



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
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File No. CT/21/000009

To,

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

Sir,

With reference to your application No GCT/CT04/FF/2021/23712 (GCT/09/21) dated 20/01/2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“Adaptive Platform Treatment Trial for Outpatients with COVID-19 (Adapt Out COVID)” Protocol number ACTIV-2/A5401, FINAL Version 2.0 dated 23/11/2020** 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, namely:-

- (i) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;
- (ii) 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;
- (iii) 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;
- (iv) 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;
- (v) 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;
- (vi) 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;
- (vii) 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;

- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvi) 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;
- (xvii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xviii) 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
GIRDHARILAL
SOMANI

(Dr. V. G. Somani)

Drugs Controller General (India)
Central Licencing Authority
Stamp

Digitally signed by VENUGOPAL
GIRDHARILAL SOMANI
DN: cn=, o=MINISTRY OF HOME AFFAIRS,
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Date: 2021.05.19 14:46:18 +05'30'

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, FINAL Version 2.0 dated 23/11/2020** in the below mentioned 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.

Date _____

**VENUGOPAL
GIRDHARILA
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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.

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	BR11-196 and BR11-198
Therapeutic class:	Fully human immunoglobulin G 1 IgG 1 mAbs
Dosage form:	Vials
Composition:	BR11 196 protine = 100.0000 milligram (mg) In House Specification Active BR11 198 protine = 100.0000 milligram (mg) In House Specification Active
Indications:	Outpatient adults (18 years) with a confirmed SARS-CoV-2 infection

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Civil Hospital & B. J. Medical College, Asarwa, Ahmedabad-380016, Gujarat, India	The Institutional Ethics Committee, B. J. Medical College & Civil Hospital, Office of Medical Superintendent building, Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat, India ECR/72/Inst/GJ/2013/RR-19	Dr. Kartikeya Parmar
Unity Trauma Center & ICU (Unity Hospital), Nr. D.R. World, opp Raghuvir Business Empire, Aai Mata Rd, Parvat Patiya, Surat-395010, Gujarat, India	Unity Hospital Ethics Committee, Unity Trauma Center And ICU, N-4 Janki Park Society, Aai Mata Rd, Parvat Patiya, Surat-395010, Gujarat, India ECR/1226/Inst/GJ/2019	Dr. Maheshkumar Vithalbhai Sutariya
Param Hospital, A Unit of Shree Giriraj Lifecare Private Limited, Ashapura Main Road, Old Dr. Rohit Thakker Hospital, Near Bus Stand Area, Rajkot-360001, Gujarat, India	Shree Giriraj Hospital Research Ethics Committee, C/O Shree Giriraj Multispeciality Hospital, A Unit of Shree Giriraj Lifecare Private Limited, 27 Navjyot Park Corner, 150 feet Ring Road, Rajkot-360005, Gujarat, India ECR/74/Inst/GJ/2013/RR-19	Dr. Thakker Mayank Rameshchandra
Rhythm Heart Institute-A Unit of Synergy Lifecare Private Limited, Near Siddharth Bungalows, Sama-Savli Road, Vadodara-390022, Gujarat	Rhythm Heart Institute Ethics Committee, Near Siddharth Bungalows, Sama-Savli Road, Vadodara-390022, Gujarat ECR/224/Inst/GJ/2013/RR-19	Dr. Nirav Bhalani
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 Condominium, Boat club Road, Pune-411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-19	Dr. Prachee Sathe
Noble Hospital, Magarpatta City Road, Hadapsar, Pune-411013, Maharashtra, India	Noble Hospital Institutional Ethics Committee, Room No. 5, Noble Hospital Clinical Research, Dept. Noble Annex, Noble Hospital Pvt. Ltd., 153A, Magarpatta City Road, Hadapsar, Pune-411013, Maharashtra, India ECR/259/Inst/MH/2013/RR-19	Dr. Reema Kashiva
Meditrina Institute of Medical Sciences, 278, Central Bazar Road, Ramdaspath, Nagpur,	Meditrina Institute Ethics Committee, Meditrina Institute of Medical Sciences, 278, Central Bazar Road, Ramdaspath, Nagpur, Maharashtra,	Dr. Sameer Paltewar

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Maharashtra, India-440010	India-440010 ECR/608/Inst/MH/2014/RR-20	
Atharva Multispecialty Hospital & Research Centre, H-4/Comm-2, Construction Div-21, UP Avas Vikas Parishad Sector-E, Lucknow-226003, Uttar Pradesh, India	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, India ECR/1241/Inst/UP/2019	Dr. Sandeep Kumar Gupta
Department of Pediatrics Dr. D.Y. Patil Medical College, Hospital & Research Centre, Sant Tukaram Nagar, Pimpri, Pune - 411018 Maharashtra, India	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, India ECR/361/Inst/MH/2013/RR-19	Dr. Sharad Agarkhedkar
BJGMC-JHU Clinical Research Site, B J Medical College & Sassoon General Hospitals, Jai Prakash Narayan Road, Pune-411001, Maharashtra, India	Ethics Committee, Department of Physiology, 2 nd Floor, B. J. Govt. Medical College & Sassoon General Hospitals, Jai Prakash Narayan Road, Pune-411001, Maharashtra, India ECR/433/Inst/MH/2013/RR-19	Dr. Shashikala Sangle
Smt. Kashibai Navale Medical College and General Hospital, Sr. No. 32/2A, Erandwana, Gulawani Maharaj Road, Near Hotel Abhishek, Pandurang Colony, Pune, Maharashtra-411004	Institutional Ethics Committee, SKNMGH, Smt. Kashibai Navale Medical College and General Hospital, Sr. No. 49/1, Of Westerly Bypass Highway, Mumbai-Pune Bypass Narhe (Ambegaon), Haveli, Pune, Maharashtra-411041 ECR/275/Inst/MH/2013/RR-19	Dr. Pophale Himanshu Shashikant
Rising Medicare Hospital, Behind Hotel Radisson Blu, Kharadi Bypass Road, Kharadi, Pune-411014, Maharashtra, India	Siddhi Hospital Laproscopy, Institutional Ethics Committee, Dhankawade-Patil Township, Near HP Petrol Pump, Pune-Satara Road, Balaji Nagar, Dhankawadi, Pune-411043, Maharashtra, India ECR/1228/Inst/MH/2019	Dr. Dipak Giri
SRV Hospital, Dr Mandakini Parihar Marg, Opposite Lokmanya Tilak Terminus, Tilak Nagar, Chembur, Mumbai, Maharashtra-400089	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 ECR/1459/Inst/MH/2020	Dr. Abhay Vispute
Aakash Healthare Pvt. Ltd., Hospital Plot, Road No-201, Sector-3, Dwarka, New Delhi-110075	Institutional Ethics Committee, Basement 1, Hospital Plot, Road No-201, Sector-3, Dwarka, New Delhi-110075	Dr. Akshay Budhreja

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	ECR/1265/Inst/DL/2019	
Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060, India	Sir Ganga Ram Hospital Ethics Committee, Room No. 1496, 4 th Floor, Old Building Rajinder Nagar, New Delhi-110060, India ECR/20/Inst/DL/2013/RR-19	Dr. Atul Gogia