D. No. 28330, P - 1007886
Date: 30-07-2018

Tele No.011-23236965
Fax.No.011-23236973

F. No. 12-124/2017-DC (Pt- Novalead-SND)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Subsequent New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 10 SEP 2018

To,

M/s. Novalead Pharma Pvt. Ltd.,
Anaahat, Plot No. 5, Ram Indu Park, S. No. 131/1b/2/11,
Baner Road, Pune-411045, Maharashtra, India.

Sub: Phase III Clinical Trial of Esmolol Hydrochloride 14.00% w/w Topical gel (Galnobax®) - Reg.

CT NOC No. CT/SND/39/2018

Sir,

Please refer your letter no. Novalead/NG-A16/18/07 dated 26-07-2018 on above noted subject.

This Directorate has no objection to your conducting Phase III clinical trials with the said drug under the supervision of following investigators mentioned and as per the **Protocol No: NG-A16; Version No. 1.0; Dated: 21-07-2017** submitted to this Directorate.

S. No.	PI Name and Address
1	Dr. Vijay Viswanathan, MD, Ph.D, FRCP (London & Glasgow) Head & Chief Diabetologist, M.V. Hospital for Diabetes Pvt. Ltd, #4, West Madha Church Street, Royapuram, Chennai - 600013, Tamil Nadu, India
2	Dr. Rajesh Kesavan,MBBS, MS., Consultant Podiatric Surgeon, Apollo Hospitals, #21, Greams Lane, Off Creams Road Chennai-600006, Tamil Nadu, India.
3	Dr. R. B. Sudhagar Singh, MBBS, MD., Associate Professor, Department of General Medicine, Sri. Ramachandra Hospital No.1, Ramachandra Nagar, Porur Chennai, 600 116, Tamil Nadu, India.
4	Dr. Muthu Ramu, MBBS, F. Diab, Assistant Director & Consultant Diabetologist, Madras Diabetes Research Foundation, No 4, Conran Smith Road, Gopalapuram, Chennai - 600 086.

5	Dr. Babu Krishna Murthy, M. S. FRCS (Edin), PGDHRM, Consultant General Surgeon & Laparoscopic Surgeon (Room no. 142), Yashoda Hospitals, Behind Hari hara Kalabhavan, S.P. Road, Secunderbad-500003, Telangana, India.
6	Dr. K. Shiva Raju, MBBS, MD (Internal Medicine), Dip (Diabetology), FIIMSA, Senior Consultant Physician & Diabetologist, HOD Medicine, Krishna Institute of Medical Sciences, Door No. 1-8-31/1, Minister Road, Secunderabad-500003, Telangana, India.
7	Dr. CH. Santhosh Babu, MBBS, MS (General Surgery), Assistant Professor, Department of General Surgery, 6th Floor, Gandhi Hospital, Musheerabad, Secunderabad - 500003, Telangana, India.
8	Dr. Kirankumar P Jadhav, MBBS, MS Gen Surgery, B.J. G.M.C. & Sassoon General Hospitals, Pune Sassoon road, Somwar Peth, Pune - 411001, India.
9	Dr. Sanjay Sukhdeo Kolte, MBBS, FCPS, DNB, Sahyadri Specialty Hospital, Erandwane, Karve Road, Pune, Maharashtra – 411004, India.
10	Dr. Abhay Amrutlal Mutha, MBBS, MD Consultant, Department of Diabetology, Cancer Building, 1st Floor, Room No. 105, Grant Medical Foundation, Ruby hall Clinic, 40, Sassoon Road, Pune - 411001, Maharashtra, India.
11	Dr. Manisha Satish Deshmukh, MBBS, MD (Medicine) Consultant, Department of Medicine, Advance wound Care Clinic Vimal Lalchand Mutha cancer centre Deenanath Mangeshkar Hospital & Research Centre Near Mahtre bridge, Erandwane Pune - 411004.
12	Dr.Unnikrishnan Ambika Gopalakrishnan, MD, DM, DNB, MNAMS, CEO and Chief, Department of Endocrinology, Chellaram Diabetes Institute, Room No. 53, 1st Floor Lalani Quantum, Pune-Bangalore Highway, Bavdhan Budruk, Pune - 411021, Maharashtra, India.
13	Dr. Brajesh B Gupta, MBBS, MS, FAMASI, Professor, Department of Surgery, Ward No: 10, first Floor, Government Medical College and Hospital, Medical Square, Nagpur- 440003, Maharashtra, India.
14	Dr. Prashant Vitthalrao Rahate, MBBS. MS, Director & Consultant Surgeon, Rahate Surgical Hospital 517, Central Avenue Kolba Swami Square, Juni Mangalwari, Nagpur, Maharashtra, India – 440008.
15	Dr. Mohammad Asif Haji Pyare Saheb Qureshi, DA Consultant Intensivist, Department of Anaesthesiology, Crescent Hospital & Heart Centre, Near Lokmat square, Dhantoli, Nagpur - 440012, Maharashtra, India
16	Dr. Vishal Rupchand Nandagawali, MBBS, MS Associate Professor, Department of Surgery, Indira Gandhi Govt. Medical College and Hospital, Nagpur, Maharashtra, India - 440018
17	Dr. Sanjay C Desai, MBBS, MS, FEVS, Professor and HOD, M. S. Ramaiah Medical College & Hospital, M.S. Ramaiah Nagar, MSRIT Post, Bangalore- 560054, Karnataka, India.
18	Dr. K. N. Nagabhushan, Consultant Vascular Surgeon, Fortis Hospital Ltd, 154/9, Bannerghatta Road, Opposite IIM-B, Bangalore – 560076, India.

19	Dr. Deepak Khandelwal, MD(Med), DM (Endo) Senior Consultant, Maharaja Agrasen, Hospital, West Punjabi Bagh, New Delhi-110026, India
20	Dr. Ajay Yadav, (MBBS, MS, FNB, MRCS), Cunsultant vascular & Endovascular, surgery, Sir Ganga Ram Hospital, Sir Ganga Ram Marg, Rajinder Nagar, New Delhi- 110060, India.
21	Dr. Ashu Rastogi, MBBS, MD, DM, Assistant Professor, Post Graduate Institute of Medical Education and Research (PGIMER), Sector 12, Chandigarh- 10012, India.

The clinical trial permission is subject to the conditions:

A. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.

B. Approval of the Ethics Committee duly registered with the office of DCG (I) shall be obtained before initiating the clinical trial.

C. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;

D. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority;

E. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

F. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority;

G. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard

Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations;

H. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

I. In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015.

J. Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the Drugs and Cosmetics Rules, 1945 must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

K. It may kindly be noted that merely granting permission to conduct clinical trials 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.

Yours faithfully,

Signature: _____

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
(Name & Designation of Licensing Authority)

Copy to: All Zonal/sub Zonal Offices, CDSCO.