger and Where to Find It

In connection with the proposed merger, Histogenics and Ocugen intend to file relevant materials with the Securities and Exchange Commission, or the SEC, including a registration statement on Form S-4 that will contain a prospectus and a proxy statement. **Investors and security holders of Histogenics and Ocugen are urged to read these materials when they become available because they will contain important information about Histogenics, Ocugen and the proposed Merger.** The proxy statement, prospectus and other relevant materials (when they become available), and any other documents filed by Histogenics with the SEC, may be obtained free of charge at the SEC website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Histogenics by directing a written request to: Histogenics Corporation, c/o Gunderson Dettmer, One Marina Park Drive, Suite 900, Boston, MA 02210, Attention: HSGX Secretary. Investors and security holders are urged to read the proxy statement, prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed merger.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities in connection with the proposed merger shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Participants in the Solicitation

Histogenics and its directors and executive officers and Ocugen and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Histogenics in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the proposed merger will be included in the joint proxy statement/prospectus referred to above. Additional information regarding the directors and executive officers of Histogenics is also included in Histogenics' Annual Report on Form 10-K for the year ended December 31, 2018. These documents are available free of charge at the SEC web site (www.sec.gov) and from the CEO at Histogenics at the address described above.

Forward-Looking Statements

This press release contains forward-looking statements based upon Histogenics' and Ocugen's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements about the structure, timing and completion of the proposed Merger; the combined company's listing on Nasdaq after closing of the proposed Merger; the possibility that any grant, sale or transfer of rights to NeoCart technology will occur; expectations regarding the ownership structure of the combined company; the expected executive officers and directors of the combined company; the combined company's expected cash position at the closing of the proposed Merger; the future operations and success of the combined company, including with respect to the continued development of Histogenics' NeoCart technology and Ocugen's product pipeline; the nature, strategy and focus of the combined company; the success, cost and timing of the combined company's product development activities, studies and clinical trials, the success of competing products that are or become available, the combined company's ability to obtain FDA approval for and commercialize its product candidates; the executive and board structure of the combined company; the location of the combined company's corporate headquarters; Ocugen having sufficient resources to advance its pipeline; the expected charges and related cash expenditures that Histogenics expects to incur; and other statements that are not historical fact. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: (i) the risk that the conditions to the closing of the proposed Merger are not satisfied, including the failure to timely obtain stockholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Histogenics and Ocugen to consummate the proposed Merger; (iii) risks related to Histogenics' ability to manage its operating expenses and its expenses associated with the proposed Merger pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed Merger; (v) the risk that as a result of adjustments to the exchange ratio, Histogenics stockholders and Ocugen stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of Histogenics common stock relative to the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; (ix) the uncertainties associated with the clinical development and regulatory approval of Ocugen's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (x) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (xiii) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, including with respect to future financial and operating results; and (xiv) risks related to unanticipated charges not currently contemplated that may occur as a result of Histogenics' prior workforce reductions, including that the workforce reduction charges, costs and expenditures may be greater than currently anticipated. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in Histogenics' Annual Report on Form 10-K for the year ended December 31, 2018, which is on file with the SEC, and in other filings that Histogenics makes and will make with the SEC in connection with the proposed Merger, including the proxy statement/prospectus/information statement described above under "Additional Information about the Proposed Merger and Where to Find It." You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. Histogenics expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Source: Histogenics Corporation and Ocugen, Inc.