Ocugen and Bharat Biotech Announce Execution of Definitive Agreement for the Commercialization of COVAXIN™ in the US Market

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- *Definitive Agreement provides details of the previously announced intent to co-develop COVAXIN™ for the US market*
- *Ocugen and Bharat Biotech to share US commercialization profits*
- *Ocugen to receive initial supply of COVAXIN™ doses from Bharat Biotech upon authorization from US regulatory authorities while it ramps up manufacturing in the US*
- *COVAXIN™ received EUA (Emergency Use Authorization) in India in January and is currently in a fully enrolled Phase 3 clinical trial involving 25,800 patients*
- *COVAXIN™ (whole-virion inactivated COVID-19 vaccine candidate) effectively neutralizes UK variant of SARS-Cov-2 reducing the possibility of mutant virus escape*

MALVERN, Pa. and HYDERABAD, India, Feb. 02, 2021 (GLOBE NEWSWIRE) -- Ocugen, Inc., (NASDAQ: OCGN), a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to fight COVID-19, and Bharat Biotech, a global leader in vaccine innovation, today announced they have entered into a definitive agreement to co-develop, supply, and commercialize Bharat Biotech's COVAXIN™, an advanced stage whole-virion inactivated COVID-19 vaccine candidate, for the United States market.

Under the terms of the agreement, Ocugen will have US rights to the vaccine candidate and will be responsible for clinical development, regulatory approval (including EUA) and commercialization for the US market. Bharat Biotech will supply initial doses to be used in the US upon Ocugen's receipt of an EUA. In addition, Bharat Biotech will support the technology transfer for manufacturing in the US. In consideration for the exclusive license to the US market, Ocugen will share the profits from the sale of COVAXIN™ in the US market with Bharat Biotech, with Ocugen retaining 45% of the profits.

The collaboration will leverage the vaccine expertise of Ocugen's leadership team. In preparation for the development of COVAXIN™ in the US, Ocugen's Vaccine Scientific Advisory Board and Ocugen management have initiated discussions with the U.S. Food & Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority (BARDA) to develop a regulatory path to EUA and, eventually, biologics license application (BLA) approval in the US market for COVAXIN™. Ocugen is also in active discussions with manufacturers in the US to produce a significant number of doses of COVAXIN™ to support its US immunization program.

"The evaluation of COVAXIN™ has resulted in several unique product characteristics including long-term persistence of immune responses to multiple viral proteins, as opposed to only the spike protein, and has demonstrated broad spectrum neutralizing capability with heterologous SARS-CoV-2 strains, thus potentially reducing or eliminating escape mutants. Requiring only a standard vaccine storage temperature of 2-8^{o}C and with the potential to treat all age-groups, COVAXIN™ may offer an important option to protect lives across America," said Dr. Shankar Musunuri, Chairman, CEO, and Co-Founder of Ocugen.

The Central Licensing Authority in India has granted permission for the sale or distribution of COVAXIN™ for restricted use in emergency situations in the public interest, in clinical trial mode. With the kickoff of what is likely to become the biggest national vaccination campaign in India's history, COVAXIN™ is being administered as one of the two COVID-19 shots available under emergency authorization with the first batch of 30 million doses being administered to health professionals and front-line workers.

"The COVID-19 pandemic has affected humanity at large. As a company determined to protect global public health, it has always been important for us to develop vaccines for a global cause. Our goal for all vaccines developed at Bharat Biotech is to provide global access. COVAXIN™ has generated excellent safety data with robust immune responses to multiple viral proteins that persist. With the recent progression of COVAXIN use under EUA in India, I am confident that we will be able to work with Ocugen to develop a plan to bring COVAXIN to the US market.," said Dr. Krishna Ella, Chairman & Managing Director of Bharat Biotech.

About COVAXIN™
COVAXIN™, India's COVID-19 vaccine by Bharat Biotech is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). COVAXIN is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform with an excellent safety track record of more than 300 million doses supplied.

In addition to generating strong immune response against multiple antigens, COVAXIN™ is shown to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. With published data demonstrating a safety profile superior to several other vaccines, COVAXIN™ is packaged in multi-dose vials that can be stored at 2-8C.

About Ocugen, Inc.
Ocugen, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing gene therapies to cure blindness diseases and developing a vaccine to fight COVID-19. 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. We are co-developing Bharat Biotech's COVAXIN™ vaccine candidate for COVID-19 in the US market. For more information, please visit www.ocugen.com.

About Bharat Biotech:
Bharat Biotech has established an excellent track record of innovation with more than 140 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 116 countries, and World Health Organization (WHO) Pre-qualifications. Located in Genome

Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 6 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and public private partnerships resulted in the introduction of path breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC® and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The recent acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the largest rabies vaccine manufacturer in the world. To learn more about Bharat Biotech visit www.bharatbiotech.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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