

File No: BIO/CT/24/000127
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

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

To,

M/s Zydus Lifesciences Limited, Plot Survey No. 23,
25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A,
Opposite Ramdev Masala, Village Changodar,
Tal. Sanand Ahmedabad (India) – 382213.

Subject: Permission for conducting a phase IV clinical trial titled “An open-label, multicentre, phase IV clinical study to assess the safety and immunogenicity of VaxiRab N® administered for prophylaxis against rabies.” (Protocol No.: VAXI.24.002; Version No. : 01; Dated 27.09.2024).”- regarding.

Reference: Your Application No. BIO/CT04/FF/2024/45612 dated 04-OCT-2024 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2024/45612 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct phase IV clinical trial of “Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine)[PCECV^{PM}]” in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

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

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

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 Licencing Authority hereby grant permission to M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) – 382213 Telephone No.: 02717664605, FAX: 02717664600 E-Mail : sanjaymaheshwari@zyduslife.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: VAXI.24.002, Version No. 01 Protocol Date 27-SEP-2024 as per the below mentioned clinical trial sites.

CT No.: CT- 06 /2025

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 Licensing Authority

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV ^{PM}]	
Therapeutic class:	Vaccine	
Dosage form:	Vaccines (Lyophilized)	
Composition:	Each vial of 1 ml after reconstitution contains:	
	Composition	Quantity
	Active Ingredients	
	Inactivated Rabies Virus (Pitman Moore Strain) Virus is propagated in chick embryo fibroblast cell culture and inactivated by β -propiolactone	Potency \geq 2.5 IU
	Inactive ingredients	
	Quantity	
	Gelatin	8.75 mg
	Human Albumin	15 mg
	Sucrose	40 – 60 mg
	Sodium Hydroxide	0.085 mg
	Di Sodium Hydrogen Phosphate Dihydrate	3.269 mg
	Potassium Dihydrogen Phosphate	0.619 mg
Sodium Chloride	5.064 mg	
Diluent for reconstitution:		
Sterile Water for Injection I.P. (In Glass ampoule)	1 ml	
Presentation	1 mL (Single dose)	
Indication	Active immunization against rabies. 1. For Intramuscular administration, use 1 full dose (1 ml) for Pre & Post exposure prophylaxis. 2. For Intradermal administration, use 0.1 ml per ID site for post exposure prophylaxis.	

Details of clinical trial sites-

S.No.	Names and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Aatman Hospital, 5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal - Ghuma Main Road, Bopal, Ahmedabad - 380058, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row house, opp. Umiya mata mandir, Bopal- Ghuma Main Road, Bopal, Ahmedabad – 380058, Gujarat [ECR/1565/Inst/GJ/2021]	Dr. Chintan B Patel

2.	PHC-Prajna Healthcare, 205 - 208, 2 nd Floor Agam Avenue, Near Adani CNG Pump, Sabarmati, Ahmedabad - 380005, Gujarat	Riddhi Medical Nursing Home IEC, Riddhi Medical Nursing Home, A/101, Jalaram Plaza Jawahar Chowk, Maninagar, Ahmedabad-380008, Gujarat [ECR/886/Inst/GJ/2016/RR-19]	Dr Prajapati Himanshu Kumar Ramabhai
3.	Shree Pragati's foundation's Hira Mongi Navneet Hospital, Valgi Ladha Road, Near Kalidas Natya Gruh, Mulund West, Mumbai-400080, Maharashtra	Hira Mongi Navneet Hospital, Valgi Ladha Road, Near Kalidas Natya Gruh, Mulund West, Mumbai-400080, Maharashtra [ECR/1793/Inst/MH/2023]	Dr Pardeshi Ashok Tukaram
4.	Health 1 Super Speciality Hospital, Near Venitian Villa, Shilaj Circle, S.P. Ring Road, Thaltej, Ahmedabad-380059, Gujarat	Health 1 Super Speciality Hospital Ethics Committee, Near Venitian Villa, Shilaj Circle, S.P. Ring Road, Thaltej, Ahmedabad-380059, Gujarat [ECR/1666/Inst/GJ/2022]	Dr Parth Rathod
5.	Meditrina Institute of Medical Sciences, 278, Central Bazar, Ramdaspath, Nagpur, Maharashtra	Meditrina Institutional Ethics Committee, Meditrina Institute of Medical Sciences, 278, Central Bazar, Ramdaspath, Nagpur, Maharashtra [ECR/608/Inst/MH/2014/RR-20]	Dr Bulle Ajay Abhimanyu
6.	Government Medical College and Government General Hospital, Srikakulam-532001, Andhra Pradesh	Institutional Ethics Committee, Government Medical College and Government General Hospital, Srikakulam-532001, Andhra Pradesh [ECR/492/Inst/AP/2013/RR-20]	Dr K Sunil Naik
7.	Medigene Multispeciality Hospital Private Limited (Akshaya Hospital), D.No.43-9- 201, Sy. No. 321-323, Railway New Colony, Visakhapatnam- 530016, Andhra Pradesh	Institutional Ethics Committee, Medigene Multispeciality Hospital Private Limited (Akshaya Hospital), D.No.43-9-201, Sy. No. 321-323, Railway New Colony, Visakhapatnam-530016, Andhra Pradesh [ECR/1965/Inst/AP/2024]	Dr A Gopal Rao
8.	GMERS Medical College and Hospital Gotri, Gotri Road, Old TB Campus, Vadodara-390021, Gujarat	Institutional Human Ethics Committee, GMERS Medical College and Hospital Gotri, Gotri Road, Old TB Campus, Vadodara-390021, Gujarat. [ECR/28/Inst/GJ/2013/RR-19]	Dr Amul N. Bhedi

9.	Hi-Tech Medical College & Hospital, Health Park, Pandra, Rasulgarh, Bhubaneswar – 751025, Odisha	Institutional Ethics Committee, Hi-Tech Medical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar– 751025, Odisha [ECR/273/Inst/OR/2013/RR-20]	Dr. Lisa Sarangi
10.	Sparsh Hospital and Criticare (P) Ltd. Plot No. A/407, Sahid Nagar, Bhubaneswar-751007, Odisha	Institutional Ethics Committee, Sparsh Hospital and Criticare (P) Ltd. Plot No. A/407, Sahid Nagar, Bhubaneswar-751007, Odisha [ECR/68/Inst/OR/2013/RR-22]	Dr Bharat Das
11.	Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Lakdikapul, Hyderabad-500004, Telangana	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad- 500059, Telangana [ECR/300/Inst/AP/2023/RR-19]	Dr N Ravi Kumar
12.	Department of Community Medicine and Family Medicine, All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019, Odisha	Institutional Ethics Committee, All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019, Odisha [ECR/534/Inst/OD/2014/RR-20]	Dr Swayam Pragyna Parida
13.	King George's Medical University, Chowk, Lucknow-226003, Uttar Pradesh.	Institutional Ethics Committee, Research Cell Administrative Block, King George's Medical University, Chowk, Lucknow-226003, Uttar Pradesh. [ECR/262/Inst/UP/2013/RR-19]	Dr D. Himanshu
14.	Narendra Modi (AMC MET) Medical College, LG Hospital, Maninagar, Ahmedabad-380008, Gujarat	AMC MET Ethics Committee, AMC MET Medical College and Seth LG Hospital, Maninagar, Ahmedabad-380008, Gujarat [ECR/17/Inst/GJ/2013/RR-20]	Dr Jayesh Dutt
15.	Care Multi Speciality Hospital, Kolte Arcade, Pune-Nagar Road, Wagholi, Pune - 412207, Maharashtra	Care Multi Speciality Hospital Ethics Committee, Kolte Arcade, Pune-Nagar Road, Wagholi, Pune-412207, Maharashtra [ECR/1662/Inst/MH/2022]	Dr Vishal Patil
16.	SCB Medical College and Hospital, Cuttack-753007, Odisha	Institutional Ethics Committee, SCB Medical College and Hospital, Cuttack-753007, Odisha [ECR/84/Inst/OR/2013/RR-20]	Dr. Pragnya Paramita Das
17.	Department of Medicine, Kailash Pant Singhania Post Graduate, LLR Hospital,	Ethics Committee, GSVM Medical College, GSVM Medical College, Swaroop Nagar, Kanpur-208002,	Dr Richa Giri

	GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh	Uttar Pradesh [ECR/680/Inst/UP/2014/RR-20]	
18.	Head Internal Medicine, Artemis Hospital, Sector-51, Gurgaon- 122001, Haryana	Artemis Health Science Institutional Ethics Committee, Artemis Hospital, Sector-51, Gurgaon-122001, Haryana [EC/53/Inst/HR/2013/RR-19]	Dr Arpit Jain
19.	Manglam Plus Medicity Hospital, Sector-5, Shipra Path, Mansarovar, Jaipur-302020, Rajasthan	IEC Manglam Medicity Hospital, Manglam Plus Medicity Hospital, Sector-5, Shipra Path, Mansarovar, Jaipur-302020, Rajasthan [ECR/1643/Inst/RJ/2022]	Dr Mohit Agarwal
20.	Department of Medicine, Institute of Medical Science and SUM Hospital, K8, Kalinga Nagar, Ghatikia, Bhubaneswar- 751003, Odisha	Institutional Ethics Committee, Institute of Medical Sciences & SUM Hospital, K8, Kalina Nagar, Ghatikia, Bhubaneswar-751003, Odisha [ECR/627/Inst/OR/2014/RR-20]	Dr Chandan Das
21.	Ethics Committee, SP Medical College, Pawanpuri, Bikaner-334003, Rajasthan	Department of General Medicine, PBM Hospital, Sardar Patel Medical College and AG Hospitals, Bikaner-334003, Rajasthan [ECR/27/SP/Inst/RJ/2013/RR-19]	Dr Babu Lal Meena
22.	Ethics Committee, Kamalnayan Bajaj Hospital, Gut No 43, Satara Parisar, Beed Bypass Road, Aurangabad-431010, Maharashtra	Kamalnayan Bajaj Hospital, Gut No 43, Satara Parisar, Beed Bypass Road, Aurangabad-431010, Maharashtra [ECR/444/Inst/MH/2013/RR-20]	Dr Milind M Vaishnav
23.	Super speciality Hospital Ethics Committee, Sabnis Plot, Kalyan Nagar, Amravati-444606, Maharashtra	Radiant Super speciality Hospital, Radiant Rehabilitation Building, Sabnis Plot, Kalyan Nagar, Amravati-444606, Maharashtra [ECR/997/Inst/MH/2017/RR-21]	Dr Ganesh Bansod
24.	Marwari Hospitals, B3, Sati Joymati Road, Athgaon, Guwahati-781008, Assam	Institutional Ethics Committee ECRC-HEC, Marwari Hospitals, Sati Joymati Road, Athgaon, Guwahati-781008, Assam [ECR/487/Inst/AS/2013/RR-19]	Dr Dinesh Agrawal
25.	Sir Ronald Ross Institute of Tropical and Communicable Diseases (Govt. Fever	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500059, Telangana	Dr S. Rajendra Prasad

	Hospital) (Affiliated to Osmania Medical College), Nallakunta Main Road, Nallakunta, Hyderabad - 500044 Telangana	[ECR/300/Inst/AP/2013/RR-24]	
26.	Department of Community Medicine ESIC Medical College and Hospital, Sanathnagar, Hyderabad - 500038, Telangana	Institutional Ethics Committee, ESIC Medical College and Hospital, Sanathnagar Hyderabad -500038, Telangana [ECR/1303/Inst/TG/2019/RR-22]	Dr. D. Surendra Babu
27.	Belagavi Institute of Medical Sciences, Dr B.R. Ambedkar Road, Sadashiv Nagar, Belagavi - 590001, Karnataka	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Dr B.R. Ambedkar Road, Sadashiv Nagar, Belagavi - 590001, Karnataka [ECR/801/Inst/KA/2016/RR-20]	Dr. Girish K. Sonwalkar
28.	BHS Lakeview Hospital, R.S. No. 73/7, C.T.S. No. :11888, Opp. Fort Lake, Gandhi Nagar, Belagavi-590016, Karnataka	BHS Lakeview Ethics Committee, BHS Lakeview Hospital, R.S. No. 73/7, C.T.S. No. : 11888, Opp. Fort Lake, Gandhi Nagar, Belagavi-590016, Karnataka [ECR/1586/Inst/ KA/2021]	Dr. Vijayalakshmi Kulgod

In addition to point 3, the permission is subject to following conditions:

1. The clinical trial should be conducted as per approved protocol titled "An open-label, multicentre, phase IV clinical study to assess the safety and immunogenicity of VaxiRab N® administered for prophylaxis against rabies. Protocol No.: VAXI.24.002, Version 1 dated 27.09.2024
2. Firm shall ensure that minimum one-third of subjects enrolled in Pre-exposure prophylaxis (PrEP) arm of the study are female.
3. Firm shall submit validation protocol for RFFIT assay developed at Clantha Research Ltd in due course of time
4. Firm is required to submit Ethics Committee approval for Phase-IV clinical trial
5. The firm is required to constitute a DSMB to review the safety data.
6. Only CDL, Kasauli certified vaccines already approved for manufacturing & marketing shall be used in the Phase-IV clinical trial in India.

Place: New Delhi
Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority