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

Investor News

Not intended for U.S. and UK Media

12th Annual Congress of the European Cardiac Arrhythmia Society (ECAS) 2016:

New Data Reaffirm Positive Benefit-Risk Balance of Bayer's Xarelto® in Patients with Atrial Fibrillation in Daily Clinical Practice

- Insights from nearly 23,000 patients with atrial fibrillation on the prevention of stroke and incidence of intracranial haemorrhage with Xarelto vs. warfarin
- Results confirm the efficacy and safety profile of Xarelto as determined in pivotal Phase III ROCKET AF and other real-world studies

---

Leverkusen, Germany, April 18, 2016 – Bayer AG and its development partner Janssen Pharmaceuticals, Inc. today announced results from a new real-world study, REVISIT-US. In REVISIT-US reduced rates of ischemic stroke accompanied by reduced rates of intracranial haemorrhage (ICH) were seen with Xarelto® (rivaroxaban) versus warfarin in patients with non-valvular atrial fibrillation (AF). These results complement and reaffirm findings from the Phase III ROCKET AF clinical trial as well as the non-interventional XANTUS study. Results from REVISIT-US, which analysed nearly 23,000 real-world patients in the United States, were presented at the 12th Annual Congress of the European Cardiac Arrhythmia Society.

REVISIT-US was a retrospective claims analysis performed using US MarketScan claims data evaluating the real-world occurrence of ischemic stroke and intracranial haemorrhage (ICH) in patients with non-valvular AF taking either rivaroxaban or warfarin. In this real-world setting rivaroxaban (n=11,411) was seen to be associated with a non-significant 29% decrease in ischemic stroke accompanied by a significant 47% reduction in ICH vs. warfarin (n=11,411). Looking at the combined endpoint of ICH and ischemic stroke, rivaroxaban resulted in a significant 39% reduction vs. warfarin in REVISIT-US. These results confirm the positive benefit-risk-profile of Xarelto as determined in the Phase III ROCKET AF clinical trial as well as the non-interventional XANTUS study.

“In the management of patients with AF, ischemic stroke and intracranial haemorrhage are the two events both physicians and patients fear most,” said Professor Craig Coleman, Professor of Pharmacy Practice at the University of Connecticut, U.S. who presented the REVISIT-US results at ECAS. “Finding the appropriate balance of benefit and risk is always the goal. It is therefore highly reassuring to see that results from the real world continue to confirm that rivaroxaban is striking the appropriate balance of reducing stroke whilst at the same time also reducing the risk of intracranial haemorrhage in patients with non-valvular AF.”

“Although pivotal Phase III studies like ROCKET AF remain the gold standard to evaluate the efficacy and safety of a drug, real-world evidence plays an important role in complementing the knowledge about the use and impact of our medicines in everyday clinical practice,” said Dr Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG’s Pharmaceuticals Division and Bayer Chief Medical Officer. “We are pleased that study after study evaluating Xarelto in the real world across the spectrum of approved indications continues to confirm the positive benefit-risk profile of Xarelto.”

REVISIT-US adds 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 REVISIT-US

The REVISIT-US study assessed the real-world effectiveness and safety of newly-initiated rivaroxaban compared with warfarin among adult patients with non-valvular AF. A total of 11,411 warfarin patients were matched to 11,411 rivaroxaban patients using US MarketScan claims data from January 1, 2012 to October 31, 2014.

Patients in REVISIT-US had a CHA_2DS_2-VASc score of greater than or equal to two, 180 days or more of continuous medical and prescription coverage, and at least two International Classification of Diseases 9th Edition (ICD-9) diagnosis codes for non-valvular AF. Exclusion criteria included prior history of stroke, systemic embolism or intracranial haemorrhage. Using the matched cohorts, Cox regression was performed for the ischemic stroke and ICH endpoints (identified using primary ICD-9 codes only) and reported as hazard ratios and 95 percent confidence intervals. REVISIT-US selected endpoints that are most likely to be coded accurately and with less variability in claims data and of equal importance to allow for benefit-risk assessment.

The rate of ischemic stroke observed for rivaroxaban was 0.54% per year vs 0.83% per year for warfarin (HR=0.71; 95% CI 0.47-1.07). The rate of ICH observed for rivaroxaban was 0.49% per year vs 0.96% per year for warfarin (HR=0.53; 95% CI 0.35-0.79). In the Phase III ROCKET AF study rivaroxaban was associated with a similar rate of ischemic stroke vs. warfarin (1.6% per year with rivaroxaban vs. 1.6% per year with warfarin) and significantly lower rates of ICH with rivaroxaban vs. warfarin (0.5% per year vs. 0.7% per year, respectively; HR=0.67; 95% CI 0.47-0.93).

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, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer 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

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.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 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.