Bharat Biotech completes clinical development for phase III trials and booster doses for BBV154 intranasal covid vaccine.

- Two separate and simultaneous clinical trials were conducted to evaluate BBV154 as a primary dose (2-dose) schedule; and a heterologous booster dose for subjects who have previously received 2 doses of the two commonly administered covid vaccines in India.

- Data from both Phase III human clinical trials have been submitted for approval to National Regulatory Authorities.

- Primary dose schedule phase III trials were conducted for safety, and immunogenicity in ~3100 subjects, and compared with COVAXIN®. The trials were conducted in 14 trial sites across India.

- Heterologous booster dose studies were conducted for safety and immunogenicity in ~875 subjects, where a booster dose (3rd dose) of BBV154 intranasal vaccine was administered to study participants who were previously vaccinated with licensed COVID vaccines. The trials were conducted in 9 trial sites across India.

- Being an intranasal vaccine, BBV154 may produce local antibodies in the upper respiratory tract which may provide the potential to reduce infection and transmission. Further studies are being planned.

- At the start of the COVID pandemic, Bharat Biotech commenced work on 4 platform technologies, the vero cell inactivated platform, and the adenoviral vector platform have been developed.

Hyderabad, Aug 15, 2022: Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced that BBV154 (intra nasal vaccine) has proven to be safe, well-tolerated, and immunogenic in subjects in controlled clinical trials.

BBV154 is a recombinant replication-deficient adenovirus vectored vaccine with a pre-fusion stabilized spike protein. This vaccine candidate was evaluated earlier in phase I and II clinical trials with successful results. BBV154 has been specifically formulated to allow intranasal delivery. In addition, the nasal delivery system has been designed and developed to be cost-effective in low and middle-income countries.

BBV154 was developed in partnership with Washington University St Louis, which had designed and developed the recombinant adenoviral vectored constructs and evaluated them in preclinical studies for efficacy. Product development related to preclinical safety evaluation, large-scale manufacturing scale-up, formulation, and delivery device development, including human clinical trials, were conducted by Bharat Biotech. The Government of India partly funded product development and clinical trials through the Department of Biotechnology's, COVID Suraksha program.

Two separate and simultaneous clinical trials were conducted to evaluate BBV154 as a primary dose (2-dose) schedule and a heterologous booster dose for subjects who have previously received 2 doses of the two commonly administered covid vaccines in India.

Immunogenicity was evaluated through serum neutralizing antibodies by PRNT assays and serum IgG's through ELISA's. To assess vaccine response through the intranasal route, secretory IgA's were evaluated by ELISA in serum and saliva. Evaluation was also carried out for the ability of BBV154 to elicit long term memory T and B cell responses against the ancestral and omicron variants.

Mrs. Suchitra K. Ella, Joint Managing Director, Bharat Biotech, said, "On this 75th Independence Day, we are proud to announce successful completion of clinical trials for BBV154 intranasal vaccine. We stay committed and focused on innovation and product development; this is yet another achievement for the multidisciplinary teams at Bharat Biotech. If approved, this intranasal vaccine will make it easier to deploy in mass immunization campaigns with an easy to administer formulation and delivery device. Vectored vaccines also enable faster development of targeted vaccines in response to emerging variants of concern. We hereby thank the volunteers, principle investigators, and clinical trial personnel for all their efforts."

BBV154 has the double benefit of enabling faster development of variant-specific vaccines and easy nasal delivery that helps mass immunization protect from emerging concern variants. It promises to become an important tool in mass vaccinations during pandemics and endemics.

BBV154 is stable at 2-8°C for easy storage and distribution. Bharat Biotech has established large manufacturing capabilities at multiple sites across India, including Gujarat, Karnataka, Maharashtra and Telangana, with operations pan India.

About Bharat Biotech

Bharat Biotech International Limited 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, BBIL 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, BBIL continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus toxoid conjugated vaccine for Typhoid. BBIL's commitment to global social innovation programs and the public-private partnership resulted in introducing path-breaking WHO pre-qualified vaccines such as BIOPOLIO®, ROTAVAC®, ROTAVAC® 5D, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. Novel vaccines against malaria and tuberculosis are under development through global partnerships. The acquisition of Chiron Behring Vaccines has positioned BBIL as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®.

For more information, please contact: : **Sheela Panicker : enright@enrightpr.com : +91 984 980 9594**