



GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/21/000106

To

M/s. PPD Pharmaceutical Development (India) Pvt. Ltd.,
101, A Wing, Fulcrum, Hiranandani Business Park,
Sahar Road, Andheri (E), Mumbai – 400099, India.

Sir,

With reference to your SUGAM application no.: GCT/CT04/FF/2021/27674 (GCT/106/21) dated 23-AUG-2021, please find enclosed herewith the permission in Form CT-06 for conduct of Phase III part of the clinical trial titled, **“Adaptive Platform Treatment Trial for Outpatients with COVID-19 (Adapt Out COVID)” vide Protocol Number: ACTIV-2/A5401, Version: 7.0 dated 29-JUN-2021 & Letter of Amendment-1 (LOA-1) dated 30-JUL-2021** under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, that: -

- 1) **The firm should submit the phase II interim analysis data, when available;**
- 2) **The study Investigator should be MD (Medicine or Pulmonologist);**
- 3) **At least 50% Govt. sites geographically distributed in the country should be selected;**
- 4) **There should be no co-enrollment in any observational or other interventional studies as per study protocol without prior approval of Central Licensing Authority;**
- 5) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Institutional Ethics Committee of that site, registered with the Central Licencing Authority under Rule 8;
- 6) where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of Rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

- 7) in case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- 8) the Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
- 9) clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
- 10) clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
- 11) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- 12) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;
- 13) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
- 14) any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;
- 15) in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
- 16) in case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
- 17) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;
- 18) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
- 19) the laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;
- 20) the Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

- 21) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- 22) merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;
- 23) the permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

VENUGOPAL
L G SOMANI

Digitally signed by VENUGOPAL G
SOMANI
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(Dr. V. G. Somani)

Drugs Controller General (India) &
Central Licencing Authority
Stamp



FORM CT-06

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

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

1. The Central Licensing Authority hereby permits **M/s. PPD Pharmaceutical Development (India) Pvt. Ltd., 101, A Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri East, Mumbai (India) – 400099** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: ACTIV-2/A5401 Version: 7.0 dated 29Jun2021 & Letter of Amendment-1 (LOA-1) dated 30-Jul-2021** in the below mentioned clinical trial sites [As per Annexure].-
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.

Place: New Delhi

Date _____

**VENUGOPA
L G SOMANI**

Digitally signed by VENUGOPAL G SOMANI
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Date: 2021.12.20 11:51:09 +05'30'

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

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	(i) SAB-185, and (ii) Interferon- β 1a (SNG001)
Therapeutic class:	(i) Tc bovines derived fully-human polyclonal IgG antibodies (hIgG) and (ii) IFN beta I-a
Dosage form:	(i) SAB-185 Injection, and (ii) Interferon B1a (SNG001) nebulizer solution
Composition:	(i) SAB-185 = 745.7000 mg/Vial Manufacturer Specification Active (as per COA) (ii) IFN beta-1a = 12.0000 MIU/mL Manufacturer Specification Active
Indications:	Treatment of SARS-CoV-2

Annexure:

Details of clinical trial site:

S. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Dayanand Medical College and Hospital, Research & Development Centre, Department of Medicine, Tagore Nagar, Civil Lines, Ludhiana-141001, Punjab	Drug Trial Ethics Committee, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001, Punjab	Dr. Dinesh Jain
2.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg Rajinder Nagar, New Delhi 110060	Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi, Delhi 110060	Dr. Atul Gogia
3.	Aakash Healthcare Private Limited, Hospital Plot, Road No-201, Sector-3, Dwarka, Delhi-110075	Aakash Healthcare Institutional Ethics Committee, Aakash Healthcare Super Speciality Hospital, Hospital Plot, Road No. 201 Sector 3 Dwarka, Delhi-110075	Dr. Akshay Budhraj
4.	Atharva Multispecialty Hospital & Research Centre, H-4/Comm-2, Construction Div-21, UP Avas Vikas Parishad Sector-E, Lucknow-226003, Uttar Pradesh	Institutional Ethics Committee for Atharva Multispecialty Hospital & Research Centre, H-4/Comm-2, Construction Div-21, UP Avas Vikas Parishad Sector-E, Lucknow-226003, Uttar Pradesh	Dr. Sandeep Kumar Gupta
5.	Shree Giriraj Multispecialty Hospital, 27-Navjot Park Corner, 150 Feet Ring Road, Rajkot-360005, Gujarat	Shree Giriraj Hospital Research Ethics Committee, C/O Shree Giriraj Multispecialty Hospital, 27-Navjot Park Corner, 150 Feet Ring Road, Rajkot-360005, Gujarat	Dr. Mayank Rameshchandra Thakker
6.	Department of General Medicine, GMERS Medical College, Gotri Rd, Gotri, Vadodara, Gujarat- 390021	Institutional Human Ethics Committee, 1st Floor, GMERS Medical College and Hospital, Vadodara-390021, Gujarat	Dr. Shubhangi Deshpande
7.	Rhythm Heart Institute- A Unit of Synergy Lifecare Pvt Ltd., Near Siddharth Bungalows Sama-Savli Road, Vadodara-390022 Gujarat	Rhythm Heart Institute Ethics Committee, Near Siddharth Bungalows, Sama-Savli Road, Vadodara-390022, Gujarat	Dr. Nirav Bhalani
8.	Civil Hospital and B.J. Medical College, Asarwa, Ahmedabad, Gujarat-380016	Institutional Ethics Committee B.J. Medical College and Civil Hospital, Office of Medical Superintendent Building, Civil Hospital, Ahmedabad, Gujarat-380016	Dr. Kartikeya Parmar

9.	Unity Trauma Centre and ICU (Unity Hospital), Nr. D.R World, Opp Raghuvir Business Empire, Aai Mata Road, Parvat Patiya, Surat, Gujarat-395010	Unity Hospital Ethics committee, Unity Trauma centre and ICU, N-4 Janki park Society, Aai Mata Road, Parvat Patiya, Surat, Gujarat-395010	Dr. Mahesh Vithalbhai Sutariya
10.	Department of Paediatrics, Dr. D. Y. Patil Medical College, Hospital & Research Centre, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra	Ethics Committee- Dr. D.Y. Patil Vidyapeeth, Pune C/o Vice chancellor, Dr. D.Y. Patil Vidyapeeth, Pune Sant Tukaram Nagar, Pimpri, Pune – 411018, Maharashtra	Dr. Sharad Agarkhedkar
11.	SRV Hospital Dr Mandakini Parihar Marg, Opposite Lokmnya Tilak Terminus, Tilak Nagar, Chembur, Mumbai, Maharashtra	Institutional Ethics Committee Centre for Research SRV Hospital (IECCRSRV), SRV Hospital, CTS 46/B/4 Mishrilalji Parihar Mandakini Parihar Street, Tilak Nagar, Chembur, Mumbai-400089	Dr. Abhay Vispute
12.	Smt. Kashibai Navale Medical College and General Hospital, S. No. 49/1, Off Westerly Bypass Highway, Mumbai-Pune Bypass Narhe (Ambegaon), Haveli, Pune, Maharashtra-411041	Institutional Ethics Committee SKNMGH, Smt. Kashibai Navale Medical College and General Hospital, S. No. 49/1, Off Westerly Bypass Highway, Mumbai-Pune Bypass Narhe (Ambegaon), Haveli, Pune, Maharashtra-411041	Dr. Himanshu Shashikant Prophale
13.	Grant Medical Foundation Ruby Hall Clinic, 40, Sassoon Road, Pune-411001	Institutional Ethics Committee, Poona Medical Foundation, E4-C to E4-F, 4 th Floor, Fifth Avenue Condominium, Dhole Patil Road, Pune-411001, Maharashtra	Dr. Prachee Sathe
14.	Rising Medicare Hospital, S. No 4/1, Off Kharadi Bypass Road, Behind Hotel Radisson Blu, Kharadi, Pune, Maharashtra-411014	Rising Medicare Hospital Institutional Ethics Committee, Rising Medicare Hospital, S. No 4/1, Off Kharadi Bypass Road, Behind Hotel Radisson Blu, Kharadi, Pune, Maharashtra-411014	Dr. Deepak Giri
15.	Noble Hospital Pvt. Ltd., Magarpatta City Road, Hadapsar, Pune, Maharashtra-411013	Noble Hospital Institutional Ethics Committee, Noble Hospitals Pvt. Ltd. Room No 5, Clinical Research Dept, Noble Annex, 153 A, Magarpatta City Road, Hadapsar, Pune, Maharashtra-411013	Dr. Reema Kashiva
16.	MGM's Medical College & Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra	Mahatma Gandhi Mission's Ethics Committee for research on human subject, N-6, Cidco, Aurangabad, 431003, MS	Dr. Anand Nikalje

17.	King George Hospital, Clinical Research Room, Department of General Medicine, Rajendra Prasad Ward, King George Hospital, Andhra Medical College, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh	Institutional Ethics Committee, King George Hospital, King George Hospital, Maharanipeta, Collector's Office Junction, Visakhapatnam-530002, Andhra Pradesh, India	Dr. Yandrapati Gnana Sundara Raju
18.	BJGMC-JHU Clinical Research Site, B J Medical College and Sassoon General Hospitals, Jai Prakash Narayan Road, Pune-411001, Maharashtra	Ethics Committee, Department of Physiology, 2 nd Floor, B. J. Govt. Medical College and Sassoon General Hospital, jai Prakash Narayan Road, Pune-411001, Maharashtra	Dr. Rohidas Tanku Borse
19.	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka	Institutional Ethics Committee, KLES University's KLE PK Hospital, Nehrunagar, Belagavi-590010, Karnataka	Dr. Jayaprakash Appajigol
20.	Victoria Hospital, Bangalore Medical College and Research Institute, K R Road, Fort, Bangalore-560002	Bangalore Medical College and Research Institute, K R Road, Fort, Bangalore-560002	Dr. C R Jayanthi
21.	Rajalakshmi Hospital & Research Centre, 21/1 Lakshmipura Main Road, Vidyananyapura Post, Bangalore-560097	Rajalakshmi Hospital Institutional Ethics Committee, 21/1 Lakshmipura Main Road, Vidyananyapura Post, Bangalore-560097	Dr. Giriraja K V
22.	Sparsh Super Super Speciality Hospital, #4/1, Tumkur Road, Yeswanthapur, Bangalore-560022	Institutional Ethics Committee Sparsh Hospital, 146 Infantry Road, Opp Police Commissioner Office, Bangalore-560001	Dr. John Paul M
23.	Mazumadar Shaw Medical Centre-Unit of Narayana Hrudayalaya Limited, 258/A, Bommasandra Industrial Estate, Anekal Taluk, Bangalore-560099	Narayana Health Medical Ethics Committee, Narayana Health Hospital, Health City, No. 258/A, Bommasandra Industrial Estate, Anekal Taluk, Bengaluru, (Bangalore) Rural, Karnataka-560099	Dr. Ranganatha R.
