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F. No. 12-01/21-DC (Pt-166)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 01 JUL 2021

To
Dr. Sheela Virendra Godbole,
ICMR-National AIDS Research Institute,
G73 Block, MIDC, Bhosari,
Pune – 411026.

Subject: Grant of permission to undertake Public Health Emergency SOLIDARITY Trial "An International Randomized Trial of Additional Treatments for COVID-19 in Hospitalized Patients who are all receiving the Local Standard of Care" - regarding.

CT NOC No.: CT-ND/89/2021

Sir,

With reference to your application no. Nil dated 10.06.2021, please find enclosed herewith the permission in Form CT-06, No. **CT-ND/89/2021** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019, granted based on evaluation in consultation with Subject Expert Committee (SEC) as part of accelerated approval process in light of Covid-19 outbreak.

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) Undertaking by the Investigators along with Curriculum Vitae, Medical Registration Certificate and GCP training certificate of the investigators shall be submitted before initiation of the trial.

(xx) Artesunate arm shall be removed in view of non availability of data.

(xxi) The definition for 'Moderate' to be elaborated to include the respiratory frequency 24-30

(xxii) Standard of Care to be well defined and uniform across the sites.

(xxiii) RT-PCR, and not rapid antigen testing, shall be used for diagnosis of COVID - 19.

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 **ICMR-National AIDS Research Institute, Plot No. 73, 'G' Block MIDC, Bhosari, Pune – 411026** to conduct clinical trial of the investigational new drug as per protocol No. **WHO Solidarity Trial Plus protocol, Version 1.0 dated 05.04.2021** in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Inj. Artesunate 60 mg
Therapeutic class:	Antimalarial
Dosage form:	Artesunate for injection
Composition:	Each vial contains Artesunate 60mg. In addition to the Artesunate vial, the package contains: 1 ml type 1 ampoule with 5% Sodium bicarbonate solution BP, 5 ml type 1 ampoule with 9 mg/ml sodium chloride
Indications:	1) Artesunate for Injection is an antimalarial indicated for the initial treatment of severe malaria in adult and pediatric patients. 2) For its immunomodulatory effects to reduce inflammation in COVID.(proposed indication)
Names of the new drug or investigational new drug:	Inj. Infliximab 100mg
Therapeutic class:	TNF-alpha inhibitor, IgG1k monoclonal antibody
Dosage form:	Lyophilised powder
Composition:	Each vial contains Infliximab 100mg
Indications:	1) Diseases of the immune system, psoriasis, rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis and severe or disabling plaque psoriasis. 2) For management of COVID 19 as It blocks the inflammation promoting protein TNF-α, which is released by macrophages. (Proposed indication)
Names of the new drug or investigational new drug:	Tab. Imatinib 400mg
Therapeutic class:	Tyrosine kinase inhibitor, Anti Cancer
Dosage form:	Film coated tablet
Composition:	Each Film coated tablet contains Imatinib 400mg
Indications:	1) Used to treat a number of leukemias, myelodysplastic/myeloproliferative disease, systemic mastocytosis, hypereosinophilic syndrome, dermatofibrosarcoma protuberans, and gastrointestinal stromal tumors.

	2) For management of COVID 19 by reversing pulmonary capillary leak and alveolar edema which cause hypoxemic respiratory failure. (proposed indication)

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1.	Dr. Rajarao Mesipogu, Gandhi Medical College / Hospital, Secunderabad Hyderabad Telangana - 500003	Institutional Ethics Committee, Gandhi Medical College and hospital Secunderabad Hyderabad Telangana – 500003 Reg. No.: ECR/180/Inst/AP/2013/RR-19
2	Dr. Dhara Bhavesh Roy Sardar Vallabhbhai Patel Institute of Medical Sciences and Research (SVPIMSR), Ahmedabad Gujarat 380006	Institutional Ethics Committee, Smt. N H L Municipal Medical College, Ahemdabad Gujarat 380006 Reg. No.: ECR/245/Inst/GJ/2013/RR-19
3	Dr E. Therani Rajan Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai 600003	Institutional Ethics Committee, Tamil Nadu Govt. Multi Super Speciality Hospital, Omandurar Govt. Estate, Anna Salai, Chennai 600002 Reg. No.: ECR/1375/Inst/TN/2020
4	Dr R. Jayanthi Government Medical College & hospital Omandurar Government Estate Chennai. 02	Institutional Ethics Committee, Tamil Nadu Govt. Multi Super Speciality Hospital, Omandurar Govt. Estate, Anna Salai, Chennai 600002 Reg. No.: ECR/1375/Inst/TN/2020
5	Dr. Jignesh Shah Department of Critical Care Medicine , Bharati Vidyapeeth (Deemed to be) University Medcial College, Pune Bharati hospital, Pune	Institutional Ethics Committee BVDU Bharati Hospital and Research Centre Bharati Hospital, Pune - Satara Road Dhankawadi Pune Maharashtra - 411043 Reg. No.: ECR/313/Inst/MH/2013/RR-19
6	Dr. Chirag Chandrakant Rathod GMERS Medical College & Hospital Gotri, Old TB Hospital Campus, Gotri Main Road, Gotri,Vadodara, Gujarat - 390021.	Institutional Human Ethics Commiittee GMERS Medical College & Hospital, Gotri, Vadodara - 390021, Gujarat Reg. No.: ECR/28/Inst./GJ/2013/RR-19

7	Dr Manish Soneja All India Institute of Medical Sciences, New Delhi	Institute Ethics Committee, All India Institute Medical Sciences, Ansari nagar, New Delhi. Reg. No.: ECR/538/Inst/DL/2014/RR-20
8	Dr. Zarir Udwadia MD, DNB, FCCP PD Hinduja National Hospital and Medical Research Centre, Veer Savarkar Marg Mahim(west) Mumbai 400016	Institutional Ethics Committee P D Hinduja Hospital and Medical Research Centre , 913, 9th floor, Research Dept., LalitaGirdhar (S1) bldg., T H KatariyaMarg, Mahim Mumbai Mumbai City, Maharashtra -400016 Reg. No.: ECR/61/Inst/MH/2013/RR-19
9	Dr. N. Kumarasamy VHS Infectious Diseases Medical Centre CART Clinical Research Site Voluntary Health Services Taramani Chennai 600113	Institutional Ethics Committee, The Voluntary Health Services, Multi speciality Hospital and Research Centre, Rajeev Gandhi Salai, Adyar, Chennai 600113 Reg. No.: ECR/752/Inst/TN/2015/RR-18
10	Dr. Dipti Chand Government Medical College and hospital Nagpur, Maharashtra	Institutional Ethics Committee, Dept.Of Pharmacology GMC Hanuman Nagar, Nagpur 440003 Reg. No.: ECR/43/Inst/MH/2013/RR-19
11	Dr. Rohidas Borse MD B J Medical College and Sassoon General Hospital, Pune Maharashtra 411001	Ethics Committee B J Medical College and SGH Jai Prakash Narayan Road Pune, Mharashtra 411001 Reg. No.: ECR/433/Inst/MH/2013/RR-19
12	Col(Dr) VikasMarwah MD Army Institute of Cardio Thoracic Sciences(AICTS) Ex. Military Hospital Cardio Thoracic Centre(MH CTC) Golibar Maidan Pune-40	Institutional Ethics Committee Armed Forces Medical College, Solapur Road, Wanowrie Pune 411040 Reg. No.: ECR/650/Inst/MH/2014/RR-17
13	Dr. Rajnish Joshi MD All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, India - 462020	Institute Human Ethics Committee, All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, India – 462020 Reg. No.: ECR/775/Inst/MP/2015

14	Dr. Guduri Chakradhara Govt. General hospital (Associated with Siddhartha Medical College, Vijayawada.) Ring Road, Gunadala, Vijayawada-520008, Andhra Pradesh, India.	Institutional Ethics Committee, SMC & GGH Ring Road, Gunadala, Vijayawada-520008, Andhra Pradesh, India. Reg. No.: ECR/633/INST/AP/2014/RR19
15	Dr. Prasan Kumar Panda All India Institute of Medical Sciences (AIIMS), Rishikesh, Uttarakhand, India-249203	Institutional Ethics committee, All India Institute of Medical Sciences (AIIMS), Veerbhadra Marg Rishikesh, Uttarakhand Reg. No: ECR/736/Inst/UK/2015/RR-18

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

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

Stamp

New Delhi
Date: 19 JUL 2021