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Investor News

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Hot Line Session at European Society of Cardiology (ESC) Congress 2014:

Once-Daily Xarelto® from Bayer Effective and Well-Tolerated Alternative to Vitamin K Antagonists in Protecting Patients with Atrial Fibrillation who Undergo Cardioversion

- X-VeRT is the first prospective study of a novel oral anticoagulant in patients with atrial fibrillation who undergo cardioversion
- X-VeRT provides important information on the utility and practical advantages of Xarelto in early and delayed cardioversion over the use of vitamin K antagonists
- X-VeRT is part of the extensive ongoing evaluation of rivaroxaban that will include more than 275,000 patients in both clinical trials and real world settings

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Leverkusen, Germany, September 2, 2014 – Bayer HealthCare today announced results from the X-VeRT study demonstrating that once-daily Xarelto® (rivaroxaban) is an effective and well-tolerated alternative to dose-adjusted vitamin K antagonists (VKAs) such as warfarin in patients with non-valvular atrial fibrillation undergoing cardioversion. X-VeRT, the first prospective trial of a novel oral anticoagulant, showed that compared with the use of VKA, rivaroxaban was associated with a numerical reduction in the risk of cardiovascular events of 50 per cent in the composite primary efficacy outcome of stroke, transient ischemic attack, peripheral embolism, myocardial infarction and cardiovascular death, with a numerically lower risk of major bleeding of 24 per cent in the primary safety outcome. The practical advantage of using rivaroxaban was demonstrated by the shorter time to cardioversion compared to VKA. The study was designed to support previous findings of rivaroxaban in the setting of cardioversion from ROCKET AF and was not powered for statistical significance. These data were presented today during the Hot Line Session at the ESC Congress 2014, and published simultaneously in the *European Heart Journal*.

Cardioversion is a common medical procedure undertaken in patients with atrial fibrillation in order to reset the heartbeat back to a regular sinus rhythm. Without adequate anticoagulation, these patients have a risk of thromboembolic complications with stroke rates of 5-7 per cent. Current guidelines recommend at least three weeks of effective anticoagulation with VKAs (target INR 2.0-3.0) prior to cardioversion (or less if a transesophageal echocardiogram has revealed no thrombus in the left atrial or left atrial appendage) and four weeks of oral anticoagulation after the procedure. However, unstable INR levels often result in cancellation or postponement of cardioversion, underlining the need for stable, effective anticoagulation in these patients to help prevent life-threatening blood clots before, during and after the procedure.

“Until now, there has been a lack of dedicated clinical data to guide physicians on the practical use of novel oral anticoagulants in AF patients who are scheduled for cardioversion,” said Dr Riccardo Cappato, M.D., Arrhythmia and Electrophysiology Center, University of Milan, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy and Co-Principal Investigator of the X-VeRT study. “The results from the dedicated X-VeRT study indicate that once-daily rivaroxaban can provide effective blood clot protection for patients with atrial fibrillation before, during and after cardioversion, reducing the risk of unstable anticoagulation and allowing prompt elective cardioversion.”

“These important insights contribute to the expansion of our understanding of the clinical utility of Xarelto across different settings and patient populations,” said Dr Michael Devoy, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer of Bayer HealthCare. “X-VeRT is a key part of Bayer’s commitment to responsible use and is an important study in our growing clinical trial programme.”

The X-VeRT study contributes to the extensive ongoing evaluation of rivaroxaban that will include more than 275,000 patients in both clinical trials and real world settings.

About the X-VeRT Study

X-VeRT was a prospective, randomized, open-label, parallel group Phase IIIb study involving 1,504 patients with hemodynamically stable non-valvular atrial fibrillation of > 48 hours or unknown duration, recruited from 16 countries worldwide. Anticoagulation naïve or experienced patients scheduled for cardioversion were randomly assigned to rivaroxaban 20mg once daily (15mg once daily if creatinine clearance was between 30 and 49 mL/min) or INR-adjusted VKA therapy (target INR 2.0-3.0) in a 2:1 ratio. The decision regarding early cardioversion (a goal of between 1–5 days of rivaroxaban or

usual VKA therapy before the procedure) or delayed cardioversion (rivaroxaban or VKA for 3-8 weeks prior to the procedure) was taken by the local investigator. AF patients on rivaroxaban demonstrated a numerically lower risk of cardiovascular events (0.51% vs. 1.02%) compared to VKA, as well as a reassuring bleeding profile with a low major bleeding incidence risk (0.61% vs. 0.8%). Overall, the mean time between randomization and cardioversion was shorter in patients assigned to rivaroxaban (early: 1.8±1.6 days; delayed: 24.6±5.6 days) than in those assigned to VKA treatment (2.1±3.0 days; 33.7±13.1 days). The positive rivaroxaban findings were consistent in both early and delayed cardioversion strategies. These results were not statistically significant, as the trial was not powered accordingly.

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 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 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.

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