COVAXIN® (BBV152) Booster Shown to Neutralize Both Omicron and Delta Variants of SARS-CoV-2

- *Booster dose of vaccine, COVAXIN® (BBV152), generated robust neutralizing antibody responses against both Omicron (B.1.529) and Delta (B.1.617.2) using a live virus neutralization assay*
- *100% of test serum samples showed neutralization of the Delta variant and more than 90% of serum samples showed neutralization of the Omicron variant*
- *These data add to the body of evidence that the broad-spectrum mechanism of action of a whole virus inactivated COVID-19 vaccine, like COVAXIN® (BBV152), is a viable option in this continuously evolving pandemic*

Hyderabad, India, January 12, 2022 - Bharat Biotech, a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced results from a study conducted at Emory University demonstrating that sera from subjects who received a booster dose of COVAXIN® (BBV152) six months after getting a primary two-dose series of COVAXIN® (BBV152), neutralized the SARS-CoV-2 Omicron and Delta variants. Earlier studies demonstrated the neutralizing potential of COVAXIN® (BBV152) against SARS-CoV-2 Variants of Concern Alpha, Beta, Delta, Zeta and Kappa.

The study will be published on the pre-print server, *medRXiv*, shortly.

Sera samples from individuals who received a booster of COVAXIN® (BBV152) were observed to be effective in neutralizing Omicron and Delta variants on a live virus neutralization assay. The neutralization activity of COVAXIN®-boosted sera was comparable to what has been observed in mRNA vaccine-boosted sera against the Omicron variant. More than 90% of all individuals boosted with COVAXIN® (BBV152) showed neutralizing antibodies. All participants received an initial two-dose schedule of COVAXIN® (BBV152) at Day 0 and Day 28.

“As the dominant COVID-19 variant throughout the world, Omicron poses a serious public health concern,” said Mehul Suthar, Ph.D., Assistant Professor, Emory Vaccine Center and who led the laboratory analysis. “Data from this preliminary analysis show individuals receiving a booster dose of COVAXIN® have a significant immune response to both the Omicron and Delta variants. These findings suggest that a booster dose has the potential to reduce disease severity and hospitalizations.”

Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech said, “We are in a continuous state of innovation and product development for COVAXIN®. The positive neutralization responses against the Omicron and Delta variants, validates our hypothesis of a multi-epitope vaccine generating both humoral and cell mediated immune responses. Our goals of developing a global vaccine against COVID-19 have been achieved with the use of COVAXIN® as a universal vaccine for adults and children.”

"The global impact of Omicron shows us that the fight against COVID-19 continues, and we're encouraged that these data demonstrate the value of COVAXIN® as a primary and booster vaccine," said Dr. Shankar Musunuri, Chairman, CEO and Co-Founder, Ocugen, Inc. "These results show how a broad-spectrum vaccine has the potential ability to address ever-shifting public health challenges such as new variants and mutations."

COVAXIN® is formulated uniquely such that the same dosage can be administered to adults and children alike. COVAXIN® is a ready-to-use, liquid vaccine, stored at 2 - 8°C, with 12 months shelf life and multi-dose vial policy. The same doses of vaccine can also be used for two-dose primary immunization in adults and children and for booster dose vaccinations, making it truly a universal vaccine.

About the study

In order to evaluate the effectiveness of COVAXIN® (BBV152) against the Omicron variant, Ocugen contracted with the Emory Vaccine Center (Atlanta, GA) to test human immune sera obtained from participants (n=13) in an ongoing Phase 2 clinical trial (ClinicalTrials.gov: NCT04471519). Sera was collected 28-days post booster – six months following the primary two-dose series. Each sera was tested in a neutralization assay. Following three doses, the FRNT50 geometric mean titers (GMTs) of neutralizing antibodies against the Omicron variant measured in the samples was 75, compared to 480 against the Delta variant and 706 against the vaccine strain, D614G.

This study was sponsored by Ocugen, Inc. and Ocugen's partner, Bharat Biotech, provided the sera of the subjects from the Phase 2 study.

About COVAXIN® (BBV152)

Covaxin was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). COVAXIN® (BBV152) is a highly purified and inactivated vaccine that is manufactured using a vero cell manufacturing platform.

With more than 200 million doses having been administered to adults and children outside the U.S., COVAXIN® (BBV152) is currently authorized under emergency use in more than 20 countries, and emergency use authorization is in process in more than 60 other countries. The World Health Organization (WHO) recently added COVAXIN® (BBV152) to its list of vaccines authorized for emergency use. And, as many as 110 countries have agreed to mutual recognition of COVID-19 vaccination certificates with India that includes vaccination using COVAXIN® (BBV152).

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the 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 4 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 introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of the rabies vaccine facility, Chiron Behring, from GlaxoSmithKline (GSK) has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer. To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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 save lives from 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 U.S. and Canadian markets. For more information, please visit www.ocugen.com.

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