Bharat Biotech's COVAXIN® Phase III data published in The Lancet

Hyderabad, November 12, 2021: Bharat Biotech, a global leader in vaccine development and innovation, announced today that the safety and efficacy analysis data from Phase III clinical trials of COVAXIN® is peer reviewed and published in The Lancet.

The Lancet peer-review confirms the efficacy analysis which demonstrates COVAXIN® to be effective against COVID-19. COVAXIN®is the only COVID-19 vaccine to have demonstrated efficacy data from phase III clinical trials against the delta variant at 65.2%.

- *Efficacy analysis demonstrates COVAXIN® to be 77.8% effective against symptomatic COVID-19, through evaluation of 130 confirmed cases, with 24 observed in the vaccine group versus 106 in the placebo group*
- *Efficacy analysis demonstrates COVAXIN® to be 93.4% effective against severe symptomatic COVID-19*
- *Safety analysis demonstrates adverse events reported were similar to placebo, with 12% of subjects experiencing commonly known side effects and less than 0.5% of subjects experiencing serious adverse events*
- *Efficacy data demonstrates 63.6% protection against asymptomatic COVID-19*
- *Efficacy data demonstrates 65.2% protection against the SARS-CoV-2, B.1.617.2 Delta*
- *Efficacy data demonstrates 70.8% protection against all variants of SARS-CoV-2 virus*

COVAXIN® was developed under a partnership with the **Indian Council of Medical Research** and the **National Institute of Virology**, with Bharat Biotech receiving the SARS-COV-2 strains through this collaboration.

Bharat Biotech had established an ongoing collaboration with ViroVax since 2019, through the Indo-U.S. Vaccine Action Program, to develop and evaluate IMDG (Alhydroxiquim-II), a novel TLR7/8 agonist molecule, which is formulated as part of the adjuvant in COVAXIN®. The Adjuvant Program of the U.S. National Institute of Allergy and Infectious Diseases (NIAID) has supported ViroVax since 2009.

Dr. Krishna Ella, CMD, Bharat Biotech, said, "The peer-review of COVAXIN® phase III clinical trial data in *The Lancet*, an authoritative voice in global medicine validates our commitment to data transparency and meeting the stringent peer-review standards of world leading medical journals.

The data from our product development and clinical trials have been published in 10 peer-reviewed journals, making COVAXIN® one of the most highly published COVID-19 vaccines in the world.

This accomplishment reflects the undeterred commitment by my team members at Bharat Biotech, our public partners, Indian Council of Medical Research, National Institute of Virology, and the trust imposed by our trial participants who made this happen."

The phase 3 trial Efficacy and Safety Study involving 25,800 volunteers across 25 sites in India is India's largest ever clinical trial conducted for a Covid-19 vaccine.

COVAXIN® was well tolerated and the Data Safety Monitoring Board has not reported any safety concerns related to the vaccine. The overall rate of adverse events observed in COVAXIN® was lower than that seen in Covid-19 vaccines. The safety profile of COVAXIN® is now well established based on inactivated vaccines technology, and in large part due to the extensive 25-year safety track record of Bharat Biotech's vero cell manufacturing platform.

Dr. Balram Bhargava, Director General, Indian Council of Medical Research (ICMR), said, "Following successful isolation of the SARS-CoV-2 virus at ICMR -National Institute of Virology (NIV), Pune, ICMR and Bharat Biotech International Ltd (BBIL) embarked upon one of the most successful public-private partnership to develop the virus isolate into an effective COVID-19 vaccine. I am delighted to see that the phase III efficacy data has also been published in THE LANCET, one of the most reputed journals worldwide. This itself speaks high about the strong position of COVAXIN® amongst other global front-runners COVID-19 vaccines. The bench to bedside journey of COVAXIN® in less than 10 months showcases the immense strength of "Atmanirbhar Bharat" along with the Indian academia and industry in fighting against the odds and carving a niche in the global community."

Recently, the World Health Organization granted emergency use listing to COVAXIN® enabling countries to expedite their regulatory approval to import and administer doses. It has also received emergency use authorizations in several countries with applications in process in more than 50 countries worldwide. Bharat Biotech has partnered with Ocugen to obtain approvals for COVAXIN® in the United States and Canada.

With more than 150 million doses manufactured, supplied, and with an excellent safety and efficacy profile, COVAXIN®is a major contributor to the global fight against the COVID-19 pandemic.

COVAXIN®is currently being evaluated in controlled clinical trials in children 2-18 years of age, with results available during Q4 2021.

Bharat Biotech is poised to achieve its goal of an annualized capacity of ~1.0 billion doses of COVAXIN® by the end of 2021.

More about COVAXIN® - https://www.bharatbiotech.com/covaxin.html

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 (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid

conjugated vaccine for Typhoid. Bharat's commitment to global social innovation programs and the public-private partnership resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®.

To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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