File No: BIO/CT/20/000038
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 Licensing Authority hereby permits M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India. Tel: 020- 26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail : SSJ@SERUMINSTITUTE.COM having bulk manufacturing of VPM1002 (rBCG) vaccine at M/s Serum Institute of India Pvt. Ltd., Building no. 14, 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028 and for VPM1002 (rBCG) vaccine at M/s Serum Institute of India Pvt. Ltd., M-SEZ-3, GF, S. no. 105-110, Manjari Budruk, Pune - 412307 to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: SII-rBCG/COVID-19/IN-01, version 3.0 dated 11.04.2020 in the below mentioned clinical trial sites.

**CT No.: CT-06/2020**

2. Details of new drug or investigational new drug and clinical trial sites [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

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Date: 2020.04.12 21:38:31 +05'30'

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

**Place: New Delhi**

Annexure:

Details of New Drug or Investigational New Drug

| | |
|---|---|
| Name of the new drug or investigational new drug: | VPM1002 (rBCG) Vaccine |
| Therapeutic class: | Vaccine |
| Dosage form: | Liquid (Lyophilized powder for reconstitution with sterile water for injection (sWFI) |
| Composition: | Each lyophilized vial (10 dose vial, single dose of 0.1 ml) contains:<br>**Name of Active Ingredient** — **Quantity**<br>*M. bovis*rBCGΔureC::Hly+ — 2 to 8 $10^6$ CFU/vial<br>**Name of Inactive Ingredients** — **Quantity**<br>Dextran — 8.3% (w/v in final bulk)<br>Dextrose anhydrous — 6.8% (w/v in final bulk) |
| Indications: | To reduce infection incidence and disease severity of SARS-COV-2/COVID-19 among high-risk subjects. |

Details of clinical trial sites-

| S. No. | Name and Address of Clinical Trial Site | Ethics Committee details | Name of Principal Investigator |
|---|---|---|---|
| 1 | KEM Hospital Research centre, Sardar Moodliar Road, Rasta Peth, Pune- 411 0112 | Institutional Ethics Committee, KEM Hospital Research Centre Ethics Committee KEMHospital Research Centre. Sardar Moodliar Road Rasta Peth, Pune - 411 011 ECR/272/Inst/MH/2013/RR-19 | Dr. Pradeep D' Costa |
| 2 | Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital,Pune - 411043, Maharashtra | Institutional Ethics Committee, Bharati Vidyapeeth Deemed University, Institutional Ethics Committee Office 4th floor, Bharati Hospital & Research Centre Pune-Satara Road Dhankawadi, Pune-4 1 1 043, Maharashtra ECR/313/Inst/MH/2013/RR-19 | Dr. Sanjay Lalwani |
| 3 | Pt. B D Sharma Postgraduate Institute of Medical Sciences (PGIMS), UHS, Rohtak -124001, Haryana | Institutional ethics Committee, Pt. B D Sharma Postgraduate Institute of Medical Sciences (PGIMS), UHS, Rohtak -124001, Haryana ECR/293/Inst/HR/2013/RR-19 | Dr.Savita Verma |
| 4 | King George Hospital, Maharanipeta, | Institutional ethics Committee, King George Hospital, Maharanipeta, | Dr. R. Vasudev |

| | | | |
|---|---|---|---|
| | Vishakhapatnam - 530002 | Vishakhapatnam – 530002<br>ECR/197/Inst/KGH/RR-16 | |
| 5 | Department of Community Medicine Institute of Medical Sciences & Sum Hospital, K-8, Kalinga Nagar, Ghatikia Bhubaneswar - 751003 | Institutional Ethics Committee, Institute of Medical Sciences & Sum Hospital, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar - 751003<br>ECR/627/Inst/OR/2014/RR-17 | Dr. E. Venkata Rao |

The clinical trial shall be conducted as per protocol titled " A multicentre, phase III, double-blind, randomized, placebo controlled study to evaluate the efficacy of recombinant BCG VPM1002 in reducing infection incidence and disease severity of SARS-COV-2/COVID-19 among high-risk subjects" vide protocol number: SII-rBCG/COVID-19/IN-01, version 3.0 dated 11.04.2020.

Firm is required to submit updated stability data as it emerges and the indication proposed to be in line with the objective and endpoints of trial, further the high risk population to be heath care worker, and one in contacts with confirmed COVID cases as defined and firm is required to use legally manufactured, tested and lot released batches for the said clinical trial and comply with the requirements of New Drugs and Clinical Trials Rules, 2019.

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**(Dr. V. G. Somani)**
**Drugs Controller General (India)**
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**Place: New Delhi**