



Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
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. BIO/CT/22/000023

Dated-29-Sep-2022

To,

M/s. Zydus Lifesciences Ltd.,
Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,
Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A,
Village-Changodar, Taluka - Sanand Gujarat -382213 (India)

Sir,

With reference to your application ref. No. BIO/FormCT10/TL/2022/52942 dated 15-Feb-2022, please find enclosed herewith the permission to manufacture new drugs for "clinical trial purposes" bearing licence No. CT11/BIO/22/000142 under the provisions of New Drugs and Clinical Trials Rules, 2019 mentioned therein.

You may obtain the relevant manufacturing license under the provisions of Drugs and Cosmetics Rules, 1945 from the concerned State Licensing Authority.

It may please be noted that the drug product which are stated as new drugs in the enclosed Form CT-11 should not be utilized in any form in commercial market and shall be used only in the clinical study titled "A Phase III, Prospective, Randomized, Multicenter, Comparative, Double blind, Parallel-group Study to Investigate the Efficacy, Safety, and Pharmacokinetics of ZRC-3276 Versus Opdivo® (Nivolumab) in Subjects with locally advanced or Metastatic Non-Small Cell Lung Cancer" vide protocol No.: NIVO.22.001 version 01 dated 29.01.2022.

Kindly acknowledge receipt of this letter and its enclosures.

Yours faithfully,

VENUGOP

AL G

SOMANI v. C. Somani

Drugs Controller General (India)

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER GENERAL (INDIA),
pseudoym=112046a34e21727ba2b2557
48732c456d240073e5e953d9d5b5b748
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serialNumber=e972d1a0c0bba41522525
f1eaf705071b4997ed6b24b6c0b81c19b2d4
2022.09.29 14:19:19

Copy together with a copy of License No. CT11/BIO/22/000142

Forwarded for information to:-

- 1) Deputy Drugs Controller (India), CDSCO Zonal Office, Air Cargo Complex, Old Terminal Building, Airport, Ahmedabad-380003.
- 2) The Commissioner, Food & Drugs Control Administration, Block no. 8, 1st Floor, Dr. Jivraj Mehta Bhavan, Gandhinagar-382010, Gujarat State, India.



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E-Mail: dci@nic.in

File No. BIO/CT/22/000023

Dated: 29-Sep-2022

To,

M/s Zydus Lifesciences Limited,
Zydus Corporate Park, Scheme No. 63,
Survey No. 536, Khoraj (Gandhinagar),
Nr. Vaishnodevi Circle, S.G Highway, Ahmedabad-,
Gujarat (India) - 382481

Sir,

With reference to your application ref. No. BIO/FormCT16/TL/2022/114566 dated 11-FEB-2022, application ref. No. BIO/FormCT16/TL/2022/114575 dated 11-FEB-2022, application ref. No. BIO/FormCT16/TL/2022/114578 dated 11-FEB-2022, application ref. No. BIO/FormCT16/TL/2022/114579 dated 11-FEB-2022, application ref. No. BIO/FormCT16/TL/2022/114581 dated 11-FEB-2022 and application ref. No. BIO/FormCT16/TL/2022/114582 dated 11-FEB-2022, please find enclosed herewith the licence bearing licence No. TL/BIO/22/000069 to import new drugs or investigational new drug for the purpose of clinical trial under the provisions of New Drugs and Clinical Trials Rules, 2019 mentioned therein.

The drug imported under this permission shall be used exclusively for the purpose of clinical trial study titled "A Phase III, Prospective, Randomized, Multicenter, Comparative, Double blind, Parallel-group Study to Investigate the Efficacy, Safety, and Pharmacokinetics of ZRC-3276 Versus Opdivo® (Nivolumab) in Subjects with locally advanced or Metastatic Non-Small Cell Lung Cancer" vide protocol No.: NIVO.22.001 version 01 dated 29.01.2022 and no part of it shall be diverted to the domestic market.

Kindly acknowledge receipt of this letter and its enclosures.

Yours faithfully,

VENUGOPA
L G SOMANI
(Dr. V. G. Somani)

Drugs Controller General (India)

Digitally signed by VENUGOPA L G SOMANI
DN: cn=IN, o=CENTRAL DRUGS STANDARD
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CONTROLLER GENERAL (INDIA),
pseudoDn=112046a34e21727ba0b255748
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13c, postalCode=110002, st=DELHI,
serialNumber=97241a0c0b0a11522525f6
a0705072b499e02b46c0d81c7f9e0a0f
Page: 2/2

Copy together with a copy of License No. TL/BIO/22/000069

Forwarded for information to:-

All port offices of CDSCO



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Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/22/000023

Dated: 29-Sep-2022

To,

M/s. Zydus Lifesciences Ltd.,
Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,
Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A,
Village-Changodar, Taluka - Sanand Gujarat -382213 (India)

Subject: Application for grant of permission to conduct clinical trial entitled "A Phase III, Prospective, Randomized, Multicenter, Comparative, Double-blind, Parallel-group, Study to Investigate the Efficacy, Safety, and Pharmacokinetics of ZRC-3276 Versus Opdivo® (Nivolumab) in Subject with locally advanced or Metastatic Non-Small Cell Lung Cancer", as per study protocol no. NIVO.22.001 version 01 dated 29.01.2022- regarding

Ref.: Your Application No. BIO/CT04/FF/2022/30668 dated 04-Mar-2022

Sir,

With reference to your above referred application dated 04-Mar-2022, 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) The firm shall ensure that the no. of evaluable subjects shall not be less than hundred in test arm for the subject Phase III clinical trial as per the 'Guidelines on Similar Biologics, 2016'.
- (II) The firm should submit copy of valid insurance certificate mentioning the protocol title and number before initiation of the study to this office.
- (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 Licensing 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) 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;
- (XVII) 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;

- (XVIII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XIX) 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.

Yours faithfully,

VENUGOPAL G SOMANI
AL G
SOMANI
(Dr. V.G. Somani)
Drugs Controller General (India)

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CONTROLLER GENERAL (INDIA),
serialNumber=92741a0c08b415225258fca
070507464997a6b2f4b5c8b81c282adeaf5d,
email=VENUGOPAL.G.SOMANI@cdsco.gov.in,
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FORM CT-11

(See rules 53, 54, 55, 56, 57 and 58)

PERMISSION TO MANUFACTURE NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR CLINICAL TRIAL

Licence Number: CT11/BIO/22/000142

The Central Licensing Authority hereby grants permission to M/s Zydus Lifesciences Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village-Changodar, Taluka - Sanand Gujarat -382213 (India) to manufacture the new drug or investigational new drug for purpose of clinical trial vide Protocol No.: NIVO.22.001 version 01 dated 29.01.2022 in the below mentioned clinical trial sites [As per Annexure].

S. No.	Name of the new drug or investigational new drug to be manufactured	Class of new drug or investigational New drug	Quantity to be manufactured
1.	Nivolumab (DS)	Monoclonal antibodies	1740 gram (g)
2.	Nivolumab 100 mg/10mL (DP)	Monoclonal antibodies	15000 Vials

2. This licence is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.
3. This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
4. Details of manufacturer and manufacturing site for formulation under this licence.

S. No.	Name and address of manufacturer (API & Formulation)	Name and address of manufacturer (API & Formulation)
1.	M/s Zydus Lifesciences Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to Address 47, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village-Changodar, Taluka - Sanand Gujarat -382213 (India) CONTACT: 02717664605 FAX: 02717664605	M/s Zydus Lifesciences Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to Address 47, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village-Changodar, Taluka - Sanand Gujarat -382213 (India) CONTACT: 02717664605 FAX: 02717664605

Place: New Delhi
Date: 29.09.2022

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

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32c456d249073e5e953d9c3b58748ee3113
c postalCode=110002, st=DELHI,
serialNumber=997241a0c0bba15225259fc
a0705074b49976eb2f4b5c8d81cf282adeaf5d,
email=VENUGOPAL.G.SOMANI@cdg.gov.in,
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Conditions

- 1) After obtaining permission in CT-11 or CT-14 or CT-15 as the case may be, the person, who intends to manufacture the new drug or investigational new drugs for CT or BA/BE study or for examination, test and analysis of new drugs or investigational new drugs, shall make an application for grant of license to manufacture the new drug or investigational new drugs by the respective State Licensing Authority (SLA) in accordance with the provisions of the Act and the Drugs and Cosmetics Rules, 1945.
- 2) This licence for manufacture of drugs is only for clinical trial purpose only and should not be utilized in any form in commercial market.
- 3) The licensee shall adhere to the relevant provisions of the Drugs and Cosmetics Act, 1940 and The New Drugs and Clinical Trials Rules, 2019.
- 4) In case of Narcotics/Psychotropic Drugs, you are also directed to approach The Narcotic Commissioner of India, 19th The Mall Morar, Gwalior-6 so far as the provisions of the NDPS Act and the Rules are concerned in the matter.

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
M/s Sanjeevani CBCC USA Cancer Hospital, in front of Jain Mandir Dawada Colony, Panchpedi Naka, Raipur, C.G. 492001	Ethics Committee, Sanjeevani Cancer Hospital Sanjeevani CBCC USA Cancer Hospital Front Of Jain Mandir Dawada Colony Pachpedi Naka Raipur Raipur Chhattishgarh - 492001 India <u>EC Reg. No.</u> ECR/818/Inst/CG/2016/RR-19	Dr. Aniket Thoke
M/s Unique Hospital Multispeciality & Research Institute, Opp. Kiran Motors, Nr. Canal, Civil Hospital Char Rasta - Sosyo Circle Lane, Off. Ring Road, Surat, Gujarat. 395002	Ethics committee, Unique Hospital Unique Hospital Opp. kiran motors, nr. canal, civil char rasta sosyo circle lane, off. ring road, surat Surat Gujarat - 395002 India <u>EC Reg. No.</u> ECR/595/Inst/GJ/2014/RR-20	Dr. Ankit Patel
M/s Sparsh Hospital and Critical Care, A 407 Back Side of Kalyan Jewellers, Shaheed nagar, Bhubaneswar, Odisha, 751007.	Institutional Ethics Committee Sparsh Hospital Sparsh Hospitals and Critical Care Private Limited Plot no-A/407 Saheed Nagar Bhubaneswar Khordha Orissa - 751007 India <u>EC Reg. No.</u> ECR/68/Inst/OR/2013/RR-19	Dr. Ghansyam Biwas
M/s Srinivasam cancer care multispeciality hospital, #36. 1st A Main Road, 5th cross, Nethravathi street, Maruthinagar, Nagarbhavi, Main Road, Bangalore, Karnataka - 560072	SCCMH- IEC Srinivasam cancer care multispeciality hospital No.36 1 st A Main Road, 5th Cross Nethravathi Street, Maruthinagar Bangalore Urban Bengaluru (Bangalore) Urban Karnataka – 560072, India <u>EC Reg. No.</u> ECR/193/Inst/KA/2013/RR-20	Dr. K C Lakhmaiah
M/s Netaji Subhas Chandra Bose Cancer Hospital, 3081, Nayabad New Garia, Kolkata, W.B. - 700094	Institutional Ethics Committee, Netaji Subhas Chandra Bose Cancer Research Institute, 16A, Park Lane, Kolkata, West Bengal - 700016 <u>EC Reg. No.</u> ECR/286/Inst/WB/2013/RR-19	Dr. Tanmoy Kumar Mandal
M/s Health Care Global Enterproses Ltd., HCG	HCG Central Ethics Committee HCG- Bangalore institute of	Dr. Satheesh CT

Tower, #8, P Kalinga Rao Road, Sampangi Ram Nagar, Bangalore-560027	Oncology HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India <u>EC Reg. No.</u> ECR/386/Inst/KA/2013/RR-19	
M/s HCG Cancer Center, Sola-Science City Road, Near Sola Bridge, S. G. Highway, Ahmedabad, Gujarat-380060.	HCG Multi Specialty Ethics Committee, HCG Hospitals Mithakali Ellisbridge Ahmedabad Ahmedabad Gujarat - 380006 India <u>EC Reg. No.</u> ECR/92/Inst/GJ/2013/RR-19	Dr. Ashish Kaushal

FORM CT-17

(See rules 68, 69, 70, 71 and 72)

LICENCE TO IMPORT NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR THE PURPOSE OF CLINICAL TRIAL

Licence Number: **TL/BIO/22/000069**

The Central Licencing Authority hereby grants licence to M/s Zydus Lifesciences Limited, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G Highway, Ahmedabad-, Gujarat (India) - 382481 to import new drug or investigational new drug from Bulgaria/Germany/Switzerland/United Kingdom/Turkey/Latvia for conduct of clinical trial study as per protocol number NIVO.22.001 version 01 dated 29.01.2022 at the below mentioned clinical trial sites [As per Annexure].

S. No.	Name of the new drug or investigational new drug to be imported	Therapeutic class of new drug or investigational new drug	Quantity to be imported*
1	Nivolumab (Opdivo®); 100 mg/10mL	Monoclonal antibodies	5219 Vials

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.
3. This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
4. Details of overseas manufacturer and manufacturing site under this licence.

S. No.	Name and address of manufacturer	Name and address of manufacturing site
01.	<u>Test Product:</u> M/s Zydus Lifesciences Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to Address 47, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village-Changodar, Taluka - Sanand Gujarat -382213 (India) <u>Reference Product :</u> M/s Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2 Dublin 15, D15 T867 Ireland, Dublin (Ireland) - D15 T867 Telephone No.: 35314833625	<u>Test Product:</u> M/s Zydus Lifesciences Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to Address 47, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village-Changodar, Taluka - Sanand Gujarat -382213 (India) <u>Reference Product :</u> M/s Swords Laboratories t/a Bristol-Myers Squibb Cruiserath Biologics, Cruiserath Road, Mulhuddart Dublin 15, D15 H6EF Ireland, Dublin (Ireland) - D15 H6EF Telephone No.: 35316764971

	FAX: 35316762517	FAX: 35316762517
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5. The licensee shall maintain the record of imported new drug or investigational new drugs.

Place: New Delhi

Date: 29.09.2022

VENUGOP

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SOMANI

(Dr. V. G. Somani)

Drugs Controller General (India)

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c=IN, email=VENUGOPAL.G.SOMANI@cdsco.gov.in,
o=CDSCO, ou=CDSCO, postalCode=110002, st=DELHI,
c=IN



Annexure:

Details of clinical trial sites:

Names and address of clinical trial site	Ethics committee details	Name of investigator
M/s Sanjeevani CBCC USA Cancer Hospital, in front of Jain Mandir Dawada Colony, Panchpedi Naka, Raipur, C.G. 492001	Ethics Committee, Sanjeevani Cancer Hospital Sanjeevani CBCC USA Cancer Hospital Front Of Jain Mandir Dawada Colony Pachpedi Naka Raipur Raipur Chhattishgarh - 492001 India <u>EC Reg. No.</u> ECR/818/Inst/CG/2016/RR-19	Dr. Aniket Thoke
M/s Unique Hospital Multispeciality & Research Institute, Opp. Kiran Motors, Nr. Canal, Civil Hospital Char Rasta - Sosyo Circle Lane, Off. Ring Road, Surat, Gujarat. 395002	Ethics committee, Unique Hospital Unique Hospital Opp. kiran motors, nr. canal, civil char rasta sosyo circle lane, off. ring road, surat Surat Gujarat - 395002 India <u>EC Reg. No.</u> ECR/595/Inst/GJ/2014/RR-20	Dr. Ankit Patel
M/s Sparsh Hospital and Critical Care, A 407 Back Side of Kalyan Jewellers, Shaheed nagar, Bhubaneswar, Odisha, 751007.	Institutional Ethics Committee Sparsh Hospital Sparsh Hospitals and Critical Care Private Limited Plot no-A/407 Saheed Nagar Bhubaneswar Khordha Orissa - 751007 India <u>EC Reg. No.</u> ECR/68/Inst/OR/2013/RR-19	Dr. Ghansyam Biwas
M/s Srinivasam cancer care multispeciality hospital, #36. 1st A Main Road, 5th cross, Nethravathi street, Maruthinagar, Nagarbhavi, Main Road, Bangalore, Karnataka - 560072	SCCMH- IEC Srinivasam cancer care multispeciality hospital No.36 1 st A Main Road, 5th Cross Nethravathi Street, Maruthinagar Bangalore Urban Bengaluru (Bangalore) Urban Karnataka - 560072, India <u>EC Reg. No.</u> ECR/193/Inst/KA/2013/RR-20	Dr. K C Lakhmaiah
M/s Netaji Subhas Chandra Bose Cancer Hospital, 3081, Nayabad New Garia, Kolkata, W.B. - 700094	Institutional Ethics Committee, Netaji Subhas Chandra Bose Cancer Research Institute, 16A, Park Lane, Kolkata, West Bengal - 700016 <u>EC Reg. No.</u> ECR/286/Inst/WB/2013/RR-19	Dr. Tanmoy Kumar Mandal
M/s Health Care Global Enterproses Ltd., HCG Tower, #8, P Kalinga Rao Road, Sampangi Ram	HCG Central Ethics Committee HCG- Bangalore institute of Oncology HCG Towers, Tower-I P. Kalinga Rao Road, Sampangiram	Dr. Satheesh CT

Nagar, Banglore-560027	Nagar Bangalore Bengaluru (Bangalore) Urban Karnataka - 560027 India <u>EC Reg. No.</u> ECR/386/Inst/KA/2013/RR-19	
M/s HCG Cancer Center, Sola-Science City Road, Near Sola Bridge, S. G. Highway, Ahmedabad, Gujarat-380060.	HCG Multi Specialty Ethics Committee, HCG Hospitals Mithakali Ellisbridge Ahmedabad Ahmedabad Gujarat - 380006 India <u>EC Reg. No.</u> ECR/92/Inst/GJ/2013/RR-19	Dr. Ashish Kaushal

