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News Release

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FDA report reaffirms safety profile and effectiveness of Bayer's Xarelto® in routine clinical practice

Berlin, January 16, 2018 – A report from the U.S. Food and Drug Administration (FDA) published in *Pharmacoepidemiology & Drug Safety* confirms the safety profile and effectiveness of Xarelto® (rivaroxaban) in people with atrial fibrillation (AF). The study is based on electronic healthcare data within the Mini-Sentinel safety programme in the US, reporting data on a large real-world population of over 115,000 people prescribed rivaroxaban or warfarin.

To examine the safety of both products, rates of gastrointestinal bleeding, ischemic stroke and intracranial haemorrhage in people with AF were evaluated. Findings from the study – part of the active drug safety surveillance of the FDA – noted that a lower risk of ischemic stroke and intercranial haemorrhage was associated with the use of rivaroxaban compared to warfarin, whilst the risk of gastrointestinal bleeding was lower with warfarin.

"We welcome the results of this safety analysis of Xarelto from the FDA, which are consistent with the findings we have seen in both our clinical trials and real-world studies," said Dr. Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG's Pharmaceuticals Division and Bayer Chief Medical Officer. "These FDA findings again confirm the positive benefit-risk profile of Xarelto in people with non-valvular AF."

The Sentinel Initiative began in 2008 as a multi-year program to create a national electronic system for monitoring the safety of approved and FDA-regulated medical products using electronic healthcare data from multiple sources in the US. The Mini-Sentinel is a working pilot project to develop an active surveillance system and to complement existing methods of safety monitoring.

For the full report, please visit: http://onlinelibrary.wiley.com/doi/10.1002/pds.4375/full

About Xarelto® (rivaroxaban)

Rivaroxaban is the most broadly indicated non-vitamin K antagonist oral anticoagulant (NOAC) worldwide 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) and one or more risk factors
- The treatment of pulmonary embolism (PE) in adults
- The treatment of deep vein thrombosis (DVT) in adults
- The prevention of recurrent PE and DVT 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 Prescriber's Guide for physicians and a Xarelto Patient Card for patients to support best practice.

To learn more about thrombosis, please visit www.thrombosisadviser.com
To learn more about Xarelto, please visit www.xarelto.com

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