

GOVERNMENT OF INDIA
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Te No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

File No: CT/18/000036

To,

M/s. JSS Medical Research India Pvt. Limited,
Plot 12/2, 6th Floor, Vatika Mindscapes, Tower-B,
Sector-27 D, Faridabad (India) -121003.

Subject: Clinical trial titled “A Phase 3, Randomized, Double-blind, Parallel-group, Vehicle controlled, Multicenter Study of the Efficacy and Safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer(GAIT 1)”– regarding.

Reference: Your Application No. GCT/Form44/FF/2018/8219 (GCT/33/18) dated 16/May/18

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the investigators mentioned below and as per the **Protocol No: 2015-DFU-301, Protocol Version 4.0, dated 23/April/2018** submitted to this Directorate.

1. Dr. Rajesh Khadgawat, Department of Endocrinology & Metabolism, All India Institute of Medical Sciences, Ansari Nagar, New Delhi – 110029, India.
2. Dr. Sandeep Kumar Mathur, SMS Medical College & Attached Hospitals, Fourth Floor, Dhanwantri OPD Block, J.L.N Marg, Jaiur-302004, Rajasthan-India.
3. Dr. Pankaj Srivastava, OM Surgical Centre & Maternity Home, SA-17/3P-4, Sri Krishna Nagar Pahariya Ghazipur Road Varanasi-221007.
4. Dr. Preetam Kashinath Ahirrao, Supe Heart & Diabetes Hospital & Research Centre, Opposite Adharashram, Gharpure Ghat, Near Rungtha School, Ashok Stambh, Nasik-422002, Maharashtra, India
5. Dr. Rupam Das, Down Town Hospital, Dispur, G.S. Road, Guwahati-781006.
6. Dr. Sanjeev Mohan, KRM Hospital and Research Centre, 3/92-93, Vijayant Khand, Gomti Nagar, Lucknow-226010, Uttar Pradesh, India.
7. Dr. Shailesh N Parikh, Aman Hospital and Research Center, 15, Shashwat, Opp. E.S.I. Hospital, Gotri Road, Vadodra-390021.
8. Dr. Vikrant Ghatnatti, KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-590010, Karnataka, India.
9. Dr. Ghanshyam Goyal, ILS Hospital, DD-6, Sector-1, Saltake City, Kolkata-700064.
10. Dr. Srinivas Seshabhataru, Apollo Hospitals, Jubilee Hills, Hyderabad-500096, Telangana, India.
11. Dr. K.P Singh, Fortis Hospital, Sector-62, Phase-8, Mohali-160062.
12. Dr. Sushil Jindal, Peoples College of Medical Science & Research Centre, Peoples Campus Bhanpur-Bhopal-462037 (M.P).

13. Dr. Bongji Vivekanand, Department of Endocrinology, Super Specialty Block, King George Hospital, Maharaniipeta, Visakhapatnam-530002, Andhra Pradesh, India.
14. Dr. Madhu B.S., Department of General Surgery, K.R. Hospital, Mysore Medical College & Research Institute, Irwin Road, Mysore-570001.
15. Dr. J.S Kushwaha, Prakhar Hospital Pvt. Ltd, 8/219, Arya Nagar, Kanpur, U.P-208002.
16. Dr. Lily Rodrigues, Surakshaka Hospital, MIG 218, KPHB Main Road, Kukatpally, Hyderabad-500072.
17. Dr. Vipul Sud, Department of Plastic, Cosmetic & Re-Constructive Surgery, Batra Hospital & Medical Research Centre I Tughlakabad Institutional Area, Mehrauli-Badarpur Road, New Delhi-110062, India.
18. Dr. Dinesh Agarwal, Marwari Hospital & Research Centre, S. J Road Athgaon, Guwahati-781008.
19. Dr. Brij Mohan, Brij Medical Centre Pvt. Ltd., 94-E Near Panki Police Station Panki, Kanpur.
20. Dr. Gyan Chand, Dept. of Endocrine Surgery, C-Block, SGPGIMS, Raebareli Road, Lucknow-226014.
21. Dr. Anirban Sinha, Medical College and Hospital, 88, College Street, MCH Building Kolkata, West Bengal-700073, India.

Note that the clinical trial permission is subject to the following 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 shall be obtained before initiation of the study.
- 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.

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- 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. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.
- j. The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.
- k. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials 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.
- l. 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.
- m. 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.

Yours faithfully,

S ESWARA
REDDY
(Dr. S. Eswara Reddy)

Digitally signed by
S ESWARA REDDY
Date: 2018.07.18
10:53'01

Drugs Controller General (India)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Tel. No: 01123236965, Fax: 01123236971
E-mail: dcic@nic.in

File No: CT/18/000036

Dated: 30-07-2018

To

M/s. JSS Medical Research India Limited,
Plot 12/2, 6th Floor, Vatika Mindscapes Tower-B,
Sector 27 D, Faridabad, Haryana -121003.

Subject: - Protocol Version 5.0 dated 31st May 2018 (Protocol No: 2015-DFU-301) –
regarding.

Ref: Your letter no. GCT/Form44/FF/2018/8219 (GCT/33/18) dated 16/May/2018 on the
subject mentioned above.

Sir,

In continuation to the letter dated 18/07/2018 issued by this office for grant of permission to conduct clinical trial titled "A Phase 3, Randomized, Double-blind, Parallel-group, Vehicle controlled, Multicenter Study of the Efficacy and Safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer(GAIT 1)" for protocol no: 2015-DFU-301, version 4.0, dated: 23/04/2018 as per the application submitted by you for version 4.0 dated: 23/04/2018. However, before SEC version 5.0, dated: 31/05/2018 was presented and therefore, it is hereby informed that the CTNOC granted has been revised to read as "**protocol version 5.0 dated: 31/05/2018**" instead of "**protocol version 4.0, dated: 23/04/2018**" subject to all other conditions mentioned in the approval letter issued to you dated 18/07/18 remaining the same, and hereby directed to initiate the study as per the **protocol version 5.0, dated 31/05/2018**.

Yours faithfully,

S ESWARA
REDDY

Digitally signed by S
ESWARA REDDY
Date: 2018.07.30
15:15:24 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)