

GOVERNMENT OF INDIA

CENTRAL DRUGS STANDARD CONTROL

ORGANISATION(Headquarter)(Dire

ctorate General ofHealthServices) Ministry of Health & Family Welfare FDA Bhavan

ITO, Kotla Road

New Delhi - 110002 (Delhi) Phone No.:91-11-23216367 Fax No.: 91-11-23236973

E-Mail : dci@nic.in

File No. CT/21/000087

To,

M/s. Roche Products (India) Private Limited, 146 B, 166 A, Unit No 7,8,9, 8th floor, R city office, R City Mall Lal Bahadur Shastri Marg, Ghatkopar (West) Mumbai (India) – 400086.

Sir.

With reference to your application No GCT/CT04/FF/2021/27266 (GCT/87/21) dated 30-07-2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "A Phase III, Randomized, Open-Label, Multicenter Study Evaluating The Efficacy And Safety of Adjuvant Giredestrant compared With Physician's Choice of Adjuvant Endocrine Monotherapy in Patients with Estrogen Receptor-Positive, Her2-Negative Early Breast Cancer", Protocol number:GO42784Version 2.0, dated 30/June/2021 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) 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;
- (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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing 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 Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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) 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 Licencing 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;
- (xv) 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;
- (xvi) the Central Licencing 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;
- (xvii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

- (xviii)Merely granting permission to conduct the clinical trial with the Investigational DrugProduct does not convey or imply that, based on the clinical trial study datagenerated with the investigational 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 Licencing Authority.

Yours faithfully,

(Dr. V. G. Somani) 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. Roche Products (India) Private Limited, 146 B, 166 A, Unit No 7,8,9, 8th floor, R city office, R City Mall Lal Bahadur Shastri Marg, Ghatkopar (West) Mumbai (India) 400086toconduct clinical trial of the new drug or investigational new drug as per Protocol number: GO42784 Version 2.0, dated 30/June/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	

(Dr. V. G. Somani)
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	Giredestrant 30mg hard capsules
new drug or	Anastrozole 1mg film-coated tablets
investigational	Exemestane 25mg film-coated tablets
new drug	Letrozole 2.5mg film-coated tablets
	Tamoxifen 20mg tablets
Therapeutic	Selective estrogen receptor degrader,
class:	Aromatase inhibitors
	Selective estrogen receptor modulator
Dosage form:	Capsules
	Tablets
Composition:	Giredestrant Tartrate 38.6 mg/ capsule In House Specification Active
	Microcrystalline Cellulose24.8mg/capsule Any Other Pharmacopeia,
	E.P., J.P. Inactive
	Lactose Monohydrate 7.5 mg/capsuleAny Other Pharmacopeia,
	E.P., J.P.Inactive

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	Croscarmellose Sodium 3.75mg/capsule Any Other Pharmacopeia,		
	E.P., J.P .Inactive		
	Magnesium Stearate 0.375mg/capsule Any Other Pharmacopeia, E.P., J.P.		
	Inactive		
	Black Iron Oxide 0.37 %Any Other Pharmacopeia, E.P. Inactive		
	Titanium Dioxide 0.4 %Any Other Pharmacopeia, E.P., J.P. Inactive		
	Yellow Iron Oxide 0.33 %Any Other Pharmacopeia, E.P. Inactive		
	Hypromellose 100.0 q.s. Any Other Pharmacopeia, E.P., J.P.I nactive		
	Tablet core: Anastrozole, Lactose monohydrate, Micro crystalline cellulose,		
	Sodium starch glycolate(Type A), Magnesium stearate, Silica colloidal		
	anhydrous, Hyprolose Tablet coating: Opadry II white: Lactose monohydrate,		
	Hypromellose, Macrogol 4000, Titanium dioxide (E171)		
	Tablet core: Exemestane, Mannitol, Cellulose Microcrystalline,		
	Crospovidone, Sodium starch Glycolate (Type A), Hypromellose E5		
	Polysorbate 80, Colloidal Anhydrous Silica, Magnesium stearateTablet		
	Coating: Hypromellose 6cp(E464), Macrogol (400), Titanium dioxide (E171)		
	Tablet core: Letrozole, Lactose monohydrate, Maize starch,		
	Hypromellose Type 2910, Cellulose microcrystalline, Sodium starch		
	glycolate Type A, Colloidal anhydrous silica, Magnesium stearate		
	Coating (Opadry 03B82927 yellow):Hypromellose 6 cp E464, Titanium		
	dioxide E171, Iron oxide yellow E172, Macrogol 400, Talc E553b		
	Tananifan Oalainna kuduanan ukasakata Misasamutallina usli kus		
	Tamoxifen, Calcium hydrogen phosphate, Microcrystalline cellulose,		
	Sodium starch glycollate (Type A), Povidone K25, Magnesium stearate, Colloidal anhydrous silica		
Indications:	For patients with Estrogen receptor positive, HER2-Negative Early		
maications.	Breast Cancer		
	Dicast Carico		

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Sujan Surgical Cancer Hospital & Amravati Cancer Foundation, 52/B, Main Road, Shankar Nagar, Amravati, Maharashtra- 444605, India	Amravati Ethics Committee, Sujan Surgical Cancer Hospital & Amravati Cancer Foundation, 52/B, Main Road, Shankar Nagar, Amravati, Maharashtra- 444605, India	Dr. Rajendra Singh Arora
2.	Asirvatham Speciality Hospital, No. 22, Rajaji Street, Gandhi Nagar, Madurai-625020, Tamil Nadu,	Institutional Ethics Committee Asirvatham Speciality Hospital, No. 22, Rajaji Street, Gandhi Nagar, Madurai-625020, Tamil	Dr.Jebasingh JosephDhanaraj

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	India	Nadu, India	
		ECR/265/Inst/TN/2013/RR-19	
3.	M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India	Ethics Committee, M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India	Dr.Nalini Kilara
4.	Sparsh Hospital and Critical	ECR/215/Inst/KA/2013/RR-19 Institutional Ethics Committee,	Dr.Ghanashyam
4.	Care (P) Ltd., A/407, Saheed Nagar, Bhubaneshwar- 751007, Orissa, India	Sparsh Hospital and Critical Care (P) Ltd., A/407, Saheed Nagar, Bhubaneshwar-751007, Orissa, India	Biswas
		ECR/68/Inst/OR/2013/RR-19	
5.	Shree Himalaya Cancer Hospital & Research Institute4, Vinod Baug, B/H Sanman Hotel, Jetalpur Bridge, Vadodara - 390007, Gujarat, India	BRU - Independent Ethics Committee, Bhanu Sadan, Opp. Nimbalkar Chamber Jambubet, Dandia Bazar, Vadodara - 390001, Gujarat, India	Dr.Kartikeya Jain
		ECR/160/Inst/GJ/2014	
6.	Dept. of Surgical Oncology, K R Hospital, Mysore Medical College & Research Institute, Irwin Road, Mysore, Karnataka-570001, India	Institutional Ethics Committee Mysore Medical College & Research Institute and Associated Hospitals, Mysore Medical College & Research Institute, Irwin Road, Mysore- 570001, Karnataka, India	Dr.Prakash S S
7.	Apex Wellness Hospital, Survey No. 799, Plot No. 187,Behind Prakash Petrol Pump, Govind Nagar, Nashik –422009, Maharashtra, India	ECR/134/Inst/KA/2013/RR-19 Apex Wellness Ethics Committee (AWEC), C/O, Apex Wellness Hospital, Survey No. 799, Plot No. 187,Behind Prakash Petrol Pump, Govind Nagar, Nashik –422009, Maharashtra, India ECR/1500/Inst/MH/2021	Dr. Shailesh A. Bondarde
8.	Sahyadri Super Speciality Hospital Hadapsar, Sr. No. 163, Bhosale Nagar, Hadapsar, Pune-411028, Maharashtra, India	Sahyadri Hospital Pvt Ltd Ethics Committee, Sahyadri Clinical Research Development Center, 33/34B Makarand, Bhave Path, Karve Road, Pune-411004, Maharashtra, India	Dr. Nag Shona Milon

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9.	Tata Memorial Hospital, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel, Mumbai-400012, Maharashtra, India Advance Centre for Treatment, Research & Education in Cancer (ACTREC), Tata Memorial Centre, Sector-22, Ove Village Kharghar, Navi Mumbai-410210, Maharashtra, India, Maharashtra, India	Institutional Ethics Committee- I, 3rd Floor, Main Building, Tata Memorial Hospital, dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India ECR/170/Inst/MH/2013/RR-19 Institutional Ethics Committee- II, 3rd Floor, Main Building, Tata Memorial Hospital, dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India ECR/414/Inst/MH/2013/RR-19 Institutional Ethics Committee- III First Floor, Paymaster Shodhika building, Advanced Centre for Treatment Research and Education in Cancer (ACTREC), Tata Memorial Centre, Sctro-22, Ove Village Kharghar, Navi Mumbai-410210, Maharashtra, India ECR/149/Inst/MH/2013/RR-19	Dr.Sudeep Gupta
10.	Sahyadri Super Specialty Hospital, 30-C Erandwane, Karve Road, Pune-411004, Maharashtra, India Sahyadri Clinical Research and Development Center, 33/34B, Makaranda Bhave Path, Karve Road, Pune- 411038, Maharashtra, India	Sahyadri Hospital Pvt. Ltd., Ethics Committee, Sahyadri Clinical Research and Development Center, 33/34B, Makaranda Bhave Path, Karve Road, Pune-411038, Maharashtra, India ECR/493/Inst/MH/2013/RR-19	Dr. Tushar Patil
11.	Erode Cancer Centre, 1/393, Velavan Nagar, Perundurai Road, Thindal, Erode- 638012, Tamil Nadu, India	Institutional Ethics Committee- Erode Cancer Centre, 1/393, Velavan Nagar, Perundurai Road, Thindal, Erode-638012, Tamil Nadu, India ECR/319/Inst/2013/RR-19	Dr. Velavan Kandappan
12.	Institute of Postgraduate Medical Education & Research & SSKM Hospital, 244 AJC Bose Road, Kolkata-700020, West Bengal, India	IPGME&R Research Oversight Committee, Institute of Postgraduate Medical Education & Research & SSKM Hospital, 244 AJC Bose Road, Kolkata- 700020, West Bengal, India	Dr.Koushik Chatterjee

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		ECR/35/Inst/WB/2013/RR-19	
13.	Health Point Hospital, 21 Prannath Pandit Street (Opposite of Lansdown Padmapukur) Kolkata, West Bengal, India, Pin No: 700 025	Health Point Ethics Committee, 21 Prannath Pandit Street (Opposite Lansdowne Padmapukur) Kolkata, West Bengal, India, Pin No: 700 025 ECR/284/Inst/WB/2013/RR-19	Dr.Bidisha Ghosh Naskar
14.	Department of Medical Oncology, Christian Medical College, Ida Scudder Road, Vellore-632004, Tamil Nadu, India	Institutional Review Board (Ethics Committee-Silver), Office of Research, Carman Block, First Floor, Christian Medical College, Bagayam, Vellore-632002, Tamil Nadu, India ECR/326/Inst/TN/2013/RR-19	Dr.Anjana Joel
15.	Lokmanya Holistic Cancer Care & Research Centre of (LMRC), Lokmanya Hospital, 314/B, Telco Road, Chinchwd, Pune, 41033, Maharashtra, India	Lokmanya Holistic Cancer Care & Research Centre of (LMRC), Lokmanya Hospital, 314/B, Telco Road, Chinchwd, Pune, 41033, Maharashtra, India	Dr. Wategaonkar Ravikumar Narayan
16.	Kolhapur Cancer Centre Pvt. Ltd., R.S. 238, Opp. Mayur Petrol Pump, Gokul, Shirgaon, Kolhapur-416234, Maharashtra, India	Kolhapur Cancer Centre Institutional Ethics Committee, Kolhapur Cancer Centre Pvt. Ltd., R.S. 238, Opp. Mayur Petrol Pump, Gokul, Shirgaon, Kolhapur-416234, Maharashtra, India	Dr.Nilesh Ashok Dhamne
17.	Dept. of Radiotherapy, AIIMS, Sijua, Partrapada, PO Dumduma, Bhubaneswar, Odisha-751019, India	Institutional Ethics Committee, Village-Sijua, Partrapada, PO Dumduma, Bhubaneswar- 751019, Odisha	Dr.Saroj Kumar Das Majumdar
18.	Yashoda Hospital, Raj Bhavan Road, Somajiguda, Hyderabad, 500082, Telangana, India	Institutional Ethics Committee, Yashoda Academy of Medical Education & Research, Yaashod Group of Hospitals, Yashoda Hospital, Behind Hari Hara Kala Bhavan, S.P. Road, Secunderabad-500003, Telangana State ECR/49/Inst/AP/2013/RR-19	Dr.Nikhil S Ghadyalpatil

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19.	Kailash Cancer Hospital and Research Center, Muniseva Ashram, Goraj, Waghodia, Vadodara-391760	IEC- Kailash Cancer Hospital and Research Center ECR/49/Inst/GJ/2013/RR-19	Dr. Niraj Navinchandra Bhatt
20.	HCG Cancer Centre, Sola Science City Road, Nr. Sola Bridge, S.G. Highway, Ahmedabad-380060, Gujarat, India	HCG Multi Specialty Ethics Committee, HCG Hospitals, Mithakhali Six Road, Ellisbridge, Ahmedabad-380060, Gujarat, India ECR/92/Inst/GJ/2013/RR-19	Dr. Manasi Shah
21.	Shalinital Meghe Hospital & Research Centre, Wanadongri, Hingna Road, Nagpur-441110, Maharashtra, India	Jasleen Hospitals Ethics Committee, Opposite Big Bazar, Dhantoli, Nagpur-440012, Maharashtra, India ECR/264/Inst/MH/2013/RR-20	Dr.Vaibhav Choudhary
22.	Nirmal Hospital Pvt. Ltd., Ring Road, Surat-395002, Gujarat, India	Nirmal Hospital Pvt. Ltd Ethics Committee, Nirmal Hospital Pvt. Ltd., Ring Road, Surat-395002, Gujarat, India	Dr.Ghanshyam N Patel
23.	Chopda Medicare & Research Centre Pvt. Ltd., magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B. H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India	Magna-Care Ethics Committee, C/o Chopda Medicare & Research Centre Pvt. Ltd., magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B. H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India ECR/79/Inst/MH/2013/RR-19	Dr.Nagesh Shrinivasrao Madnoorkar
24.	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi-590010, Karnataka, India	Institutional Ethics Committee, KLE University's, KLE PK Hospital, Nehrunagar, Belagavi- 590010, Karnataka, India	Dr.Rohan Bhise
25.	Fortis Hospital Ltd., 154/9, Bannerghatta Road, Opp. to IIM-B, Bangalore-560076, India	Fortis Hospital Ethics Committee, 154/9, Bannerghatta Road, Opp. to IIM-B, Bangalore- 560076, India ECR/378/Inst/KA/2013/RR-19	Dr.Niti Raizada
26.	State Cancer Institute,Indira Gandhi Instituteof Medical Sciences,Sheikhpura,Patna- 800014	Institutional Ethics Committee,Indira Gandhi Instituteof Medical Sciences,Sheikhpura, Patna- 800014,Bihar	Dr. Rajesh Kumar Singh

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		ECR/640/Inst/BR/2014/RR-20	
27.	Kiran Hospital Multi Super Specialty Hospital & Research Center, Near Sumul Dairy, Surat-395004, Gujarat, India	Kiran Hospital Ethics Committee, Kiran Hospital Multi Super Specialty Hospital & Research Center, Near Sumul Dairy, Surat-395004, Gujarat, India	Dr.Shanti Prakash Shrivastav
		ECR/1020/Inst/GJ/2018/RR-21	
28.	The Gujarat Cancer and Research Institute, M.P. Shah Cancer Hospital, New Civil Hospital Campus, Asarwa, Ahmedabad - 380016, Gujarat, India	GCRI/GCS Ethics Committee, The Gujarat Cancer and Research Institute, M.P. Shah Cancer Hospital, New Civil Hospital Campus, Asarwa, Ahmedabad -380016, Gujarat, India	Dr.Harsha P. Panchal
		ECR/41/Inst/GJ/2013/RR-19	
29.	HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik- 422002, Maharashtra, India	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik-422002, Maharashtra, India	Dr.Rajnish Nagarkar
	LIGO NOUBLOANGER	ECR/500/Inst/MH/2013/RR-20	D. Ala Carralad
30.	HCG NCHRI CANCER CENTRE,50,51 Mouja Wanjri, Bande Nawaz Nagar,NearAutomotive square, Kalamna Ring Road, Nagpur-440026Maharashtra, India	HCG NCHRI Cancer Centre- Institutional Ethics Committee, 50, .51 Mouja Wanjri, Bande Nawaz Nagar,Near Automotive square, Kalamna Ring Road, Nagpur-440026-Maharashtra, India	Dr. Ajay Omprakash Mehta
		ECR/108/Inst/MH/2013/RR-20	
31.	HematoOncology Clinic Ahmedabad Pvt Ltd, Opp. HDFC 8ank, Beside Occura Eye Hospital & Pandit Deeyandayal Auditorium,Rajpath Club Road Lane. OffS. G. Highway, Ahmedabad	Ethics Committee of CIMS (Care Institute of Medical Sciences),Care Institute of Medical Sciences,Near Shukan Mall, Off Science City Road, Sola, Ahmedabad- 380060 Gujarat,India	Dr. Chirag Jyotiker Desai
	380054, Gujarat, India	ECR/206/Inst/GJ/2013/RR-20	
32.	King George's Medical University, Shah Mina Road, chowk, Lucknow-226003, U.P., India	Institutional Ethics Committee, King George's Medical University, ShatabdiHospital phase II Shah Mina Road, Chowk, Lucknow-226003, U.P., India	Dr Anand Kumar Mishra

		ECR/262/Inst/UP/2013/RR-19	
33.	Department of Radiation Oncology, Government Medical College & Medical college Square Road, Nagpur-440003, Maharashtra, India	Institutional Ethics Committee, Department of Pharmacology, Government Medical College, Nagpur-440003, Maharashtra, India ECR/43/Inst/MH/2013/RR-19	Dr. Ashok Kumar Diwan
34.	HCG City Cancer Centre, 33- 25-33, Ch Venkata Krishnayya Street, Suryarao Pet, Vijayawada-520002, Andhra Pradesh, India	Institutional Ethics Committee, HCG Curie City Cancer Centre, 44-1-1/3, Beside Gowthami Public School, Padavala Revu, Gunadala, Vijayawada-520004 Andhra Pradesh, India	Dr.Gopichand Mamillapalli