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Investor News

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Late-Breaking Science at ESC Congress 2015:

New Real-World Evidence Reaffirms Low Major Bleeding Rates for Bayer's Xarelto® in Patients with Non-Valvular Atrial Fibrillation

- Insights from more than 45,000 real-world patients with atrial fibrillation (AF) confirm low bleeding rates for Xarelto
- Late-breaking XANTUS study expands on ROCKET AF data, demonstrating Xarelto provides highly effective stroke prevention in both high- and lower-risk patients
- Two-year findings from an ongoing post-marketing safety surveillance (PMSS) study show rates and patterns of major bleeding to be consistent with ROCKET AF

Leverkusen, Germany, September 1, 2015 – Bayer HealthCare and its development partner Janssen Pharmaceuticals, Inc. today announced results from two real-world studies, XANTUS and a post-marketing safety surveillance (PMSS) study, both demonstrating that the rates of major bleeding in patients with atrial fibrillation (AF) taking the oral Factor Xa inhibitor Xarelto® (rivaroxaban) for stroke prevention were low in routine clinical practice and consistent with findings from the Phase III ROCKET AF clinical trial. Results from the two studies, which collectively included more than 45,000 patients from across Europe, Canada and the U.S., were presented at ESC Congress 2015. The XANTUS findings have also been accepted for publication in the European Heart Journal.

"Real-world evidence is increasingly important for physicians as it complements and expands on what is already known from clinical trials," said XANTUS Principal Investigator Professor A. John Camm, Professor of Clinical Cardiology in the Cardiovascular and Cell Sciences Research Institute at St George's University of London, UK. "XANTUS is a real-world study that does just that – the findings demonstrate the safety and effectiveness of rivaroxaban across a broader range of patients than included in the Phase III trial, specifically those at lower risk of stroke yet still in need of anticoagulation therapy. XANTUS gives physicians reassurance to prescribe rivaroxaban

as an effective and generally well-tolerated treatment option for both their high- and lower-risk patients with AF."

XANTUS, the first international, prospective real-world evidence study in patients with AF with a non-vitamin K antagonist oral anticoagulant (NOAC), reaffirms the positive benefit-risk profile of Xarelto for stroke prevention in patients with AF. This was first demonstrated in the Phase III clinical trial ROCKET AF, in which Xarelto was shown to be associated with a similar overall bleeding profile compared to warfarin with significantly lower rates of the most feared bleeding events such as intracranial and fatal bleeds, but with a significant increase in gastrointestinal bleeds. While patients in ROCKET AF were moderate to high risk with a mean $CHADS_2$ score of 3.5, patients studied in XANTUS had a lower average risk of stroke, with a mean $CHADS_2$ score of 2.0. The incidence of major bleeding in patients taking rivaroxaban was 3.6 per 100 person-years in ROCKET AF. In XANTUS, the incidence of major bleeding associated with rivaroxaban was 2.1 per 100 person-years. Additionally, the findings from the 39,052-patient PMSS study further confirm the favourable safety profile of rivaroxaban with an incidence of major bleeding of 2.9 per 100 person-years.

"Bayer is committed to supporting physicians and patients in the safe and responsible use of Xarelto," said Dr Michael Devoy, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer of Bayer HealthCare. "And as part of that commitment, these studies are invaluable as the real-world insights help physicians make more informed treatment decisions in the management of AF for the various types of patients that they see in daily clinical practice."

XANTUS and the PMSS study are part of the extensive evaluation of rivaroxaban – both completed and ongoing – that will include more than 275,000 patients in clinical trials and real-world settings.

About XANTUS

XANTUS is an international, prospective, single-arm, observational study designed by Bayer HealthCare and in agreement with the European Medicines Agency (EMA) to evaluate the safety and effectiveness of rivaroxaban for stroke prevention in 6,784 patients with non-valvular AF from 311 centres across Europe, Canada and Israel in routine clinical practice. All treatment and dosing decisions were at the discretion of the treating physicians and patients were followed up for one year or until 30 days after premature discontinuation. Bleeding events and major thromboembolic events were

centrally adjudicated by an independent committee. By the end of the observation period the majority (96.1%) of patients had not experienced treatment-emergent major bleeding, all-cause death or stroke / systemic embolism. Rates for on-treatment all-cause mortality were 1.9 events per 100 person-years. Overall, patients experienced treatment-emergent major bleeding at a rate of 2.1 events per 100 person-years; most of these major bleeds were treated using standard clinical measures. Rates of fatal bleeding were 0.2 events per 100 person-years. Critical organ bleeding occurred at a rate of 0.7 events per 100 person-years, which included intracranial haemorrhage (ICH) at a rate of 0.4 events per 100 person-years. Stroke occurred at a rate of 0.7 events per 100-person-years. 75.1% of patients reported to their physician that they were ‘very satisfied’ or ‘satisfied’ with their treatment.

About the PMSS Study

PMSS is an ongoing, five-year, retrospective, observational U.S. study designed by Janssen in conjunction with the U.S. Department of Defense (DoD) and Health ResearchTx LLC (HRTX), and in agreement with the U.S. Food and Drug Administration (FDA) as part of a post-marketing requirement, to analyse and report major bleeding events, associated risk factors and bleeding-related clinical outcomes in patients with non-valvular AF taking rivaroxaban. Researchers analysed data from January 1, 2013 to December 31, 2014 using DoD integrated electronic healthcare records. Major bleeding cases were ascertained using a validated Cunningham (2011) algorithm, which was generally consistent with, but not identical to the definition of major bleeding used in clinical studies, because it relied on retrospectively identified electronic medical records.

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, 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.

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