

Bharat Biotech signs agreement with Precisa Medicamentos for supply of 'COVAXIN™' to Brazil

Hyderabad, January 12, 2020: Bharat Biotech announced that it has signed an agreement with Precisa Medicamentos for the supplies of COVAXIN™ to Brazil.

A team from Precisa Medicamentos has visited the Bharat Biotech facility last week to discuss potential export possibilities of COVAXIN™, India's 1st Indigenous vaccine for COVID-19. The team met Dr. Krishna Ella at Bharat Biotech on the 7th and 8th of January at the Bharat Biotech facility in Genome Valley, Hyderabad. During the discussion, his Excellency Ambassador of Brazil to India, André Aranha Corrêa do Lago joined on a virtual platform. He expressed his keen interest on behalf of the Govt. of Brazil, towards the procurement of COVAXIN™. In principle, it is understood between both parties that supplies of COVAXIN™ to be prioritized for the public market, through a direct procurement by the Govt. of Brazil. Supplies to the private market would be based upon receipt of market authorization from ANVISA, the Brazilian regulatory authority.

Pleased with the interest expressed by the Brazilian government, **the Chairman and Managing Director of Bharat Biotech Dr. Krishna Ella said** *"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. COVAXIN™ is an innovation and a perfect example of novel product development from India. Our goal for all vaccines developed at Bharat Biotech is to provide global access to populations that need it the most. COVAXIN™ has generated excellent safety data with robust immune responses to multiple viral proteins that persist. We are happy to note that vaccines innovated in India are able to address the public health needs of Brazil."*

After the technical visit to Bharat Biotech's Genome Valley facility in Hyderabad, the pharmaceutical director of Precisa Medicamentos, Emanuela Medrades said *"We identified highly technological, scientific and sanitary control levels. There were also excellent outcomes in clinical trials, which will be published soon. Bharat Biotech has exceeded our expectations, demonstrating quality and safety at the level of the largest vaccine suppliers in the world."*

COVAXIN™ is a highly purified and inactivated 2 dose SARS-CoV-2 vaccine, manufactured in a Vero cell manufacturing platform with an excellent safety track record of more than 300 million doses.

The Phase III human clinical trials of COVAXIN™ began mid-November and are currently ongoing in ~26,000 volunteers across India. This is India's first and only Phase III efficacy study for a COVID-19 vaccine, and the largest phase III efficacy trial ever conducted for any vaccine in India. COVAXIN™ has been evaluated in approximately 1000 subjects in Phase I and Phase II clinical trials, with promising safety and immunogenicity results, with acceptance in international peer reviewed scientific journals.

COVAXIN™, India's indigenous COVID-19 vaccine by Bharat Biotech is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). This indigenous,

inactivated vaccine is developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) bio-containment facility, one of its kind in the world.

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. It has also shown to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. Its most critical characteristic is the demonstrated safety profile, which is significantly lower than several other vaccines with published data. COVAXIN™ is presented in multi dose vials, can be stored at 2-8°C.

The product development and clinical trial data thus far has generated 5 publications, which have been submitted to international peer reviewed journals, 4 of which have been accepted and will be published soon. The publication of phase II trial data is undergoing the peer review process.

Bharat Biotech COVAXIN™ Publications

Preclinical Product Development

<https://www.biorxiv.org/content/10.1101/2020.09.09.285445v2>

Animal Challenge Studies – Hamsters

<https://www.researchsquare.com/article/rs-76768/v1>

Animal Challenge Studies - Rhesus Macaques

<https://vaccine.icmr.org.in/images/pdf/934dd262-405d-43c6-af12-e59901253050.pdf>

Human Clinical Trials – Phase I

<https://www.medrxiv.org/content/10.1101/2020.12.11.20210419v1>

Human Clinical Trials – Phase II

<https://www.medrxiv.org/content/10.1101/2020.12.21.20248643v1>

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 with registrations in more than 123 countries and WHO Pre-qualifications of its products.

Founded in 1996 in Genome Valley, Hyderabad, the company has built world-class vaccines & bio-therapeutics, research & product development, including Bio-Safety Level 3 manufacturing facilities, for vaccine production, supply and distribution.

Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for Hepatitis-B, influenza H1N1, Polio, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

The company has proven proficiency in conducting extensive multi-center clinical trials, having completed more than 75 trials enrolling more than ~ 700,000 participants across continents. Our 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® combating Polio, Rotavirus and Typhoid infections respectively. Bharat Biotech has successfully partnered with NIV-ICMR having developed JENVAC®, a licensed Japanese Encephalitis vaccine.

The 2019 acquisition of Chiron Behring (CHIRORAB®), has positioned Bharat Biotech as the largest Rabies vaccine manufacturer in the world.

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

Media contact for Bharat Biotech: Sheela Panicker | +91 984 980 9594 | enright@enrightpr.com