Ocugen Engages Kemwell Biopharma for cGMP Manufacture of OCU200

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Paves the way towards getting OCU200 in the clinic by 1H 2022 as planned

MALVERN, Pa., Oct. 06, 2020 (GLOBE NEWSWIRE) -- Ocugen, Inc., (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing transformative therapies to cure blindness diseases, today announced it has entered into an agreement with Kemwell Biopharma Pvt. Ltd. (Kemwell) to manufacture OCU200, Ocugen's novel biologic product candidate in preclinical development for treating severely sight-threatening diseases like Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Wet Age-Related Macular Degeneration (Wet-AMD).

Under this agreement, Kemwell will manage all CMC and clinical manufacturing activities as well as provide OCU200 supplies for IND-enabling toxicology studies and Phase 1/2a clinical trials. Kemwell offers proven expertise in supporting companies with process development, clinical and commercial manufacturing of biologicals at their state-of-the-art facilities located in Bangalore, India.

"Biological manufacturing is critical and rate-limiting for Phase 1/2 clinical trials, and this partnership paves the way for us to potentially enter the clinic by 1H2022 as planned. We are picking a CMO with commercial capabilities with a goal of ensuring product consistency throughout development and minimizing regulatory issues as we drive the development of OCU200," said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder of Ocugen."

"We are delighted to partner with Ocugen as they advance their portfolio of transformative therapies to cure blindness diseases. We believe our expertise in process development and manufacturing solutions will play a critical role to advance OCU200 into the clinic and could deliver hope to patients with severely sight-threatening diseases who do not respond to currently available therapies," said Anurag Bagaria, Chairman and CEO of Kemwell.

Ocugen is planning to initiate IND-enabling studies, including GLP toxicology studies next year. DME is the first targeted indication for OCU200, and the Company plans to advance into Phase 1/2a trials in 1H2022. Based on early clinical success in DME, the Company will undertake evaluation of broader indications such as DR and Wet-AMD. In the US alone, over 9.5 million patients struggle with these retinal diseases. Approximately 50% of patients do not respond to current therapies including anti-VEGF treatments. This patient population represents a significant underserved population who are looking for new therapies. OCU200 has a distinct method of action compared to current anti-VEGF therapies and has potential to be a disease-modifying drug based on *in vivo* and *in vitro* preclinical studies to date.

About OCU200
OCU200 is a biologic product candidate in preclinical development for treating severely sight-threatening diseases like Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Wet Age-Related Macular Degeneration (Wet-AMD). Patients affected by these diseases share common symptoms, such as blurriness in vision and progressive vision loss as the disease progresses. The formation of fragile and leaky new blood vessels leads to fluid accumulation in and around the retina, causing damage to vision.

OCU200 is a novel fusion protein consisting of two human proteins, tumstatin and transferrin, that are already present normally in retinal tissues. OCU200 possesses unique features which enable it to (a) efficiently target leaky blood vessels, (b) regress the existing abnormal blood vessels, and (c) inhibit the growth of new blood vessels in the retina and choroid. Tumstatin, which acts as an anti-VEGF, anti-inflammatory and anti-oxidative agent, is the active component of OCU200. It binds to integrin receptors, which play a crucial role in disease pathogenesis. Transferrin facilitates the targeted delivery of tumstatin into the retina and choroid and potentially helps increase the interaction between tumstatin and integrin receptors.

About Ocugen, Inc.
Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing transformative therapies to cure blindness diseases. Our breakthrough modifier gene therapy platform has the potential to treat multiple retinal diseases with one drug – "one to many" and our novel biologic product candidate aims to offer better therapy to patients with underserved diseases such as wet age-related macular degeneration, diabetic macular edema, and diabetic retinopathy. For more information, please visit www.ocugen.com.

About Kemwell Biopharma Pvt. Ltd.
Kemwell is a leading biologics CDMO in Asia which provides services to global biopharmaceutical organizations for both clinical and commercial needs. Kemwell, located in Bangalore, India provides customers with high quality and cost-effective access to state-of-the-art technology for development and manufacturing of all mammalian cell culture-based products. Kemwell's facilities consists of cGMP drug substance manufacturing suites with over 4500L bioreactor capacity, sterile fill and finish line for cGMP drug product manufacturing and development laboratories to support process and analytical development and production of protein therapeutics such as monoclonal antibodies, bi-specific antibodies and fusion proteins. For more information, please visit www.kemwellbiopharma.com.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from our current expectations. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission (the "SEC"), including the risk factors described in the section entitled "Risk Factors" in the quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events or otherwise, after the date of this press release.

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