

File No: BIO/CT/24/000112
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 11.04.2025

To,

M/s. Sanofi Healthcare India Pvt. Ltd.
Sanofi House, CT Survey No. 117-B, L&T Business Park,
Saki Vihar Road, Powai, Mumbai 400072

Subject: Application for grant of permission to conduct Phase IV clinical trial titled – “A Phase 4, open-label, single-arm clinical study to describe safety and efficacy outcomes associated with the use of Nirsevimab in neonates and infants born during or entering their first respiratory syncytial virus (RSV) season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season” vide protocol No. VAS00017 version 2.0 dated 11 Feb 2025 - regarding

Ref.: Your Application No. BIO/CT04/FF/2024/45268 dated 05 Sept. 2024

Sir,

With reference to your Application No.: BIO/CT04/FF/2024/45268 dated 05 Sept. 2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing 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 Licensing 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 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;
- (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 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;
- (VIII) 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;
- (IX) 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;
- (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 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;
- (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 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;
- (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 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;
- (XIII) 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 authorized 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;
- (XIV) The laboratory owned by any person or a company or any other legal entity and utilized 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;
- (XV) 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;
- (XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XVII) You are required to submit the clinical study report after completion of the study.

Yours faithfully,
RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

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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 Licensing Authority hereby permits M/s. Sanofi Healthcare India Pvt. Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072 to conduct clinical trial of the new drug or investigational new drug trial titled as – “A Phase 4, open-label, single-arm clinical study to describe safety and efficacy outcomes associated with the use of Nirsevimab in neonates and infants born during or entering their first respiratory syncytial virus (RSV) season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season” vide Protocol No.:- VAS00017 version 2.0 dated 11 Feb 2025 in the below mentioned clinical trial sites.

2. Details of 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:11-Apr-2025

RAJEEV SINGH
RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)

Central Licensing Authority

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Nirsevimab solution for injection in prefilled syringe 50mg/ 100 mg (r-DNA origin)		
Therapeutic class:	Recombinant human IgG1k mAb		
Dosage form:	Solution for injection in pre-filled syringe.		
Composition:	Each PFS contains-		
	Ingredient	Unit Formula (50 mg PFS)	Unit Formula (100 mg PFS)
	Nirsevimab IH	50 mg	100 mg
	L-Histidine USP-NF/ Ph. Eur./ JP	1.1 mg	2.2 mg
	L-Histidine hydrochloride monohydrate Ph. Eur./ JP	1.6 mg	3.3 mg
	L-Arginine hydrochloride USP-NF/ Ph. Eur./ JP	08 mg	17 mg
	Sucrose USP-NF/ Ph. Eur./ JP	21 mg	41 mg
	Polysorbate 80 USP-NF/ Ph. Eur./ JP	0.1 mg	0.2 mg
	Water for injection (WFI) USP-NF/ Ph. Eur./ JP	Approx. 440 mg	Approx. 880 mg
Indications:	Nirsevimab Indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in: <ul style="list-style-type: none"> • Neonates and infants born during or entering their first RSV season. • Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. 		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Medipoint Hospital Pvt. Ltd 241by1, New D. P. Road, Aundh, Pune, Maharashtra	Penta-Med Ethics Committee Medipoint Hospitals Pvt. Ltd Medipoint Hospitals Pvt. Ltd 241/1, New D. P. Road, Near Sai Heritage, Aundh, Pune Maharashtra - 411007 India. EC Reg. No.: ECR/357/Inst/MH/2013/RR-20	Dr. Jog Pramod Prabhakar

2	Sir Ganga Ram Hospital Ethics Committee Room No 1496. IV Floor, Old Building, Old Rajinder Nagar, New Delhi, Not Available, Delhi	Institutional Ethics Committee Sir Ganga Ram Hospital Ethics Committee Address: Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi-110060 EC Reg. No.: ECR/20/Inst/DL/2013/RR-24	Dr Pankaj Garg
3	Institutional Kids Clinic India Pvt. Ltd. (Cloudnine Hospital), Institutional Ethics Committee, Kids Clinic India Pvt. Ltd. (Cloudnine Hospital), #1533, 9th Main, 3rd Block, Jayanagar, Bangalore, Not Available, Karnataka.	Institutional Ethics Committee Kids Clinic India Ltd, Cloudnine Hospital No 1533 9th Main 3rd Block Jayanagar Bengaluru Bengaluru (Bangalore) Urban Karnataka – 560011 EC Reg. No.: ECR/791/Inst/KA/2015/RR-22	Dr Kishore Kumar R
4	Institute of Child Health Institute of Child Health 11, Dr. Brijesh Guha Street, , Kolkata, Not Available, West Bengal	Institutional Ethics Committee Institute of Child Health 11, Dr. Bires Guha Street Kolkata Kolkata West Bengal - 700017 India EC Reg. No.: ECR/359/Inst/WB/2013/RR-19	Dr Jaydeep Choudhury