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Investor News

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Late Breaking Clinical Trial Session at Heart Rhythm 2015:

New Data on Bayer's Xarelto® Versus Vitamin K Antagonists in Patients Undergoing Catheter Ablation for Atrial Fibrillation

- VENTURE-AF is the first prospective study of a novel oral anticoagulant in patients with atrial fibrillation undergoing catheter ablation
- VENTURE-AF adds to findings from a subgroup analysis on catheter ablation of the pivotal Phase III ROCKET AF study

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Leverkusen, Germany, May 20, 2015 – Bayer HealthCare and its development partner Janssen Pharmaceuticals Inc. today announced results from the VENTURE-AF trial. In this study, once-daily Xarelto® (rivaroxaban) was investigated as an alternative to dose-adjusted Vitamin K Antagonists (VKAs) to reduce the risk of blood clots in patients with non-valvular atrial fibrillation (AF) undergoing catheter ablation. Results of the VENTURE-AF study were presented today as a late breaking presentation at the Heart Rhythm Society's 36th Annual Scientific Sessions, taking place from May 13-16 in Boston, US and were published simultaneously in the *European Heart Journal.*

Catheter ablation is a technique routinely used in patients with AF in order to restore normal heart rhythm. Bleeding and thromboembolic events are the most common complication patients with AF face when undergoing catheter ablation. Current AF Guidelines therefore recommend uninterrupted oral anticoagulation for these patients before, during and after the procedure to reduce the risk of bleeding and thromboembolic events.

VENTURE-AF was a randomised, open-label, comparative Phase IIIb exploratory trial; the first prospective study of a novel oral anticoagulant in these patients. 248 patients were randomised from 37 sites across five countries (Belgium, France, Germany, UK and US). Patients with AF scheduled for catheter ablation were randomly assigned in a 1:1 ratio to rivaroxaban 20 mg orally once-daily or to dose-adjusted VKA (target INR 2.0-3.0).

In patients treated with rivaroxaban, there were no thromboembolic events. In those patients receiving a VKA, two thromboembolic events (one vascular death and one ischaemic stroke) occurred. There was one ISTH major bleeding event in the VKA treatment arm versus none in the rivaroxaban treatment group. There were no major bleeding events in either group using TIMI and GUSTO-defined scales. The incidence of non-major bleeding events and procedure-attributable events was low for both treatment arms.

“The VENTURE-AF study provides physicians additional insights for the clinical management of patients with AF undergoing catheter ablation,” said Dr Riccardo Cappato, M.D., Arrhythmia and Electrophysiology Research Center, IRCCS Humanitas Clinical Institute, Rozzano, Milan, Italy, Head of Second Arrhythmia & EP Units, Cliniche Gavazzeni, Bergamo, Italy and Co-Principal Investigator of the VENTURE-AF study. “Catheter ablation is frequently performed in patients with AF and uninterrupted oral anticoagulation is important in these patients to protect them from the consequences of potentially devastating blood clots.”

“These study results further expand our understanding of Xarelto in the management of blood clots and add to the findings of the pivotal ROCKET AF study, investigating stroke prevention in patients with atrial fibrillation,” said Dr Michael Devoy, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer of Bayer HealthCare. “The VENTURE-AF study is part of the extensive ongoing evaluation of rivaroxaban in different settings and across patient populations at risk of venous and arterial blood clots.”

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.

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