File No: BIO/CT/20/000087
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi 110 002
Date : 21-AUG-2020

To,

M/s Sun Pharmaceutical Industries Limited,
Tandalja Vadodara Vadodara (India) – 390012

Subject: Application for grant of clinical trial permission to conduct a Phase III clinical trial titled "A Phase III, Comparative, Double Blind, Randomized, Multi-centric study to compare the Efficacy, Safety and Immunogenicity of Sun's Ranibizumab with Reference Biologic in Patients with Neovascular Age-related Macular degeneration (wet AMD).", vide Protocol Number: Protocol No. ICR/19/009, Version No. 1.1, dated 10th August 2020 under the D&C Act and Rules thereunder-Regarding

Ref: Your application no. BIO/CT04/FF/2020/20408 dated 01-JUL-2020

Sir,

Please refer to your application no. BIO/CT04/FF/2020/20408 dated 01-JUL-2020, received by this office on the above subject. Please find enclosed herewith permission to conduct Phase III clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same

Yours faithfully,

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
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(Dr. V.G. Somani)
Drugs Controller General (India)

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Directorate General of Health Services
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(Biological Division)

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 Licencing Authority hereby permits to M/s Sun Pharmaceutical Industries Limited, Tandalja Vadodara Vadodara (India) - 390012 to conduct clinical trial of the new drug or investigational new drug as per protocol number: ICR/19/009, Version No. 1.1, dated 10th August 2020 in the below mentioned clinical trial sites.-

Details of new drug or investigational new drug:	
Name of the new drug or investigational new drug:	Ranibizumab Solution for Injection 10 mg/ml, 0.23 ml vial
Therapeutic class:	A vascular endothelial growth factor inhibitor
Dosage form:	Solution for injection
Composition:	Ranibizumab In-House 10 mg/mL L-Histidine hydrochloride monohydrate Ph. Eur. 1.662 mg/mL L-Histidine Ph. Eur. 0.321 mg/mL α-α Trehalose dihydrate USP 100 mg/mL Polysorbate-20 IP 0.1 mg/mL Water for Injection IP q.s to 1.0 mL
Indications:	For improvement and maintenance of visual acuity and function and for reduction of vascular leakage and retinal oedema, in patients with neovascular age related macular degeneration (AMD)

Details of clinical trial sites-

S.No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Department of Ophthalmology, Charak Bhawan, OPD block, SMS Hospital, Jaipur302004, Rajasthan	Ethics Committee, Department of Ophthalmology, Charak Bhawan, OPD block, SMS Hospital, Jaipur302004, Rajasthan EC Reg. No: ECR/26/Inst/RJ/2013/RR-19	Dr. Sandeep Parwal
2.	Department of Ophthalmology, King George's Medical University, Shahmina road Chowk, Lucknow-226003, Uttar Pradesh, India.	Institutional Ethics Committee, Department of Ophthalmology, King George's Medical University, Shahmina road Chowk, Lucknow-226003, Uttar Pradesh, India EC Reg. No: ECR/262/Inst/UP/2013/RR-19	Dr. Sandeep Saxena
3.	Chopda Medicare & Research Centre Pvt. Ltd; Magnum Heart Institute, 3/5, Patil Lane No.1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India	Magna-Care Ethics Committee, Chopda Medicare & Research Centre Pvt. Ltd; Magnum Heart Institute, 3/5, Patil Lane No.1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India EC Reg. No: ECR/79/Inst/M H/2013/RR-19	Dr. Rohit Sanjay Laul
4.	Sankat Mochan Nethralaya and dental care, B 36/4-KH, Saket nagar road, near Sankatmochan, Saket nagar colony, Lanka, Varanasi, Uttar Pradesh 221005	Opal Institutional Ethics Committee, Sankat Mochan Nethralaya and dental care, B 36/4-KH, Saket nagar road, near Sankatmochan, Saket nagar colony, Lanka, Varanasi, Uttar Pradesh 221005 EC Reg. No: ECR/976/Inst/U P/2017	Dr. Abhishek Dixit
5.	Consultant Room No-3, First Floor, Diva Eye Institute, 17 Parimal Society ,Core House Lane Near Parimal Garden, Ahmedabad380006	Shrey Hospital Institutional Ethics Committee Shrey Hospital Private Limited 270/B/5 Near AMCO Bank, Stadium Circle, Navrangpura Ahmedabad Gujarat380009 India EC Reg. No: ECR/1302/Inst/GJ /2019	Dr. Malli Shiv Shantilal
6.	M & J Institute of Ophthalmology, , Retina Department , First Floor, Manjushri Mill compound ,	Institutional Ethics Committee, B.J.Medical College & Civil Hospital, Office of the Medical	Dr.Aggarwal Somesh Vedprakash

	Asarwa, Ahmedabad -16, Gujarat ,India	superintendent, Ahmedabad380016,Gujarat,India EC Reg. No: ECR/72/Inst/GJ/2 013/RR-19	
7.	OPD no. 69,1ST Floor, Deptartment of Ophthalmology,B. J.Govt .Medical College And Sassoon General Hospital,Pune411001	Institutional Ethics Committee of B.J .G.M. C AND SASSOON GENERAL HOSPITAL EC Reg. No: ECR/280/Inst/M aha/2013/RR-19	Dr. Nikumbh Usha Subhash
8.	1st Floor Krishna Ward, Room number 17, KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar.Belagavi590010	Institutional Ethics Committee, KLE University EC Reg. No: ECR/211/Inst/K A/2013/RR-19	Dr. Smitha K S
9.	Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara. P.O.. Kochi - 682041, Kerala, India	Institutional Ethics Committee, Amrita Institute of Medical Sciences, AIMS Ponekkara. P.O. Kochi -682041, Kerala, India EC Reg. No: ECR/129/Inst/K L/2013/RR-19	Dr Natasha Radhakrishnan
10.	JPM Rotary Club of Curtack Eye Hospital & Research Institute. CDA. Sector-VI, Market Nagar, Cuttack-753014. Odisha India	Institutional Ethics Committee, JPM Rotary Club of Cuttack Eye Hospital & Research Institute, CDA. Sector-VI, Market Nagar, Cuttack-753014. Odisha India EC Reg. No: ECR/856/Inst/O R/2016	Dr. Santosh Kumar Mahapatra
11.	Sankara Eye Hospital, Varthur Main Road, Kundalahalli Gate, Bangalore560037, Karnataka-India.	Institutional Ethics Committee , Sankara Eye Hospital, Varthur Main Road, Kundalahalli Gate, Bangalore560037, Karnataka- India. EC Reg. No: ECR/705/Inst/K A/2015/RR-18	Dr. Divyansh Mishra
12.	Regional Institute of Ophthalmology, Medical College, Kolkata 88, College Street, Kolkata – 700073, West Bengal	Institutional Ethics Committee for Human Research , Regional Institute of Ophthalmology, Medical College, Kolkata 88, College Street, Kolkata – 700073, West Bengal EC Reg. No: ECR/287/Inst/W B/2013/RR-19	Dr. Asim Kumar Ghosh
13.	LV Prasad Eye Institute, Kallam Anji Reddy Campus, LV Prasad Marg, Banjara Hills, Road No. 2, Hyderabad – 500034, Telengana	L V Prasad Eye Institute Ethics Committee , LV Prasad Eye Institute, Kallam Anji Reddy Campus, LV Prasad Marg, Banjara Hills, Road No. 2, Hyderabad – 500034, Telengana EC Reg. No: ECR/468/Inst/A P/2013/RR-19	Dr. Dave Vivek Pravin
14.	Dr. B.R Ambedkar medical College Gandhinagar, Kadugondanahalli , Bangalore560045	Institutional Ethics Committee ,Dr. B.R Ambedkar medical College Gandhinagar, Kadugondanahalli , Bangalore560045 EC Reg. No: ECR/508/Inst/K A/2014/RR-17	Dr. Rani Sujatha M A
15.	Aravind Medical Research Foundation, Institutional Ethics Committee, Aravind Medical Research Foundation, 1, Anna Nagar, Madurai Tamil Nadu - 625020	Institutional Ethics Committee , Aravind Medical Research Foundation, Institutional Ethics Committee, Aravind Medical Research Foundation, 1, Anna Nagar, Madurai Tamil Nadu – 625020 EC Reg. No: ECR/182/Inst/TN/ 2013/RR-19	Dr Kim Ramasamy
16.	Aravind Eye Hospital & Postgraduate Institute of Opthalmology, Avinashi Road, Coimbatore, 641014, Tamilnadu, India	Institutional Human Ethics Committee,Aravind Eye Hospital & Postgraduate Institute of Opthalmology, Avinashi Road, Coimbatore, 641014, Tamilnadu, India EC Reg. No: ECR/252/Inst/TN/ 2013/RR-19	Dr Narendran Venkatapathy
17.	Narayana Nethralaya, 121/C, Chord Road, 1st Block, Rajaji Nagar, Bangalore, Karnataka – 560010	Narayana Nethralaya Ethics Committee, Narayana Nethralaya, 121/C, Chord Road, 1st Block, Rajaji Nagar, Bangalore, Karnataka – 560010 EC Reg. No: ECR/187/Inst/Kar/ 2013/RR-19	Dr Naresh Kumar Yadav

18.	L V Prasad Eye Institute MTC Campus, Patia, Bhubaneswar PIN – 751024, Odisha	Institutional Ethics Committee, L V Prasad Eye Institute MTC Campus, Patia, Bhubaneswar PIN – 751024, Odisha EC Reg. No: ECR/496/Inst/O R/2013/RR-19	Dr. Anup Kelgaonkar
19.	LV Prasad Eye Institute, Kode Venkatadri Chowdary Campus (KVC), Tadigidapa, Vijayawada, Andhra Pradesh – 521134	L V Prasad Eye Institute Ethics Committee , LV Prasad Eye Institute, Kode Venkatadri Chowdary Campus (KVC), Tadigidapa, Vijayawada, Andhra Pradesh – 521134 EC Reg. No: ECR/468/Inst/A P/2013/RR-19	Dr. Shashwat Behera
20.	OPD 51 Department of Ophthalmology Dr. D.Y. Patil Medical College Hospital & Research Centre, Plot No. 2 Sector 5,Nerul,Navi Mumbai 400706	Institutional Ethics Committee D.Y. Patil Medical College Sector 5,Nerul,Navi Mumbai Thane Maharashtra - 400706 EC Reg. No: ECR/195/inst/M H2013/RR-19	Dr. (Ms.) Archana Tadwalkar (Mistry)

Conditions of permission for conduct of clinical trial—

The permission granted by the Central Licencing Authority to conduct clinical trial under this Chapter 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 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) The bulk drug to be used in the manufacturing of finished formulation intended to be used in the clinical trial and clinical trail batches of finished formulation shall be manufactured under GMP conditions using validated procedure and shall have ongoing stability programme.

Yours faithfully,

VENUGOPAL GIRDHARILAL SOMANI

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(Dr. V. G. Somani)
Drugs Controller General (I)
Central Licencing Authority

Place: New Delhi
Date: 21-AUG-2020

(Protocol No.: Protocol No. ICR/19/009, Version No. 1.1, dated 10th August 2020 File No: BIO/CT/20/000087)