File No. CT/40/19-DCG(I)

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

सत्यमेव जयते

File No. CT/19/000042

To,

M/s. Roche Products (India) Private Limited,
1503, 15th Floor, "The Capital", Plot No. C-70,
Behind ICICI Bank, Bandra Kurla Complex,
Bandra (E), Mumbai - 400051.

Sir,

With reference to your application No GCT/Form44/FF/2019/14354 (GCT/40/19) dated 24-05-2019, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A phase IIIB, multicenter, randomized, double-blind, placebo-controlled, clinical efficacy study of baloxavir marboxil for the reduction of direct transmission of influenza from otherwise healthy patients to household contacts"**, **Protocol number MV40618 Version 1.0, dated 14/03/19** 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) This trial should not be considered as basis for approval of marketing authorization of the drug in India.

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xix) 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,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION , 2.5.4.20=cec9e6dd3ecf4caa36d3ae9e432d59a6f4c3a02cb467e76d5ed6cdb3a731ee144, oid=DGHS,CID - 6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.08.13 15:17:41 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Central Licensing Authority
Stamp

File No. CT/40/19-DCG(I)

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. Roche Products (India) Private Limited, 1503, 15th Floor, "The Capital", Plot No. C-70, Behind ICICI Bank, Bandra Kurla Complex, Bandra (E), Mumbai – 400051** to conduct clinical trial of the new drug or investigational new drug as per protocol number **MV40618 Version 1.0, dated 14/03/19** 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 _____

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION , 2.5.4.20=cec9e6dd3ecf4caa36d3ae9e432d59a6f4c3a02cb467e76d5edcdb3a731ee144, ou=DGHS,CID - 6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.08.13 15:17:51 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Central Licensing Authority
Stamp

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	Baloxavir Marboxil Tablet 20mg
Therapeutic class:	Antiviral
Dosage form:	Tablets
Composition:	Povidone (K Value: 25) = 5.500 milligram (mg) U.S.P., E.P., J.P. Inactive Croscarmellose Sodium = 5.500 milligram (mg) Any Other Pharmacopeia, E.P., J.P. Inactive Sodium Steryl Fumarate = 1.700 milligram (mg) Any other Pharmacopeia, E.P., J.P. Inactive Baloxavir Marboxil = 20.000 milligram (mg) In House Specification Active Microcrystalline Cellulose = 11.400 milligram (mg) Any Other Pharmacopeia, E.P., J.P. Inactive Purified Water = 0.000 q.s. U.S.P., E.P., J.P. Inactive Lactose Monohydrate = 77.900 milligram (mg) Any Other Pharmacopeia, E.P.,J.P. Inactive
Indications:	Influenza in patients aged 12 and above who have been symptomati for no more than 48 hours

File No. CT/40/19-DCG(I)

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
lshwar Institute of Health Care, lshwar Heights, plot no 7, gut no 6/1, beside Punjabi Bhawan, Padegaon, Aurangabad - 431002, Maharashtra, lndia	Ethics Committee of lshwar lnstitute of Health Care, lshwar Institute of Health Care, lshwar Heights, 3rd floor, plot no 7, gut no 6/1, beside Punjabi Bhawan, Padegaon, Aurangabad - 431002,Maharashtra,lndia ECR/988/Inst/MH/2017	Dr. Abhijeet Deshmukhe
M S Ramaiah Medical College and Hospitals, MS Ramaiah Nagar, MSRIT Post, Bangalore 560054	Ethics committee, M S Ramaiah Medical College and Hospitals, MS Ramaiah Nagar, MSRIT Post Bangalore-560054, Karnataka, India ECR/215/Inst/KA/2013/RR-16	Dr. Sanjay V Kulkarni,
Mazumdar Shaw Medical Center - A Unit of Narayana Health 258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore - 560099	Narayana Health Medical Ethics Committee, # 258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore-560099, Karnataka, India ECR/390/Inst/ka/2013/RR-16	Dr. Murali Mohan
Global Hospitals & Health City, No:439,Cheran Nagar, Perumbakkam, Chennai-600100	Institutional Ethics Committee, Global Hospitals & Health City, 439, Cheran Nagar, Perumbakkam, Chennai-600100 ECR/44/Inst/TN/2013/RR-16	Dr. Vijil Rahulan
Sir Ganga Ram Hospital, New Delhi-110060,India	Ethics Committee, Sir Ganga Ram Hospital, , Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060,India ECR/20/Inst/DL/2013/RR-16	Dr. Atul Gogia
Krishna Institute of Medical Sciences “Deemed To Be University”, Karad, Pune Bangalore Highway-4 Malkapur Road Karad-415539, Dist-Satara, Maharashtra, India	Institutional Ethics Committee of Krishna Institute of Medical Sciences “Deemed To Be University”, Krishna Institute of Medical Sciences Deemed To Be University Karad, Pune-Bangalore Highway 4 Malkapur Karad Dist. Satara-415539 ECR/307/Inst/MH/2013/RR-16	Dr. Shilpa Patil
Ajanta Research Centre, Ajanta Hospital & IVF Centre, 765 ABC Complex, Kanpur Road, Alambagh Lucknow 226005.	Institutional Ethics Committee Ajanta Hospital and IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow 226005, ECR/611/Inst/UP/2014/RR-17	Dr. Anil Kumar Awasthi

File No. CT/40/19-DCG(I)

MV Hospital and Research Centre 314/30, Mirza Mandi Chowk, Lucknow 226003, UP, India	Institutional Ethics Committee, 1st Floor of MV Hospital and Research Centre 314/30, Mirza Mandi Chowk, Lucknow 226003, UP, India ECR/13/Inst/UP/2013/RR-16	Dr Sandeep Kumar Gupta
GT Hospital, Near Police Commissioners Office, Lokmanya Tilak Garg, Mumbai 400001, Maharashtra, India	Institutional Ethics Committee, Grant Government Medical College & Sir JJ Hospital, Department of Pharmacology, Opposite Central Canteen, Byculla, Mumbai-400008, India ECR/382/Inst/MH/2013/RR-16	Dr. Priti L. Meshram
JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, India	Institutional Ethics Committee, 3rd Floor, JSS Medical College, S S Nagar, Mysuru-570015, India ECR/387/Inst/KA/2013/RR-16	Dr. Jayaraju B.S
Jehangir Clinical Development Centre Pvt. Ltd, Jehangir Hospital Premises 32, Sassoon Road, Pune-411001	Ethics Committee, Jehangir Clinical Development Centre Pvt. Ltd, Jehangir Clinical Development Centre Pvt. Ltd, Jehangir Hospital Premises 32, Sassoon Road, Pune-411001 ECR/352/Inst/MH/2013/RR-16	Dr. Ashish Goyal
Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune 411057, Maharashtra, India	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune 411057, Maharashtra, India ECR/751/Inst/MH/2015/RR-18	Dr. Nikalje Rajkumar Gautam
MTES's Sanjeevan Hospital, Plot No. 23, Off Karve Road, Erandwane, Pune-411004	Ethics Committee Sanjeevan Hospital, MTES'S Sanjeevan Hospital, Plot No. 23, Off Karve Road, Erandwane, Pune-411004 ECR/54/Inst/Maha/2013/RR-16	Dr. Himanshu Pophale
Sterling Hospital, Sterling Hospital Road, Memnagar, Ahmedabad-380052, Gujarat, India	Sterling Hospital Ethics Committee, Basement, Sterling Hospital, Sterling Hospital Road, Memnagar, Ahmedabad-380052, Gujarat, India ECR/340/Inst/Guj/2013/RR-16	Dr. Tushar Bhagvatprasad Patel