File No: BIO/CT/21/000077

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: BIL/BBV154-II/2021 Version No: 3.0; Date: 07-08-2021** in the below mentioned clinical trial sites.

CT No.: CT- 25/2021

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d4896323 79a1471bfdae9f0b2bea56c83bfbb e2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.08.08 14:30:06 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: 08/08/2021

Stamp

CDSCO CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for intranasal route of administration	
Composition:	Each single dose (0.5 ml) contains	
	Ingredients	**Quantity**
	Chimpanzee adenovirus 36 encoding SARS-CoV-2 pre-fusion stabilized spike protein (ChAd36-SARS-CoV-S)	NLT $5x10^{10}$ virus particles per mL
	Tris-HCl (pH 7.4)	20 mM
	Sodium Chloride	25 mM
	Magnesium Chloride	2 mM
	Glycerol	2.5%
	Polysorbate-80	0.1%
Indications:	For active immunization against Corona Virus Infections (COVID-19) caused by SARS-CoV-2.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Gleneagles Global Hospitals, 6-1-1070/1 to 4, Lakdi Ka Pool, Hyderabad 500004	Institutional Ethics Committee, Gleneagles Global Hospitals, 6-1-1070/1 to 4, Lakdi Ka Pool, Hyderabad 500004 ECR/158/Inst/AP/2013/RR-19	Dr. Tapaswi Krishna Patibandla
2	Radiant Superspeciality Hospital, Sabnis Plot, Kalyan nagar Square, Amravati, Maharashtra	Radiant Super Speciality Hospital Ethics Committee, Radiant Superspeciality Hospital, Sabnis Plot, Kalyan nagar Square, Amravati ECR/997/Inst/MH/2017/RR-21	Dr. Ganesh Babarao Bansod
3	Rana Hospital Pvt. Ltd.Rail Vihar Medical College Road Chargawa Gorakhpur 273001	Institutional Ethics Committee, Rana Hospital Pvt. Ltd.Rail Vihar Medical College Road Chargawa Gorakhpur 273001 ECR/1332/Inst/UP/2020	Dr. Ajeet Pratap Singh
4	Dept. of Community & Family Medicine AIIMS, Patna, Bihar- 801507	Institutional Ethics Committee, All India Institute of Medical Science, Patna, Bihar- 801507 ECR/1387/Inst/BR/2020	Dr. Sanjay Pandey

In addition to point 3, the permission is subject to following condition(s):

I. The Phase II clinical trial should be conducted as per protocol titled “A Phase 2, Randomized, Double Blind, Multicenter Study to Evaluate the Immunogenicity, Reactogenicity and Safety of an Intranasal Adenoviral vector COVID-19 vaccine (BBV154) in

Healthy Volunteers." vide Protocol No: BIL/BBV154-II/2021 Version No: 3.0; Date: 07-08-2021.

II. The firm is required to constitute a DSMB to review the safety data.

III. Firm is required to submit copy of the IMP label as per ND & CT Rules, 2019 including Clinical trial site details.

IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.

V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.08.08 14:30:33 +05'30'

Place: New Delhi
Date: 08.08.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA