



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/22/000006

To,

M/s. Novartis Healthcare Private Limited,
Inspire BKC, Part of 601 & 701, Bandra Kurla Complex,
Bandra (East), Mumbai (India) – 400051, Maharashtra.

Sir,

With reference to your application No. GCT/CT04/FF/2022/30222(GCT/06/22) dated 25-01-2022, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A randomized, double-blind, parallel group, placebo controlled, multicenter phase 3 trial to evaluate the efficacy, safety and tolerability of ianalumab on top of standard-of-care therapy in participants with active lupus nephritis (SIRIUS-LN), Protocol No: CVAY736K12301; Version number: 01 dated 14-12-2021, with a total of up-to 14 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) **The volume of blood to be drawn at each time of sample collection and the frequency of sample collection during the study should be mentioned in protocol and Informed consent document.;**
- (ii) **The applicant/Sponsor should adhere to the condition for SAEs reporting as stipulated in ND & CT Rules 2019 and the applicant/Sponsor & all PI/site shall report all SAEs including death irrespective of its cause i.e. due to progression of disease, to Central Licensing Authority;**
- (iii) **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;**
- (iv) **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;

- (v) 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;
- (vi) 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;
- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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;
- (xvii) 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;
- (xviii) 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;

- (xix) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;
- (xx) 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;
- (xxi) 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,

VENUGOPAL G SOMANI
(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority

Stamp

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727ba2b2557
48732e456d319073455e052d0d15b58748
ee3113c, postalCode=110002, st=DELHI,
serialNumber=e97f241aa1c6b0522525
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Date: 2023.02.15 14:39:46 +05'30'

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

1. The Central Licensing Authority hereby permits **M/s. Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai (India) – 400051** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No: CVAY736K12301; Version number: 01, dated 14-12-2021** 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 _____

**VENUGO
PAL G
SOMANI**

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727bac625574
8f32a45c7249873e5549f1a9c45b86748ee
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serialNumber=e97f21a6b0b0b1522525f
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Date: 2023.02.15 14:39:58 +05'30'

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 Licensing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	VAY736
Therapeutic class:	Human monoclonal antibody of the IgG1
Dosage form:	Solution for Injection
Composition:	VAY736 = 150.0000 mg/ml In House Specification Active
Indications:	Active lupus nephritis (SIRIUS-LN)

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
ChanRe Rheumatology and Immunology Center and Research, No. 414/65, 20th Main, West of Chord Road, 1 st Block, Rajajinagara, Bangalore-560010, India	Institutional Ethics Committee, ChanRe Rheumatology and Immunology Center and Research, No. 414/65, 20th Main, West of Chord Road, 1 st Block, Rajajinagara, Bangalore, Karnataka-560010, India ECR/190/Inst/KR/2013/RR-19	Dr. Chandrashekara Srikantiah
Yashoda Hospital, Behind Harihara Kalabhavan, SP Road, Secunderabad-500003, Telangana	Institutional Ethics Committee Yashoda Academy of Medical Education and Research, Yashoda Hospital, Behind Harihara Kalabhavan, SP Road, Secunderabad-500003, Telangana ECR/49/Inst/AP/2013/RR-19	Dr. Urmila Gupta
Department of Nephrology, PGIMER, Sector-12, Chandigarh	Institutional Ethics Committee (IEC), 6 th Floor, PN Chuttani Block, PGIMER, Chandigarh ECR/25/Inst/CH/2013/RR-20	Dr. Manish Rathi
Department of Rheumatology & Clinical Immunology, Krishna Institute of Medical Sciences Limited, 1-8-31/1, Minister Road, Secunderabad-500003, Telangana, India	KIMS Ethics Committee, Krishna Institute of Medical Sciences Limited, 1-8-31/1, Minister Road, Secunderabad-500003, Telangana, India ECR/142/Inst/AP/2013/RR-19	Dr. Jugal Kishore Kadel
Department of Nephrology, SGPGIMS, Raebareli Road, Lucknow-226014	Institutional Ethics Committee, Room No. 205, 2 nd Floor, Administrative Block SGPGIMS, Raebareli Road, Lucknow ECR/16/Inst/UP/2013/RR-20	Dr. Narayan Prasad
