File No. SND/CT/21/000084
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 02 NOV 2021

To

M/s. Qascent Research Solutions Pvt. Ltd.,
B-103, Street No. 4, Jyoti Colony, Near Durgapuri Chowk,
Shahdara, Delhi (India) – 110032.

Subject: Permission to conduct Phase III Clinical trial of Several therapies, including antiviral therapies - An open-label, multicentre, randomised, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild cases of COVID-19. (Protocol No. 02-COV, Version No. 2.0, dated 13 October 2021) - Reg.

CT NOC No.: CT/SND/181/2021

Sir,

With reference to your Application No. SND/CT04/FF/2021/27937 dated 04-09-2021 please find enclosed herewith the permission in Form CT-06, CT NOC No. **CT/SND/181/2021** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully,

(Dr. V. G. Somani)
Central Licensing Authority

Conditions of Permission

(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 of the New Drugs and Clinical Trials Rules, 2019;

(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 the Chapter VI of the said Rules 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 the 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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) It may kindly be noted that merely granting permission to conduct Clinical trial with the drug does not convey or imply that based on the Clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

(xx) **The Maximum daily dose of paracetamol should be revised to 2g/day.**

FORM CT-06

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

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

CT NOC NO.: CT/SND/181/2021

The Central Licensing Authority hereby permits **M/s Qascent Research Solutions Pvt. Ltd., B-103, Street No. 4, Jyoti Colony, Near Durgapuri Chowk, Shahdara, Delhi (India) - 110032** to conduct clinical trial of the new drug ~~or investigational new drug~~ as per **Protocol No. 02-COV, Version Number 2.0 dated 13 October 2021** in the below mentioned clinical trial sites.

2. Details of new drug or ~~investigational new drug~~:

Names of the new drug:	Nitazoxanide Tablet 2000mg/day Inhaled ciclesonide 640mcg/day
Therapeutic class:	Antiprotozoal & Glucocorticoid
Dosage form:	Tablets & Inhaler
Composition:	Nitazoxanide Tablet 500mg Ciclesonide Inhaler 80/160mcg per actuation
Indications:	Mild COVID-19

Details of clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/ Registration Number
1	Dr. Madhavi Eerike All India Institute of Medical Sciences (AIIMS) Bibinagar Hyderabad Metropolitan Telangana – 508126.	Maarg Independent Ethics Committee Maarg Research Foundation Sree Nilayam, Plot No.38, PNT Colony, Near RTA Office, Secunderabad trimulgherry Hyderabad Telangana - 500015 India ECR/77/Indt/AP/2013/RR-19
2	Dr. Yogesh Bahurupi Department of Community & Family Medicine, AIIMS Rishikesh, Dehradun, Uttarakhand 249203 India.	Lnstitutional Ethics Committee, All India Institute of Medical Sciences Department of Physiology Veerbhadra Marg, Rishikesh, Uttrakhand-249201 India. ECR/736/Inst/UK/2015/RR-18
3	Dr. Pooja Goyal Employee State Insurance Corporation Medical College & Hospital NH-3 NIT Faridabad, Haryana 121001	Institutional Ethics Committee for ESIC Faridabad ESIC Medical College And Hospital NH-3 NIT Behind BK Hospital, Faridabad, Haryana - 121001. ECR/1539/Inst/HR/2021
4	Dr. Dineshbabu S Department of Medicine, Third Floor, Institute Block, Dhanvantri Nagar, JIPMER, Pondicherry- 605006.	IEC Intervention Studies JIPMER JIPMER Dhanvantari Nagar Pondicherry- 605006 India. ECR/342/Inst/PY/2013/RR-19
5	Dr. Prathibha Pereira JSS Hospital, Mahatma Gandhi Road, Ramachandra Agrahara, Mysuru - 570004 Karnataka.	Institutional Ethics Committee JSS Medical College & Hospital 3'd floor, JSS Medical College, Mysore,Karnataka-570015. ECR/387/Inst/KA/201 3/RR-19

6	Dr. Avinash Agarwal King George Medical University, Shah Mina Road Chowk Lucknow 226003.	Ethics Committee, King George Medical University, Shah Mina Road Chowk Lucknow 226003. ECR/262/Inst/UP/2012/RR-19
7	Dr. S Suneeti Kanyari Kalinga Institute of Medical Sciences, Kushabhadra Campus (KIIT Campus 5), KIIT University, P0-KIT, Patia, Bhubaneswar. District: Khordha Odisha -751024 India.	Institutional Ethics Committee Kalinga Institute of Medical Sciences Kushabhadra Campus (KIIT Campus 5), KIIT University, PO-KIT, Patia, Bhubaneswar. District: Khordha Odisha -751024 India. ECR/321/Inst/OR/2013/RR-20
8	Dr. Anupam Prakash Lady Hardinge Medical College C-604 Shaheed Bhagat Singh Road DIZ Area Connaught Place New Delhi 110001.	Institutional Ethics Committee Lady Hardinge Medical College and Associated Hospitals Ground floor (opposite Labour Cell) Smt. Suchita Kriplani Hospital Panchkulian Road New Delhi 110001. ECR/435/Inst/DL/2013/RR-16
9	Dr. Paul Mathai Malabar Medical College Hospital & Research Centre Modakkallur Ulliyeri PO Kozhikode Kerala 673323 India	Institutional Ethics Committee Malabar Medical College Hospital Modakkallur Kozhikode Kerala 673323 India. ECR/1248/Inst/KL/2019
10	Dr. Sonam Solanki Masina Hospital Trust Sant Savta Marg, Near Gloria Church, Byculla (East), Mumbai – 400027, Maharashtra, India.	Masina Hospital Ethics Committee 1/Main Bldg, Masina Hospital Trust, Sant Savata Marg, Near Gloria Church, Byculla (East), Mumbai – 400027, Maharashtra, India. ECR/1179/Inst/MH/2019
11	Dr. Sumedh Ulhas Jajoo Kasturba Hospital Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra - 442102,	Institutional Ethics Committee, Mahatma Gandhi Institute of Medical Sciences Sevagram Wardha-442102, Maharashtra, India ECR/47/Inst/MH/2013/RR-19
12	Dr. Anand Marutirao Nikalje Mahatma Gandhi Mission's Medical college and Hospital (MGM) N-6, CIDCO, Aurangabad, Maharashtra, India, 431003	MGM Ethics Committee for research on human subject(MGM_ECRHS) Gandhi Mission's Medical College and Hospital, N-6, CIDCO, Aurangabad, Maharashtra, India-431003. ECR/581/Inst/MH/2014/RR-20
13	Dr. Prasanna Kumar M S Ramaiah Medical College and Hospital, MS Ramaiah Nagar, MSRIT Post Bangalore 560054	Ethics Committee, M S Ramaiah Medical College and Hospital, MS Ramaiah Nagar, MSRIT Post Bangalore-560054. ECR/215/Inst/KA/2013/RR-19
14	Dr. Arvinder Pal Singh Sri Guru Ram Das Institute of Medical Science and Research VPO Vallah, Mehta Road Amritsar, Punjab 143006.	Institutional Ethics Committee SGRDIMSAR Sri Guru Ram Das Institute of Medical Science and Research VPO Vallah, Mehta Road Amritsar, Punjab-143006. ECR/1345/Inst/PB/2020
15	Dr. Surendra Kumar Sardar Patel Medical College & Associated Groups Hospital, Bikaner Rajasthan Near Medicine ICU Ground Floor P.B.M. Hospital Bikaner, Rajasthan -334003.	Ethics Committee, Sardar Patel Medical College, Bikaner Rajasthan S.P. Medical College, Bikaner Pawanpuri, Bikaner Rajasthan - 334003 ECR/27/SP/Inst/RJ/2013/RR-19
16	Dr. Satyajit Mohapatra SRM Medical College Hospital & Research Centre, SRM Nagar, Kattankulathur - 603203, Tamil Nadu, India.	Institutional Ethics Committee SRM Medical College Hospital & Research Centre, SRM Nagar, Kattankulathur-603 203, Tamil Nadu, India. ECR/431/Inst/TN/2O13/RR-1 9

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.

(Dr. V. G. Somani)
Central Licensing Authority
Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

New Delhi
Date:

02 NOV 2021