

To
Mr. Elcio Franco
Executive Secretary
Ministry of Health, Brazil

Sub: COVAXIN™ Supplies for the Ministry of Health Brazil

Respected Sir,

Greetings from Bharat Biotech, wishing you a health and safe 2021!

In response to the global COVID-19 pandemic, BBIL has developed a vaccine candidate against the SARS-COV-2 virus; COVAXIN™. COVAXIN™ is a whole virion inactivated vaccine which is being developed in collaboration with the Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV). As of today BBIL have also received an Emergency Use License (EUL) for COVAXIN™ from the Central Drugs Standard Control Organization India.

We are writing to you today to provide a letter of intent for the initiation of supplies of COVAXIN™ to esteemed government. Bharat Biotech is tentatively willing to commit 12 million doses of COVAXIN™ to the Ministry of Health, Brazil at a price of USD 15.00 per dose (INCOTERMS: FCA, Hyderabad). The total quantity shall be provided to the Ministry of Health, Brazil in three shipments highlighted in the supply schedule below;

1. The First shipment of 2 million doses of COVAXIN™ will be shipped by the 31st of January 2021
2. The Second shipment of 4 million doses of COVAXIN™ will be shipped by the 28th of February 2021
3. The Last shipment of 6 million doses of COVAXIN™ will be shipped by the end of 31st March 2021

Supplies of COVAXIN™ shall be subject to the terms and conditions detailed in Annexure I. The following commitment shall be formalized upon receipt of a Letter of acceptance from the Ministry of Health of Brazil by the 15th of January 2021, along with the Purchase order addressed to Bharat Biotech.

We also humbly request for a formal letter from the esteemed Government of Brazil to be addressed to the Government of India and the Ministry of Health and Family Welfare regarding the above mentioned supplies of COVAXIN™.

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 along with a VVM-7 (Vaccine Vial Monitor-7) and can be stored at 2-8 °C. The multi dose presentations of COVAXIN™ are formulated with a preservative which makes it one of the only COVID-19 vaccine to be compliant with the WHO 28-day open vial policy, which has been specially formulated to reduce wastage of doses from open vials.

We would like to also take this opportunity to mention that 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. Please view the list of publications that we have submitted to peer-reviewed Journals in Annexure II.

Thanking you for your consideration and looking forward to your response in this regard!

Sincerely,



Dr. V. Krishna Mohan
Executive Director



Annexure I: Terms and Conditions for supply of COVAXIN™

1. All regulatory clearances from the Central Drugs Laboratory, Kasauli have been procured for each batch being shipped to the Ministry of Health, Brazil.
2. Clearance from the Government of India and The Ministry of Health and Family Welfare, India to export the above suggest quantity have been procured through a formal lette
3. Supplies of COVAXIN™ are accepted by the Ministry of Health, Brazi based on the existing Emergency Use License provided to Bharat Biotech by the Central Drugs Standard Control Organization, and no requirement of Agência Nacional de Vigilância Sanitária (ANVISA) approval or approval from a World Health Organization (WHO) identified Stringent Regulatory Authority.
4. Supplies of COVAXIN™ are accepted by the Ministry of Health, Brazil based on the existing Emergency Use License provided to Bharat Biotech by the Central Drugs Standard Control Organization, India and no WHO Emergency Use Licensure or Pre-Qualification is requested by the Ministry of Health, Brazil.
5. Based upon availability of Raw materials and packing materials,
6. Based upon no production failures, and force Majeure clauses, that is outside our scope

Annexure II: Clinical Development of COVAXIN™

1. Title: Remarkable immunogenicity and protective efficacy of BBV152, an inactivated SARS-CoV-2 vaccine in rhesus macaques. <https://www.researchsquare.com/article/rs-65715/v1>
2. Title: Immunogenicity and protective efficacy of BBV152: a whole virion inactivated SARS CoV-2 vaccine in the Syrian hamster model. <https://doi.org/10.1016/j.isci.2021.102054>
3. Title: Evaluation of Safety and Immunogenicity of an Adjuvanted, TH-1 Skewed, Whole Virion InactivatedSARS-CoV-2 Vaccine - BBV152.
<https://www.biorxiv.org/content/10.1101/2020.09.09.285445v2.full>
4. A Phase 1: Safety and Immunogenicity Trial of an Inactivated SARS-CoV-2 Vaccine-BBV152.
<https://www.medrxiv.org/content/10.1101/2020.12.11.20210419v1.full.pdf>
5. Safety and immunogenicity clinical trial of an inactivated SARS-CoV-2 vaccine, BBV152 (a phase 2, double-blind, randomised controlled trial) and the persistence of immune responses from a phase 1 follow-up report.
<https://www.medrxiv.org/content/10.1101/2020.12.21.20248643v1.full.Pdf>

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