Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

Not intended for U.S. and UK Media

Bayer Forms Collaboration with Academic and Governmental Institutions for Rivaroxaban Study in Patients with a recent Embolic Stroke of Undetermined Source

- Embolic stroke of undetermined source is caused by a blood clot, and affects approximately 300,000 people each year in North America and Europe
- Phase III NAVIGATE ESUS study will investigate once-daily rivaroxaban for the secondary prevention of stroke in approximately 7,000 patients
- Indication-seeking trial will be conducted in partnership with Population Health Research Institute and Canadian Stroke Prevention Intervention Network

---

Leverkusen, Germany, January 27, 2015 – Bayer HealthCare, in partnership with its development partner Janssen Research & Development, LLC, announced today a collaboration with the Population Health Research Institute (PHRI) and the Canadian Stroke Prevention Intervention Network (C-SPIN) to conduct the global Phase III NAVIGATE ESUS study. The study will investigate the benefits of the once-daily, novel oral anticoagulant rivaroxaban in approximately 7,000 patients with a recent embolic stroke of undetermined source (ESUS). Enrollment of patients for the study has started successfully.

Annually, an estimated 300,000 people suffer from ESUS in North America and Europe alone. Preventing recurrence of stroke in patients with a recent ESUS is an important unmet medical need as the risk of recurrent stroke in patients on guideline-recommended antiplatelet(s) including acetylsalicylic acid (ASA), clopidogrel or ASA plus dipyridamole is three to six per cent per year.

ESUS accounts for approximately 25 per cent of all ischaemic strokes, yet the underlying cause of the ischaemic stroke cannot be identified by standard diagnostic assessments in these patients. Although there is limited knowledge or data on which to guide treatment decisions for secondary prevention, more recent information indicates that most of these

strokes are due to a blood clot that has travelled to the brain from another location in the body (embolus).

“Based on our knowledge and the clinical utility of the novel oral anticoagulants in patients with atrial fibrillation, we assume that they will be more efficacious than antiplatelet therapy for the secondary prevention of ESUS,“ said Co-Principal Investigator Dr Stuart Connolly, M.D.,FRCPC, Professor of Medicine (Cardiology), McMaster University, Hamilton, Ontario, Canada and Member of the Executive Committee of C-SPIN. “Through this partnership between the PHRI, C-SPIN, Bayer HealthCare and Janssen, we are now able to initiate the randomised clinical research and are committed to finding innovative ways to reduce the incidence of recurrent stroke.”

“The ROCKET AF study confirmed that once-daily rivaroxaban is highly effective in preventing stroke in patients with non-valvular atrial fibrillation, with and without previous stroke or transient ischaemic attack, so we believe there is potential for rivaroxaban to provide a similar protective benefit to patients with a recent ESUS,” said Dr Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Rivaroxaban is already approved to prevent and treat more venous and arterial thromboembolic conditions than any other novel oral anticoagulant, and it has the potential to benefit even more patients at risk of the serious and often life-threatening conditions caused by blood clots.”

The NAVIGATE ESUS study will contribute important knowledge to the extensive evaluation of rivaroxaban, a program that – by the time of its completion – is expected to include more than 275,000 patients in both clinical trials and real world settings.

About NAVIGATE ESUS

NAVIGATE ESUS is a randomised double-blind, event-driven superiority Phase III study of secondary prevention of stroke and prevention of systemic embolism in patients with a recent embolic stroke of undetermined source (ESUS). The study will include approximately 7,000 patients from 350 sites, across more than 25 countries worldwide. The primary efficacy outcome is the composite of the first occurrence of all recurrent strokes (ischaemic, hemorrhagic, and undefined stroke, and transient ischaemic attack (TIA) with positive neuroimaging) and systemic embolism. The primary safety outcome is modified ISTH major bleeding. Patients will be randomised to receive either rivaroxaban 15mg once daily or acetylsalicylic acid (ASA) 100mg once daily.

About the Population Health Research Institute (PHRI)
Based in Hamilton, Ontario, Canada, PHRI is Canada's premiere global health research institute and a world leader in large clinical trials and population studies. Originally formed with a focus on cardiovascular disease (CVD) and diabetes, PHRI's research areas have broadened to include population genomics, perioperative medicine, stroke, thrombosis, CV surgery, renal disease, obesity, childhood obesity, bone and trauma and implementation science. Over the years, the PHRI has developed outstanding expertise in epidemiology, population health and clinical trials. Examining biological and genetic determinants of health, as well as social, environmental and policy factors, the research focuses on the prevention of cardiovascular disease, diabetes and other common conditions. To date, PHRI studies have enrolled almost 1,000,000 participants worldwide. More information can be found at www.phri.ca.

About The Canadian Stroke Prevention Intervention Network (C-SPIN)
The Canadian Stroke Prevention Intervention Network (C-SPIN) is funded by the Canadian Institutes of Health Research (CIHR) and the Heart and Stroke Foundation of Canada. C-SPIN is a network of highly experienced members from a wide-range of scientific backgrounds, including medicine, surgery, nursing, pharmacy, population health and social sciences who aim to develop integrated stroke-prevention strategies to reduce the incidence of embolic stroke in Canada by ten per cent within ten years and address the specific challenges facing this population.

About Xarelto® (Rivaroxaban)
Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto®. Xarelto is approved for five indications across seven distinct areas of use, protecting patients across more venous and arterial thromboembolic (VAT) conditions than any other novel oral anticoagulant:

- The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors
- The treatment of deep vein thrombosis (DVT) in adults
- The treatment of pulmonary embolism (PE) in adults
- The prevention of recurrent DVT and PE in adults

- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip replacement surgery

- The prevention of VTE in adult patients undergoing elective knee replacement surgery

- The prevention of atherothrombotic events (cardiovascular death, myocardial infarction or stroke) after an Acute Coronary Syndrome in adult patients with elevated cardiac biomarkers and no prior stroke or transient ischaemic attack (TIA) when co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine

Whilst licences may differ from country to country, across all indications Xarelto is approved in more than 125 countries.

Rivaroxaban was discovered by Bayer HealthCare, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life-threatening conditions. Before initiating therapy with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of Xarelto is a very high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Xarelto Patient Card for patients to support best practice.

To learn more, please visit https://prescribe.xarelto.com
To learn more about thrombosis, please visit www.thrombosisadviser.com
To learn more about Xarelto, please visit www.xarelto.com
To learn more about the NAVIGATE ESUS study, please visit
www.multivu.com/players/English/7425851-navigate-esus-study-bayer-xarelto/

About Aspirin®

Acetylsalicylic acid, the active ingredient in Aspirin®, has been extensively investigated in more than 200 studies involving more than 200,000 patients across varying levels of cardiovascular (CV) risk. Given the existing body of clinical evidence, low-dose aspirin is approved by regulatory authorities around the world for secondary CV event prevention (i.e recurrent heart attack and ischaemic stroke). Additionally, low-dose aspirin is approved in more than 50 countries for the prevention of a first heart attack (primary prevention) in patients at appropriate risk.

When used as directed by a physician for its approved CV indications, aspirin is well-tolerated, safe and effective, and, for the vast majority of patients, is infrequently associated with clinically relevant side effects.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

Bayer AG, Investor Relations contacts:
Dr. Alexander Rosar (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Dr. Olaf Weber (+49-214-30-33567)