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

Investor News

Not intended for U.S. and UK Media

Bayer Extends Clinical Investigation of Xarelto® for the Prevention and Treatment of Life-Threatening Blood Clots in Patients with Cancer

- Cancer increases a person's risk of venous thromboembolism (VTE) four- to seven-fold, with chemotherapy increasing the risk further by up to 6.5 times
- Outside the cancer itself, blood clots are the leading cause of death in patients with cancer
- Current Clinical Guidelines lack recommendations for routine VTE prevention in most ambulatory patients with cancer
- Bayer and Janssen initiating CALLISTO, a multi-trial prospective clinical research initiative in the management of cancer-associated thrombosis

---

Leverkusen, Germany, May 28, 2015 – Bayer HealthCare and its development partner Janssen Pharmaceuticals, Inc. announced today the initiation of the CALLISTO Clinical Research Programme to explore the potential benefits of the oral Factor Xa inhibitor Xarelto® (rivaroxaban) for the prevention and treatment of pulmonary embolism and deep vein thrombosis in patients with various types of cancer.

In patients with active cancer, the risk of VTE is four to seven times higher than in people of the same age without cancer. And importantly, chemotherapy significantly increases the risk further by up to 6.5 times. Despite this, none of the current Clinical Guidelines recommend the routine use of VTE prevention in most ambulatory cancer patients. Regarding the use of anticoagulation therapy for the treatment and secondary prevention of VTE, current Clinical Guideline recommendations are based on few and small clinical trials.

"Today, there is limited evidence and guidance on the routine use of anticoagulants for the long-term treatment and prevention of pulmonary embolism and deep vein thrombosis in patients with cancer, despite blood clots being the leading cause of death in patients with cancer outside the cancer itself," said Professor Guy Meyer, Université Paris

Descartes, European Hospital Georges Pompidou, Paris, France and one of the Principal Investigators within the CALLISTO Programme. “I am optimistic that results from the CALLISTO Programme will provide important clinical insights to help reduce the risk of pulmonary embolism and deep vein thrombosis, conditions that can be treated and prevented.”

The CALLISTO Programme is a multi-trial prospective clinical research initiative aimed at generating new evidence to help manage cancer-associated thrombosis (CAT). The Programme will consist of nine initiatives in total, comprising both clinical studies and Registries, and will involve more than 4,000 patients worldwide. CALLISTO addresses three key areas of cancer-associated thrombosis:

- **Prevention of VTE**
  Evaluation of rivaroxaban in comparison to placebo for the prevention of pulmonary embolism and deep vein thrombosis in patients at high risk of blood clots undergoing chemotherapy for different forms of cancer

- **Treatment and Secondary Prevention of VTE**
  A series of five initiatives (three clinical studies and two Registries) will assess rivaroxaban for the treatment and secondary prevention of pulmonary embolism and deep vein thrombosis in patients with active cancer

- **Important Clinical Aspects**
  Three additional studies will focus on important clinical aspects such as enhancing the clinical knowledge on rivaroxaban treatment in patients with cancer receiving standard cancer therapies, e.g. chemotherapy, and the assessment of a bridging strategy between rivaroxaban and low-molecular-weight heparin in instances where chemotherapy-induced vomiting makes oral therapy challenging

“The CALLISTO Programme is an important milestone for Bayer in our ongoing work to address unmet medical needs through our experience in both oncology as well as thrombosis management,” said Dr Michael Devoy, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer of Bayer HealthCare. “CALLISTO will build on the existing clinical evidence for rivaroxaban in the prevention and treatment of potentially deadly blood clots across a broad range of indications and patients.”

The CALLISTO Clinical Research Programme will add to the overall investigation of rivaroxaban, which – by the time of its completion – is expected to include more than 275,000 patients in both clinical trials and real world settings.

About Xarelto® (Rivaroxaban)
Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto®. Xarelto is approved for seven indications, 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

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 around EUR 20.0 billion (2014), 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 60,700 employees (Dec 31, 2014) 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)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.