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D. No. 35949, P-1153864
Dated – 13.12.2018

F. No. 12-29/2009-DC (Pt-Bayer-II PMS-SND)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

Dated **15 APR 2019**

To,

M/s Bayer Pharmaceuticals Pvt., Ltd.,
Bayer House, Central Avenue,
Hiranandani Estate, Thane (West) – 400607.

Subject: Permission for conducting structured post-marketing surveillance study on Rivaroxaban tablets 2.5mg (Xarelto®) - regarding.

CT NOC No. CT/SND/19/2019

Reference: Your application dated 13.12.2018 on the subject mentioned above.

Sir,

This Directorate has no objection for conducting the structured post-marketing surveillance on Rivaroxaban tablets 2.5mg (Xarelto®) under supervision of the following investigators and sites as per the **Protocol No: 20402, Version 1.1, dated 07-08-2018** submitted to this Directorate subject to the condition that **at least 1000 patients should be included in the structured post marketing surveillance (PMS) study.**

S. No	Investigator and Trial site	Ethics Committee Name and Registration Number
1	Dr. Jitendra Pal Singh Sawhney Sir Ganga Ram Hospital, 6th floor, Clinical Research room, Dharam Veera, Heart Centre, Old Raj inder Nagar, New Delhi, Delhi, 110 060, India.	Sir Ganga Ram Hospital Ethics Committee, Room No. 1496, IV Floor, old Building, old Rajinder Nagar, New Delhi, 110060, India. Registration Number: ECR/20/INST/DL/2013/RR-16
2	Dr. Sandeep Bansal Safdarjung Hospital, Safdarjung Campus, Safdarjung, New Delhi, Delhi 110029.	Institute Ethics Committee, At Room No. 17A, Ground Floor, College building, VMMC and Safdarjung Hospital, New Delhi, 110029, India.

3	Dr. Nishith Chandra Fortis Hospital, Okhla Road, New Delhi, 1 1 0 025, India.	Independent Ethics Committee Academic and research department , Room no. 23A, IInd Floor Residential tower, Fortis Escorts Heart Institute Okhla road, New Delhi, 110025. Registration Number: ECR/261/INST/DL/2013/RR-16
4	Dr. Shireesh Sathe Deenanath Mangeshkar Hospital, Near Mhatre Bridge, Pune, Maharashtra 411004.	Institutional Ethics Committee Department of Research, 14th Floor, C Wing Super specialty Building Deenanath Mangeshkar Hospital and Research Centre, Off Karve Road, Erandwane, Pune-41100, Maharashtra, India. Registration Number: ECR/15/INST/Maha/2013/RR-16
5	Dr. Atul Abhaynkar Shree Mahavir Health and Medical Relief Society, Shri Bachubhai Dahyabhai Mehta Heart Institute, Shree Mahavir Health Campus, Athwagate, Ring Road, Surat, 395001, Gujarat, India.	Shri B. D. Mehta Mahavir Heart Institutute, Shree Mahavir Health Campus, Opposite Vanita Vishram Ground, Athwagate, Ring Road, Surat, 395001, Gujarat India.
6	Dr. Sameer Dani Apollo Hospitals International Limited, Plot No. 1A, Bhat GIDC Estate,, Gandhinagar, Gujarat 382428.	Institutional Ethics Committee- Clinical Studies (IECCS) Apollo Hospitals, Ahmedabad Apollo Hospitals International Ltd Site Office Building , Near ICICI ATM, Bhat, GIDC Estate, Gandhinagar- 382428, Gujarat India Registration Number: ECR/30/INST/GJ/2013/RR-16
7	Dr. Nazir Juvale Saifee Hospital, 15/17, Maharshi Karve Marg, Mumbai, Maharashtra 400004	Saifee Hospital, Post Box No. 3771, 15/17, Maharshi Karve Marg, Mumbai, Maharashtra 400004, India. Registration Number: ECR/159/INST/MH/2013/RR-16

8	Dr. Abraham Oomman Apollo Hospital Chennai, Department of Cardiology, No. 645/646, T.H. Road, Tondiarpet, Chennai, Tamil Nadu, 600081, India.	Institutional Ethics Committee- Clinical Studies, Apollo Hospital Enterprise Ltd. No - 21, Greams Lane, Off Greams road, Chennai, 600006, Tamil Nadu. Registration Number: ECR/37/INST/TN/2013/RR-16
9	Dr. R. Sivakumar Meenakshi Mission Hospital & Research Centre, Lake Area, Melur Road, Madurai, Tamil Nadu, 625107, India.	Institutional Ethics Committee Meenakshi Mission Hospital and Research Centre Room No. 6701, Ethics Room, 6th Floor, Lake Area, Melur Road, Madurai- 625107, Tamil Nadu, India. Registration Number: ECR/398/INST/TN/2013/RR-16
10	Dr. P. B. Mohanan WestFort HiTech Hospital, Department of Cardiology, Poonkunnam, Thrissur, Kerala, 680002, India.	Institutional Ethics Committee WestFort HiTech Hospital Room No. 206, First Floor, Main Block, Pookunnam, Trissur-680002, Kerala, India. Registration Number: ECR/222/INST/KL/2013/RR-16
11	Dr. Abdullakutty Jabir P.B Lisie Hospital, 3053, Kochi, Kerala, 682018, India.	Institutional Ethics Committee, Lisie Hospital, P. B. No 3053, Cochin 682018, Kerala, India. Registration Number: ECR/40/INST/KL/2013/RR-16
12	Dr. Keyur Parikh CIMS Hospital, Near Shukan Mall, Off. Science City Road, Sola, Ahmedabad- 380060.	Ethics Committee of Care Institute of Medical Sciences Care Institute of Medical Sciences Near Shukan Mall, Off Science City Road Ahmedabad, 380060, Gujarat, India. Registration Number: ECR/206/INST/GJ/2013/RR-16
13	Dr. Sunil Wani Kokilaben Dhirubhai Ambani Hospital, Rao Saheb Achutrao Patwardhan Marg, Four Bunglows, Andheri West, Mumbai, Maharashtra 400053.	Institutional Ethics Committee Medical Research Department, 2nd Floor, Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute Rao Saheb Achutrao Patwardhan Marg Four Bunglows, Andheri West, Mumbai, Maharashtra 400053, India. Registration Number: ECR/141/INST/MH/2013/RR-16

14	Dr. Nilesh Gautam Asian Heart Hospital, G / N Block, Bandra Kurla Complex, Bandra East, Mumbai, Maharashtra 400051.	Institutional Ethics Committee Asian Heart Institute and Research centre Pvt. Ltd G/N Block, Bandra Kurla Complex, Bandra East Mumbai- 400051 Maharashtra 400004, India Registration Number: ECR/205/INST/MH/2013/RR-16
15	Dr. Nagamallesh Madappa M.S. Ramaiah Narayana Hrudatyalaya, MSRIT Post, New BEL Road, Bangalore Karnataka, 560054, India.	Narayana Health Medical Ethics Committee Narayana Hrudayalaya Ltd Anekal Taluk, Bangalore-560099, Karnataka, India. Registration Number: ECR/390/INST/KA/2013/RR-16
16	Dr. Naveen Chander Reddy Mediciti Hospitals, 5-9-22, Secretariat Road, Hyderabad- 500063, Andhra Pradesh, India.	Mediciti Ethics Committee Maxcure Mediciti Hospital, 5-9-22, Secretariat Road, Hyderabad-500063, Andhra Pradesh, India. Registration Number: ECR/283/INST/AP/2013/RR-16
17	Dr. Babu Ramesh Pothineni Dr. Ramesh Cardiac & Multispecialty Hospital Ltd. Ring Road, Near ITI College, Vijayawada-520008, Andhra Pradesh, India.	Institutional Ethics Committee Dr. Ramesh Cardiac & Multispecialty Hospital Pvt. Ltd. Near ITI College, Ring Road Vijayawada-520008, Andhra Pradesh, India. Registration Number: ECRJ81/INST/AP/2013/RR-16
18	Dr. Sudhir Naik Apollo Hospitals, Jubilee Hills, Hyderabad, Andhra Pradesh, 500 033, India.	Institutional Ethics Committee Apollo Hospitals, (Apollo Health City) Jubilee Hills, Hyderabad, 500096 Telangana, India. Registration Number: ECR/38/INST/AP/2013/RR-16
19	Dr. Vijay Kumar Chopra Medanta Heart Institute, Department of Cardiology, Sector-38, Gurgaon Haryana, 122001, India.	Medanta Institutional Ethics Committee (MIEC) Medanta-The Medicity , Regulatory office, 2nd Floor, Opposite medical library, Training Block, Sector-38, Gurgaon, Haryana, 122001, India. Registration Number: ECR/282/INST/HR/2013/RR-16

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20	Dr. Vinod Sharma National Heart Institute, 49, Community Centre, East of Kailash, New Delhi, 110 065, India.	All India Heart Foundation, 49-50, Community Centre, East of Kailash, New Delhi, 110065, India. Registration Number: ECR/625/INST/DL/2014/RR-17
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Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)
& Licensing Authority