



File No. IND/CT/26/000004

Dated

To

M/s. Zydus Lifesciences Limited,
Survey No. 417, 419 & 420 Sarkhej-Bavla National Highway No. 8A,
Village-Moraiya Sanand (India) – 382210

Subject: A phase III, multicenter, randomized, assessor-blind, active comparator study to determine the efficacy, safety, and tolerability of orally administered Zintrodiazine in patients with uncomplicated Plasmodium vivax malaria” vide Protocol number ZINT.25.001, version 02 dated 30-Mar-2026 - regarding.

Ref.: Your Application No IND/CT04/FF/2026/54257 dated 19-Jan-2026

Sir,

With reference to your Application No. IND/CT04/FF/2026/54257 dated 19-Jan-2026, 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 center, as the case may be:
Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence center, 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) 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) It may kindly be noted that merely granting permission to conduct clinical trial 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.
- (XIX) 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 Licensing Authority.
- (XX) The firm should submit Clinical study report (CSR) to this office after completion of trial.
- (XXI) The firm shall ensure that batches used for clinical trial shall be manufactured in GMP compliant facility and shall have adequate shelf life for the duration of clinical trial.**

Yours faithfully,
RAJEEV SINGH SINGH RAGHUVANSHI
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Digitally signed by RAJEEV
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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. Zydus Lifesciences Limited, Survey No. 417, 419 & 420 Sarkhej-Bavla National Highway No. 8A, Village-Moraiya Sanand (India) – 382210 to conduct Phase III clinical trial entitled “A phase III, multicenter, randomized, assessor-blind, active comparator study to determine the efficacy, safety, and tolerability of orally administered Zintrodiazine in patients with uncomplicated Plasmodium vivax malaria” vide Protocol number ZINT.25.001, version 02 dated 30-Mar-2026 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:

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

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

Names of the new drug or investigational new drug	Therapeutic class	Dosage form	Composition	Indications																																																		
Zintrodiazine	Antimalarial	Tablets	<p>Each film coated tablet contains: ZY-19489.....900 mg Excipients..... q.s. Colour: Titanium Dioxide IP</p> <p>Excipients: Lactose Monohydrate, Sodium Starch Glycolate, Povidone, Purified water, Colloidal Silicon Dioxide, Magnesium Stearate and Opadry EZ 254U180002 White (Titanium Dioxide, Talc, Guar gum, Polyvinyl alcohol, Maltodextrin, Hypromellose and Medium-chain triglycerides)</p> <table> <tr> <th>Sr #</th><th>Ingredients</th><th>Specifications</th><th>Qty/ tablet (mg)</th><th>% w/w</th></tr> <tr> <td>1</td><td>ZY-19489</td><td>IH</td><td>900.00</td><td>69.34</td></tr> <tr> <td>2</td><td>Lactose Monohydrate (Pharmatose 200M)</td><td>IP</td><td>210.56</td><td>16.22</td></tr> <tr> <td>3</td><td>Sodium Starch glycolate (Type A)</td><td>IP</td><td>86.44</td><td>6.66</td></tr> <tr> <td>4</td><td>Povidone (Kollidone 30)</td><td>IP</td><td>37.80</td><td>2.91</td></tr> <tr> <td>5</td><td>Colloidal silicon dioxide (Aerosil 200)</td><td>IP</td><td>12.60</td><td>0.97</td></tr> <tr> <td>6</td><td>Magnesium stearate</td><td>IP</td><td>12.60</td><td>0.97</td></tr> <tr> <td>7</td><td>Opadry EZ 254U180002 White</td><td>IH</td><td>38.00</td><td>2.93</td></tr> <tr> <td>8</td><td>Purified water</td><td>Ph. Eur. / US P/ IP/ BP</td><td>q.s.</td><td>NA</td></tr> <tr> <td colspan="3">Total</td><td>1298.00</td><td>100.00</td></tr> </table>	Sr #	Ingredients	Specifications	Qty/ tablet (mg)	% w/w	1	ZY-19489	IH	900.00	69.34	2	Lactose Monohydrate (Pharmatose 200M)	IP	210.56	16.22	3	Sodium Starch glycolate (Type A)	IP	86.44	6.66	4	Povidone (Kollidone 30)	IP	37.80	2.91	5	Colloidal silicon dioxide (Aerosil 200)	IP	12.60	0.97	6	Magnesium stearate	IP	12.60	0.97	7	Opadry EZ 254U180002 White	IH	38.00	2.93	8	Purified water	Ph. Eur. / US P/ IP/ BP	q.s.	NA	Total			1298.00	100.00	Uncomplicated Plasmodium vivax malaria
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8	Purified water	Ph. Eur. / US P/ IP/ BP	q.s.	NA																																																		
Total			1298.00	100.00																																																		

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of Investigator
G B Vaghani Multispeciality Hospital, 75-80, Ishwarkrupa soc., Opp. Maharana Pratap Udhyan, Varachha Main Rd, Chowpatty, Surat, 395006, Gujarat, India	Global Ethics Committee, Global Hospital, 4 Floor Room Number 110, Sarthana Jakatnaka, Surat Gujarat – 395006 India ECR/1616/Inst/GJ/2021	Dr. Vaghani Alpeshkumar Dhanjibhai
IPGME&R and SSKM Hospital, 244, Acharya Jagadish Chandra Bose Road, Kolkata - 700020, West Bengal, India	IPGME and R Research Oversight Committee, IPGME&R and SSKM Hospital, 244, Acharya J.C. Bose Road, Kolkata- 700020, West Bengal, India. ECR/35/Inst/WB/2013/RR-24	Dr. Kausik Bhar
Dr. DY Patil University School of Medicine, Hospital and Research Centre, Sector-5, Nerul, Navi Mumbai-400706 Maharashtra, India	Institutional Ethics Committee DY Patil Medical College, Sector-5, Nerul, Navi Mumbai, Thane, Maharashtra-400706, India. ECR/195/Inst/MH/2013/RR-24	Dr. Akay Aashi Aboobacker
BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg. Adajan Char Rasta, Adajan, Surat-395009, Gujarat, India	BAPS Hospital Institutional Ethics Committee BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg Adajan Char Road, Adajan, Surat-395009, Gujarat India. ECR/639/Inst/GJ/2014/RR-25	Dr. Parshottam Govindbhai Koradia
Shivam Hospital, Plot No. 57, C.R.W. CHS, Kalyan Rd, near M.I.D.C. Water Tank, Dombivli East-421201, Dombivli, Maharashtra, India.	Altezza Institutional Ethics Committee Shri Ashirwad Hospital, C/3 Shree Complex, Opposite Mahavir Nagar Road, Manpada Road, Dombivli (E), 421201, Maharashtra, India. ECR/1457/Inst/MH/2020/RR-25	Dr. Bangar Kushal Daivavan
Department of Clinical Pharmacology, Calcutta School of Tropical Medicine, 108, Chittaranjan Ave, Calcutta Medical College, College Square, Kolkata, West Bengal-700073, India	Clinical Research Ethics Committee, School of Tropical Medicine 108, Chitta Ranjan Avenue, Kolkata, West Bengal -700073, India. ECR/194/Inst/WB/2013/RR-25	Dr. Santanu Munsu
Lion Tarachand Bapa Hospital and Research Centre, C.U. Shah Complex, Jain Society, Sion (W), Mumbai, Maharashtra – 400022, India	Institutional Ethics Committee of Aayush Hospital, Aayush Hospital, 102-1, 1st Floor, Laxman Arcade Vivekanand, Co-op Hsg 90 Feet Road Dharavi Mumbai City, Maharashtra-400017, India. ECR/1472/Inst/MH/2020	Dr. Keny Amitabh Madhukar

Rajendra Institute of Medical Sciences, Bariatu, Ranchi, Jharkhand-834009	Institutional Ethics Committee, RIMS, Ranchi, Rajendra Institute of Medical Sciences, 4th Floor Administrative Building Bariatu, Ranchi, Jharkhand, 834009, India ECR/769/Inst/JH/2015/RR-21	Dr. Rashmi Sinha
Clinical Research Unit, Near Medicine ICU & Maharaja MRI, Department of medicine, S.P. Medical College & A.G. of Hospitals, Bikaner - 334001, Rajasthan	Ethics Committee, S.P. Medical College, S.P. Medical College, Pawanpuri, Bikaner, Rajasthan – 334003 India ECR/27/SP/Inst/RJ/2013/RR-24	Dr. Surendra Kumar
Rajiv Gandhi Medical College & Chhatrapati Shivaji Maharaj Hospital (CSMH), Old Thane-Belapur Road, Budhaji Nagar, Kalwa, Thane-400605, Maharashtra, India,	Institutional Clinical Ethics Committee, RGMC and Chatrapati Shivaji Maharaj Hospital, Thane-Belapur Rd, Kalwa Thane Maharashtra – 400605 India ECR/469/Inst/MH/2013/RR-25	Dr. Rathod Suman Shivaji
SMS Medical College and Hospital, Department of Medicine, Ground Floor, Dhanvantri OPD Block, SMS Hospital, Jaipur-302004, Rajasthan, India.	Ethics Committee S.M.S. Medical College and Attached Hospitals, J.L.N. Marg Jaipur, 302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-24	Dr. Sunil Kumar Mahavar
Zydus Medical College and Hospital, Opp Nehru Baug, Station Road, Dahod, Gujarat-389151, India	Zydus Medical College and Hospital, Civil Hospital, Opp. Nehru Baug, Station Road, Dahod-389151, Dahod, Gujarat, India. ECR/1464/Inst/GJ/2020	Dr. Mohit Gajendrabhai Desai
GMERS Medical College & Hospital, Near Polytechnic College, Hadiol Road, Himmatnagar-383001, Gujarat, India	Institutional Ethics Committee GMERS, GMERS Medical College & General Hospital, Dean Office, Ground Floor, Near Government Polytechnic, Gadhoda Road, Himmatnagar-383001, Sabarkantha, Gujarat, India ECR/1340/Inst/GJ/2020/RR-25	Dr. Panchal Manisha Vishnuprasad
S.N. Medical College and Hospital, Near Central Library, Moti Katra, Mantola, Agra, Uttar Pradesh-282003, India	Institutional Ethics Committee S.N Medical, S.N. Medical College, Agra Raja Mandi Near Agra College, Near Central Library, Moti Katra, Mantola, Agra, Uttar Pradesh-282003, India ECR/1409/Inst/UP/2020/RR-25	Dr. Prabhat Kumar Agrawal
Department of General Medicine, Nil Ratan Sircar Medical College and Hospital 138, Acharya Jagdish Chandra Bose Road, Raja Bazar, Kolkata-700014, West Bengal, India	Ethics Committee, NRS Medical College, NRS Medical College & Hospital, NRS Medical College, 138, Acharya Jagdish Chandra Bose Rd, Rajabazar, Kolkata, West Bengal-700014, India ECR/609/Inst/WB/2014/RR-25	Dr. Badal Kumar Sahu

GMERS Medical College and Hospital, Old TB Hospital Campus, Gotri Rd, Gotri, Vadodara 390021 Gujarat	Institutional Human Ethics Committee, GMERS Medical College and Hospital, Gotri Old TB Hospital Campus Gotri Main Road, Gotri Vadodara Vadodara Gujarat – 390021 ECR/28/Inst/GJ/2013/RR-24	Dr. Shubhangi Deshpande
MGM Medical College & Hospital, N-6 CIDCO, Chhatrapati Sambhaji Nagar (Aurangabad), Maharashtra 431003, India	MGM Ethics committee for Research on human subject, MGM Medical College and Hospital N-6, CIDCO Aurangabad Maharashtra - 431003, India. ECR/581/Inst/MH/2014/RR-25	Dr. Syed Umar Quadri Syed Abdul Jabbar
Community Welfare Society Hospital, Jagda, Rourkela, Sundergarh, 769042, Odisha, India.	CWS Hospital Institutional Ethics Committee, Community Welfare Society Hospital, Rourkela, Jagda P.O. Rourkela Sundargarh Orrisa-769042, India. ECR/1306/Inst/OD/2019/RR-24	Dr. Sanghamitra Satpathi
Rajindra Hospital, Department of Community Medicine, Including Public Health, New Academic Insitute Building, Including Public Health Government Medical College, Patiala, Punjab, 147001, India.	Institution Ethics Committee, Govt medical college, Patiala Sangrur road Sangrur road, Patiala Punjab - 147001 India ECR/2135/Inst/PB/2025	Dr. Aman Dev Singh
Atal Vihari Vajpayee Institute of Medical Sciences (ABVIMS) (formerly PGIMER) Dr. RML Hospital, GGSIP University, Baba Kharag Singh Marg, New Delhi, India-110001	Ethics Committee, PGIMER, Dr. RML Hospital, PGIMER, DR. RAM Manohar Lohia hospital, New Delhi, Baba Khadakh Singh Marg, New Delhi, Central Delhi - 110001 India ECR/78/Inst/DL/2013/RR-24	Dr. Pulin Kumar Gupta
Department of Infectious Disease, Kasturba Medical College, Manipal, Madhav Nagar, Manipal, Udupi, Karnataka-576104	MAHE Ethics Committee, Manipal Academy of Higher Education, Manipal.edu bldg, Madhav Nagar, Manipal Udupi, Karnataka-576104, India ECR/191/Inst/KL/2013/RR-24	Dr. Kavitha Saravu
Shri Balaji Institute of Medical Sciences, Shri Balaji Hospital Campus, Department of General Medicine, Mowa-Raipur, Chhattisgarh, 492014	Shri Balaji Ethics Committee, Shri Balaji Institute of Medical Science Mowa Raipur Chhattishgarh-492007, India. ECR/1065/Inst/CG/2018/RR-21	Dr. Hemshikha Tambrey
MR Bangur Hospital, 241, Deshpren Sashmal Road, Tala, Kolkata, West Bengal, 700033, India	IPGMEandR Research Oversight Committee IPGME&R SSKM hospital 244 Acharya J. C. Bose Road - Kolkata Kolkata West Bengal - 700020 India ECR/35/Inst/WB/2013/RR-24	Dr. Arindam Bauri
Vedant Kalyan Hospital, Building No. 5, Rutu Riverview Estate, Adharwadi Road, Near K.M. Agarwal College, Opp. Gandhari Octori Naka, Kalyan	Vedant Hospital Institutional Ethical Committee Tieten Medicity Hospital Ghodbunder Road, Kasarvadavali, Thane, Maharashtra - 400615 India ECR/1154/Inst/MH/2018/RR-22	Dr. Patil Yogesh Namdeo

(W)-421301, Maharashtra, India.		
Infectious Diseases & Belegghata General Hospital 57, Beliaghata Main Road, Sarobar Park, Phoolbagan, Belegghata, Kolkata-700010, West Bengal, India.	Institutional Ethics Committee Infectious Diseases and Bellaghata General Hospital Infectious Diseases AndBeliaghata General Hospital 57, Beliaghata Main Road, Kolkata-700010, West Bengal, Indla ECR/2052/InstWB/2025	Dr. Tapan Biswas
Samarth Hospital, Opp. Dipak Theatre, 12 Bungalow, Camp Road, Malegaon, Nashik, 423203, MH	Samarth Hospital Institutional Ethics Committee, Samarth Hospital S No 318/2A/3/2,OP. DEEPAK THEATRE,BARA BUNGLOW CAMP ROAD,MALEGAON,NASHIK. Malegaon Nashik Maharashtra - 423203 India ECR/2177/Inst/MH/2026	Dr. Nikam Abhay Shrawan
Global Super specialty and cancer hospital, Block no 108, old survey no 111 EMERALD Avenue Surat-Kamrej road, Valak Char Rasta Surat Gujarat - 394180	Global Ethics Committee , Global Hospital Global Hospital,4 Floor Room Number 110,sarthana Jakatnaka, Surat Gujarat – 395006 ECR/1616/Inst/GJ/2021	Dr Dhaduk Milankumar Bhupatbhai
Harmony Hospital, 301,401,402, Puskar Icon, Nr. Shukan Cross Road, Nikol - Naroda Rd, above Croma, New India Colony, Nikol Ahmedabad Gujarat - 382350	IEC Momentous Mental Health and Rehabilitation Centre , Momentous Mental Health And Rehabilitation Centre The Urbania Complex, Palm Road Kudasan, Gandhinagar, Gujarat - 382419 ECR/2218/Inst/GJ/2026	Dr Pareshkumar Laljibhai Gohel
New Mangalmurti Hospital, Plot no. 09, Ganeshwadi, Near Pande Dairy Chowk Jalgaon Maharashtra - 425001	Mangalmurti Institutional Ethics Committee , New Mangalmurti Hospital Plot No. 09, Ganeshwadi Near Pande Dairy Chauk, Jalgaon Jalgaon Jalgaon Maharashtra – 425001 ECR/2019/Inst/MH/2024	Dr Chaudhari Suyog Gambhir