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Investor News

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2015 American Society of Hematology (ASH) Annual Meeting:

New Real World Data of Bayer's Xarelto® in Deep Vein Thrombosis Treatment Confirm Low Rates of Major Bleeding Seen in Pivotal Trial

- XALIA is the first published prospective real world study to confirm the benefit of a NOAC in the treatment of patients with deep vein thrombosis (DVT) in routine clinical practice
- Real world evidence from CALLISTO Research Programme shows low rates of major bleeding with Xarelto in the treatment of patients with cancer-associated thrombosis
- Real world insights expand on pivotal Clinical Trial Programme confirming the safety and effectiveness of Xarelto in a broad range of patients

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Leverkusen, Germany, December 8, 2015 – Bayer and its development partner Janssen Pharmaceuticals, Inc. today announced results from two real world studies – the non-interventional XALIA study in patients with deep vein thrombosis (DVT) and a study in patients with cancer-associated thrombosis (CAT) – both showing low rates of major bleeding and recurrent venous thromboembolism (VTE) with Xarelto® (rivaroxaban). Results from the two studies were presented at the 2015 ASH Annual Meeting, and XALIA findings were also simultaneously published in the *Lancet Haematology*.

"On average, every 37 seconds someone in the Western world dies from a venous blood clot, so it is important we understand the effectiveness and safety of available treatment options for these potentially life-threatening blood clots in real world patient populations," said XALIA Principal Investigator Professor Alexander G. G. Turpie, McMaster University and Hamilton Health Sciences in Hamilton, Ontario, Canada. "The real world insights from XALIA confirm the positive benefit-risk profile of rivaroxaban for the treatment of deep vein thrombosis that was established in the Phase III EINSTEIN DVT study, endorsing that these pivotal data for rivaroxaban can be translated to the patients physicians typically see in everyday clinical practice."

“These important findings from XALIA add to the growing prospective real world insights, including the previously reported XANTUS and XAMOS studies, confirming the safety and effectiveness of Xarelto in a broad range of patients across numerous indications,” said Dr Michael Devoy, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer of Bayer HealthCare. “At Bayer, we are committed to supporting physicians and the patients they see every day who are at risk of venous and arterial blood clots.”

In the recently initiated CALLISTO Clinical Research Programme Bayer is exploring the potential benefits of rivaroxaban in patients with cancer. The risk of VTE is four to seven times higher in patients with active cancer than in people of the same age without cancer. As part of the CALLISTO programme the Memorial Sloan Kettering Cancer Center in the U.S. has conducted a Quality Assurance Initiative (QAI) under which a Clinical Pathway was established to guide the use of rivaroxaban as an alternative to injectable LMWH for cancer-associated thrombosis. The study tracked a cohort of 200 patients with cancer-associated thrombosis and PE or symptomatic proximal DVT, whose full course of anticoagulation was with rivaroxaban.

In this study rates of major bleeding and recurrent VTE with rivaroxaban were relatively low based on results from randomized clinical trials with LMWH and VKA published to date. These results suggest that despite the majority of the solid tumor patients being at cancer stage IV, the safety and effectiveness of rivaroxaban is comparable to currently recommended LMWH with the advantage of reduced patient treatment burden, supporting and validating the ongoing use of the center’s Clinical Pathway Guidelines.

Both XALIA and CALLISTO add to the extensive 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 XALIA

XALIA is the first large-scale, prospective, observational, real world study to evaluate the safety and effectiveness of a non-VKA oral anticoagulant (NOAC) in patients with DVT in routine clinical practice. As an oral single-drug therapy, rivaroxaban demonstrated low rates of major bleeding, recurrent VTE and all-cause mortality in a broad range of patients. To help address differences in baseline characteristics between the two treatment groups, a propensity score analysis was pre-specified in the protocol. In this

analysis, major bleeding was observed in 0.8% of patients in the rivaroxaban group and 2.1% of patients in the standard anticoagulation group (propensity score-adjusted HR 0.77; 95% CI 0.40-1.50; p=0.44; n.s.), while recurrent VTE occurred in 1.4% and 2.3% of patients respectively (propensity score-adjusted HR 0.91; 95% CI 0.54-1.54; p=0.72; n.s.). All-cause mortality occurred in 0.4% of patients in the rivaroxaban group compared with 3.4% of patients in the standard anticoagulation group (propensity score-adjusted HR 0.51; 95% CI 0.24-1.07; p=0.07; n.s.). Furthermore, XALIA confirmed shorter hospital stays with rivaroxaban compared to standard anticoagulation therapy, suggesting an economic benefit by providing simplified treatment management from hospital to home without the need for injections or routine coagulation monitoring.

XALIA observed the safety and effectiveness of rivaroxaban compared to standard therapy (usually consisting of initial treatment with unfractionated heparin, LMWH, or fondaparinux, overlapping with and followed by a VKA) in patients with objectively confirmed DVT. Type, dose and duration of therapy were at the discretion of the treating physician.

The prospective, non-interventional study, designed by Bayer HealthCare and in agreement with the European Medicines Agency (EMA), included 5,142 patients with DVT from 19 countries in Europe, as well as Canada and Israel, and each patient was followed up for at least 12 months. Propensity score-adjusted analyses were performed for 2,505 patients treated with rivaroxaban and 2,010 patients treated with standard anticoagulation therapy, to account for potential imbalances between the two groups. All reported outcome events were adjudicated by a blinded Central Committee.

About CALLISTO

A multi-trial prospective clinical research programme, CALLISTO consists of a collection of nine clinical studies and Registries. The programme will involve more than 4,000 patients worldwide to generate new evidence that will help physicians better manage cancer-associated thrombosis (CAT).

One 200-patient CAT real world evidence study conducted by the Memorial Sloan Kettering Cancer Center in the U.S. evaluated the use of rivaroxaban as an alternative to LMWH for treatment of pulmonary embolism (PE) or symptomatic proximal DVT in patients with advanced cancer. Under a Quality Assurance Initiative (QAI), which was first started in January 2014, a Clinical Pathway was established to guide the use of rivaroxaban for CAT.

About Xarelto® (Rivaroxaban)

Rivaroxaban is the most broadly indicated non-vitamin K antagonist oral anticoagulant (NOAC) 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 NOAC:

- 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 130 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. (Janssen Research & Development, LLC and Janssen Pharmaceuticals, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.).

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 and agriculture. 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.

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