File No CT/183/12-DCG(I) Clinical Trial NOC No:- GCT/35/13

13

64331/24/12/13

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Te No: 01123236965, Fax: 01123236971
E-mail: dci@nb.nic.in, cdscog@gmail.com

File No: CT/183/12-DCG (I) Dated: 03/02/2014

To
M/s. Sanofi -Sythelabo India Ltd,
54/A, Sir Mathuradas Vasanji Road,
Andheri East, Mumabi-400 093

Subject: Permission for conducting a phase III clinical study entitled, "A randomized, Double-blind, Placebo-controlled, parallel group study to evaluate the effect of SAR236553/REGN727 on the occurrence of Cardiovascular events in patients who have recently experienced an acute coronary syndrome" – regarding.

Clinical Trial NOC No. GCT/35/13

Reference: Your letter no. 2013/12/19/EFC11570/1 dated 19/12/13 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: EFC11570 version 01 dated 17-09-2012** submitted to this Directorate.

1. Dr. Sudeep Kumar, Sanjay Gandhi PGIMS, Raebarely Road, Lucknow-226014,
2. Dr Prafulla Kerkar, K.E.M Hospital & Seth G.S. Medical College, 4th Floor, CVTC Building, Department of Cardiology, Acharya Donde Marg , Parel, Mumbai – 400012
3. Dr D Srinivas Rao, King George Hospital, Andhra Medical College, Visakhapatnam – 530002
4. Dr. Sudhir R Pawar, Lokamanya Tilak Municipal Medical College & General hospital, Dr. B R Ambedkar Road, Mumbai-400022
5. Dr. D P Sinha, ICVS, IPGME &R, SSKM Hospital, 244 Acharya Jagdish Chandra Bose Road, Kolkata-700020.6.

6. Dr. Girish Rajadhyaksh, T N Medical College & B Y L Nair Ch. Hospital Medical, Dr. A.L. Nair Road, Mumbai-400 008
7. Dr. Bhagirath Solanki, B.J. Medical College & Civil Hospital, Dept. of Internal Medicine, Civil Hospital, Asarwa, Ahmedabad-380 016
8. Dr. Prasant Bhansali, AMC MET Medical college and Sheth L. G. General Hospital, Rambag, Maninagar, Ahmedabad--380008
9. Dr. P Nagasri Haritha, Dept. of Cardiology, Govt. General Hospital, Guntur Medical college, Near Railway Station, Guntur-522004
10. Dr. Bhupesh Shah, V.S. General Hospital and Sheth Chainai Maternity Hospital and NHL Medical College, Ellis Bridge, Ahmedabad-380006
11. Dr. Santanu Guha, Calcutta Medical College, 88, College Street, Kolkata, West Bangal -700073
12. Dr. Devang Desai, Dept. of Medicine, govt. Medical College, New Civil hospital, Majuragate, Surat-395001
13. Dr. BLN Prasad, Dept. of Medicine, Rajiv Gandhi Institute of Medical Sciences & (RIMS) & Govt. General Hospital, Srikakulam-532001
14. Dr. Vijay Pathak, SMS Hospital, JLN Marg, Jaipur-302004
15. Dr. Rohidas Borse, Dept. of Medicine, B.J. Govt. Medical College and Sassoon General Hospital, Sassoon Road, Somwar Peth, Pune-411001
16. Dr. Kalashetti Suhas, KEM Hospital, 489 Rasta Peth, Sardar Moodlier Road Pune-411011
17. Dr. Narendra S Hiregoudkar, Karnataka Institute of Medical Sciences, P.B. Road, Vidyanagar, Hubli, Karnataka-22
18. Dr. Saibal Mukhopadhyay, Dept. of Cardiology, G.B. Pant Hospital, JNU Marg New Delhi-110002
19. Dr. Gurappa Gojanur, St John's Medical College and Hospital, Sarjapur Road, Bangalore-560034
20. Dr. Naresh Kumar Goyal, Max Super Speciality Hospital FC 50, C & D block, Shalimar Bagh, New Delhi-110088
21. Dr. Abraham Oomman, Apollo Hospitals 21, Greams Lane Off Greams Road, Thousand Light, Chennai- 600006.

22. Dr. Keshava Ramaiah, Fortis Hospital No 14, Cunningham Road, Sheriffs Chamber, Bangalore-560052.
23. Dr. Sachin Patil, Krishna Institute of Medical Sciences Deemed University, Karad Pune Bangalore Highway 4 Malkapur Karad Dist. Satara-415110.
24. Dr. Shamanna Iyengar, Manipal Hospital, 98, HAL Airport Road, Bangalore-560017.
25. Dr. Ramesh Byrapaneni, Medwin Hospital Raghava Ratne Towers, Chirag Ali Lane, Nampally, Hyderabad-500001.
26. Dr. Tiny Nair, PRS Hospital, Killipalam, Karnataka(PO),Trivandrum-695002.
27. Dr. Rufino Monteiro, Vintage Hospital & Medical Research Centre, Caculo enclave, St. Inez, Panji-403001.
28. Dr. Surya Prakash Gulla, Care Hospital, Near clock Tower, Market Street, Secunderabad-500003.
29. Dr. Jabir Abdullakutty, Lisie Hospital, PB# 3053, Kochi-682018.
30. Dr. Ravishankar Airody Govinda, K.R.Hospital, Opp. Mysore Medical College & Research Institute, Irwin Road, Mysore-570001.
31. Dr. Rahul Patil, Noble Hospital,Dept. of Cardiology, 153 A/1Magarpatta City, Magarpatta City Road, Hadapsar, Pune-411013.
32. Dr. Sujatha Vipperla, Indus Hospital, KGH down Road, Vishakhapatnam-530002.
33. Dr. Rituparna Shinde, Sanjeevan Hospital,Dept. of Cardiology, 23 Karve Road, Erandawane, Pune-411004.
34. Dr. Sharath Annam, Sunshine Hospital, Behind Paradise Hotel, Penderghast Road, Opp. Parsi Dharamsala, Secunderabad-500003.
35. Dr. Nitin Patki, Maharashtra Medical Foundation Joshi Hospital, Dept. of Cardiology, 778, Opp. Kamala Nehru Park, Pune-411004.
36. Dr. Ramesh Babu Pothineni, Dr. Ramesh Cardiac & Multispeciality Hospital Ltd., Ring Road, Near ITI College, Vijayawada-520008.
37. Dr .Ajit Bhagwat, Kamal Nayan Bajaj Hospital, Gut No. 43, Satara Parisar, Bajaj Marg, Beed Bypass Road, Aurangabad-431005.
38. Dr. Mohanan Padinhare, Westfort Hi-Tech Hospital Ltd., Post Box No. 930, Punkunnam, Thrissur, Kerala-680002.

39. Dr. Anand Kumar Valsakumar, Lakeshore Hospital & Research Centre, NH-47, By pass, Maradu, Nettoor Post, Kochi-682040.

Kindly note that the clinical trial permission is subject to the following conditions:

a. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations;

b. Approval of the Ethics Committee shall be obtained before initiation of the study;

c. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;

d. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority;

e. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within ten days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

f. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority;

g. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations;

h. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

j. The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc. However, under no circumstances the number of trials should be more than three at a time.

k. The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

l. You are also informed that audio visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done duly adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. All the sponsors /investigators /institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate effect.

m. It may kindly be noted that merely granting permission to conduct clinical trials 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,

(Dr. G.N. Singh)
Drugs Controller General (India)

48896/30/11/12

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
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E-mail: dci@nb.nic.in, cdscog@gmail.com

File No: CT/96/12-DCG (I) Dated: 31/01/14

To
M/s. Novartis Healthcare Private Limited,
Sandoz House, Dr. Annie Besant Road,
Worli, Mumbai – 400018.

Subject: Permission for conducting a phase III clinical study entitled, "A phase III randomized, double-blind, placebo-controlled, multicentre study of subcutaneous secukinumab in prefilled syringes to demonstrate the efficacy at 24 weeks and to assess the safety, tolerability, usability and long term efficacy upto 5 years in patients with active rheumatoid arthritis who have an inadequate response to anti-TNF α agents." – regarding.

Clinical Trial NOC No. GCT/24/13

Reference: Your letter no. nil dated 27/11/12 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: CAIN457F2311 versions 00 dated 07-06-2012** submitted to this Directorate.

1. Dr. Bhatia Girish Gokuldas, Medipoint Hospital Pvt. LTd., D.P. Road, Anuth, Pune-411007.
2. Dr. Sarathchandra Mouli Veeravalli, Krishna Institute of Medical Sciences, Secunderabad.
3. Dr. Atul Kakar, Sir Ganga Ram Hospital, Sir Ganaga Ram Hospital, Rajinder nagar, New Delhi
4. Dr. Ajit Nalawade, Inamdar Multi speciality Hospital, Fatima Nagar, Pune

Kindly note that the clinical trial permission is subject to the following conditions:

a. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations;

b. Approval of the Ethics Committee shall be obtained before initiation of the study;

c. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;

d. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority;

e. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within ten days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

f. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority;

g. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations;

h. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

j. The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available

with the Investigator etc. However, under no circumstances the number of trials should be more than three at a time.

k. The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

l. You are also informed that audio visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done duly adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. All the sponsors /investigators /institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate effect.

m. It may kindly be noted that merely granting permission to conduct clinical trials 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,

(Dr. G.N. Singh)
Drugs Controller General (India)

47040/20/09/13

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
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Te No: 01123236965, Fax: 01123236971
E-mail: dci@nb.nic.in, cdscog@gmail.com

File No: CT/11/13-DCG (I) Dated: 31/01/14

To

M/s. Boehringer Ingelheim India Pvt. Ltd.,
1102,11th Floor, Hallmark, Business Plaza,
Gurunanak Hospital, Near Gurunanak Hospital,
Bandra (East), Mumbai – 400 051.

Subject: Permission for conducting a phase III clinical study entitled, "A randomised, double-blind, placebo-controlled, phase III study to evaluate the efficacy and safety of afatinib (BIBW 2992) as adjuvant therapy after chemo-radiotherapy in primary unresected patients with stage III, IVa, or IVb locoregionally advanced head and neck squamous cell carcinoma." – regarding.

Clinical Trial NOC No. GCT/22/13

Reference: Your letter no. BI/DCGI/CT/132/2013 dated 17/09/13 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: 1200.131 versions 1.0 dated 22-01-2013** submitted to this Directorate.

1. Dr Murali Voona, Mahatma Gandhi Cancer research institute, Vishakapatnam-530017, Andhra Pradesh.
2. Dr Radheshyam Naik, HCG Bangalore Institute of Oncology, Kalinga Rao Road, Sampangi Rama Nagar, Bangalore
3. Dr Ravi Mohan, King George Hospital, Cancer Clinical Trial New Medicine Block, King George Hospital, Visakhapatnam - 530 002, AP
4. Dr. Rejnish Kumar, Regional Cancer Centre, Division of Head & Neck Radiation oncology, Medical college campus, Thiruvananthapurum, Kerala--695 011

5. Dr Sachin Almel, P. D. Hinduja National Hospital & Research Center, Mahim (West), Mumbai-400016
6. Dr. Neeti Sharma, Acharya Tulsi Regional Cancer Treatment & Research Institute, Sardar Patel. Medical college and Associated Group of Hospitals, Department of Medical Oncology, Bikaner -334001
7. Dr. A. K. Anand, Max Cancer Centre, Max Super Speciality Hospital Department of Radiation Oncology, New Delhi
8. Dr Minish Jain, Ruby Hall Clinic, 40 Sassoon Road, Pune-411001
9. Dr. Kirushna Kumar, Meenakshi Mission Hospital, Department of Oncology, Lake area, Melur Road, Madurai-625107
10. Dr. Chiramana Haritha, M.S.Patel Cancer Centre, ShriKrishna Hospital & Medical Research Centre, Gokal Nagar, Kramsad
11. Dr Amit Joshi, Tata Memorial Hospital, Dr. E Borges Marg, Parel, Mumbai - 400012, Maharashtra,
12. Dr Ghanshyam Biswas, Sparsh Hospital and Critical care, A-407, Sahed Nagar, Behind Metro House, Bhubaneshwar,
13. Dr Srinivasan V, Kamakshi Memorial Hospital, Pallikkaranai, Chennai
14. Dr. Hemant Malhotra, Birla Cancer Centre, SMS Medical College & Hospital, J L N Marg, Jaipur
15. Dr RK Grover, Delhi State Cancer research Institute, Dilshad Garden, Delhi
16. Dr BK Mohanti, Fortis Memorial research hospital, Gurgaon, Opposite to HUDA city centre metro station
17. Dr Meenu Walia, Dharamshila Hospital and research centre. Vasundra Enclave, Delhi 110095
18. Dr. Sachin Hingmire, Deenanath mangeshkar Hospital and Research Centre, Erandwane, Pune-411004
19. Dr Maheboob Basade, Jaslok Hospital and Research Centre Department of Medical Oncology, 15 - Dr. Deshmukh Marg, Pedder Road, Mumbai
20. Dr Apurva Ashokbhai Patel, The Gujarat Cancer & Research Institute, M. P. Shah Cancer Hospital, Asarwa, Ahmedabad

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Yours faithfully,

(Dr. G.N. Singh)
Drugs Controller General (India)