



GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
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File No. CT/23/000118

To,

M/s IQVIA RDS (India) Private Limited,
Omega Embassy TechSquare Marathahalli-Sarjapur,
Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103.

Sir,

With reference to your application No. GCT/CT04/FF/2023/39700 (GCT/118/23) dated 21-09-2023, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase3, randomised, double-blind, parallel-group, event-driven, cardiovascular safety study with BI456906 administered subcutaneously compared with placebo in participants with overweight or obesity with established cardiovascular disease (CVD) or chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD” Protocol No.: 1404-0040 Version 1.0, dated 03/Aug/2023 with a total of up-to 100 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

- (i) **Atleast 50% trial sites should be govt. sites & atleast 50% subjects shall be enrolled from govt. sites;**
- (ii) **Investigators in the study should be Cardiologist only;**
- (iii) **Co-medication & Other treatment including follow up should be borne by the sponsor;**
- (iv) 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;
- (v) 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;

- (vi) 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;
- (vii) the Central Licensing 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;
- (viii) 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;
- (ix) 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;
- (x) status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (xi) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal;
- (xii) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;
- (xiii) 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 Licensing 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;
- (xiv) 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter;
- (xv) 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter;
- (xvi) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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;
- (xvii) 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 Licensing 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;
- (xviii) 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;
- (xix) the Central Licensing 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;

File No. CT/118/23-DCG(I)

- (xx) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xxi) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;
- (xxii) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

FORM CT-06

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

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

1. The Central Licensing Authority hereby permits **M/s IQVIA RDS (India) Private Limited, Omega Embassy TechSquare, Marathahalli - Sarjapur Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103 Telephone No.: 8071313508 FAX: 7966303366 E-Mail: QINDIAREGULATORY@QUINTILES.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: 1404-0040 Version 1.0, dated 03/Aug/2023** in the below mentioned clinical trial sites [As per Annexure].-

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

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.

Place: New Delhi

Date _____

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Survodutide
Therapeutic class:	Anti obesity
Dosage form:	Solution for injection
Composition:	BI 456906 NA = 0.6000 mg/ml In House Specification Active BI 456906 NA =1.2000 mg/ml In House Specification Active BI 456906 NA =2.4000 mg/ml In House Specification Active BI 456906 NA =4.8000 mg/ml In House Specification Active BI 456906 NA =7.2000 mg/ml In House Specification Active BI 456906 NA =9.6000 mg/ml In House Specification Active BI 456906 NA =12.0000 mg/ml In House Specification Active Disodium edetate =0.0500 mg/ml Ph. Eur Inactive

File No. CT/118/23-DCG(I)

	Sodium chloride =9.0000 mg/ml U.S.P., Ph. Eur Inactive
Indications:	Obesity with CV risk and NASH

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Apollo Hospitals, No: 21, Greams Lane, Off Greams Road, Chennai-600006, Tamil Nadu, India	Institutional Ethics Committee-Clinical Studies, No: 21, Greams Lane, Off Greams Road, Thousand Lights, Chennai-600006, Tamil Nadu, India ECR/37/Inst/TN/2013/RR-19	Dr. Abraham Oomman
2.	Kamalnayan Bajaj Hospital, Gut no, 43, Satara Parisar, Beed bypass road, Aurangabad-431010 ,MH, India	Ethics Committee Kamalnayan Bajaj Hospital, Kamalnayan Bajaj Hospital, Gut no, 43, Satara Parisar, Beed bypass road, Aurangabad-431010 ,MH, India ECR/444/Inst/MH/2013/RR-20	Dr. Ajit Raghunath Bhagwat
3.	Batra Hospital & Medical Research Centre, 1, Tughlakabad, Institutional Area, MB Road, New Delhi-110062	Scientific Research and Ethical Review Committee, Department of Laboratory Medicine, Batra Hospital & Medical Research Centre, 1,Tughlakabad,Institutional Area, MB Road, New Delhi-110062 ECR/295/Inst/DL/2013/RR-22	Dr. Upendra Kaul
4.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi -110060	Sir Ganga Ram Hospital Ethics Committee, Room No. 1643, 6th Floor, Casualty Building, Old Rajinder Nagar, New Delhi - 110060 EC/20/Inst/DL/2013/RR-2019	Dr. Ashwani Mehta
5.	JIPMER, Dhanvanthri Nagar, Puducheny-605006	IEC Intervention Studies JIPMER, Ist Floor, Administrative Block, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Phone:0413- 2296106 ECR/342/Inst/PY/2013/RR-19	Dr. Santhosh Satheesh

File No. CT/118/23-DCG(I)

6.	LPS Institute of Cardiology, GSVM Medical College, Swaroop Nagar, Kanpur-208002, UP, India	Ethics Committee, GSVM Medical College, Swaroop Nagar, Kanpur-208002, UP, India ECR/680/Inst/UP/2014/RR-20	Dr. Awadhesh Kumar Sharma
7.	Shri B.D. Mehta Mahavir Heart Institute, Shree Mahavir Health Campus, Athwa Gate, Ring Road, OPD Area, Surat, Gujarat, India-395001	Shri B.D. Mehta Mahavir Heart Institute Ethics Committee, Shree Mahavir Health and Medical Relief Society, Athwagate, Ring Road, Surat-395001, Gujarat, India ECR/850/Inst/GJ/2016/RR-20	Dr. Atul Damodar Abhyankar
8.	Shree Krishna Hrudayalaya and Critical Care Centre, Tikekar Road Congress Nagar Square, Dhantoli, Nagpur	Virtuous Institutional Medical Research Ethics Committee, IVth Floor, Shree Krishna Hrudayalaya and Critical Care Centre, Tikekar Road Congress Nagar Square, Dhantoli, Nagpur ECR/548/Inst/MH/2014/RR-20	Dr. Mahesh Fulwani
9.	VMMC & Safdarjung Hospital, New Delhi-110029	Institutional Ethics Committee VMMC & Safdarjung Hospital, Room No. 505 & 506, 5 th Floor, College Building, VMMC & Safdarjung Hospital, New Delhi-110029 ECR/593/Inst/DL/2014/RR-20	Dr. Sandeep Bansal
