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## Investor News

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### **New Real-World Evidence on Venous and Arterial Blood Clot Management including Bayer's Xarelto<sup>®</sup> Accepted for Presentation at ESC Congress 2016**

- New real-world data will provide further insights on the use of Xarelto across diverse patient populations seen in everyday clinical practice
  - Results from the real-world observational XAPASS study of Xarelto in everyday patients with non-valvular AF in Japan will be presented during a Late-Breaking Registries Session
  - New real-world data from REVISIT-US investigating rivaroxaban, apixaban and dabigatran, each compared with warfarin, in patients with non-valvular AF will be presented during a Poster Session
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**Leverkusen, Germany, August 22, 2016** – Bayer AG announced today that new clinical and real-world data on its oral Factor Xa inhibitor Xarelto<sup>®</sup> (rivaroxaban) will be presented at ESC Congress 2016, to be held from August 27 to 31 in Rome, Italy. Notably, a total of 20 late-breaking, oral and poster presentations will feature real-world studies, highlighting the increasing significance of real-world evidence. This is important as it better represents the diverse patient populations treated in everyday clinical practice, providing insights complementary to the Phase III clinical trials.

*Note: Per ESC Embargo Policy, all below mentioned abstracts are under embargo until the start of the ESC Press Conference or scientific presentation, whichever comes first.*

#### **Real-World Evidence in the Routine Management of Blood Clots Provides Additional Insights Beyond the Randomised Clinical Trials**

The real-world observational XAPASS study investigating the safety and effectiveness of rivaroxaban in patients with non-valvular atrial fibrillation (AF) in Japan will be presented as part of a Late-Breaking Registry Session:

- [\*XAPASS: Evidence of Safety and Effectiveness in Japanese Patients Treated with Rivaroxaban for Stroke Prevention in Atrial Fibrillation under Real-World Clinical Practice\*](#)
  - Oral Session: Registries atrial fibrillation
  - Monday 29 August, 09:15-09:30, Raphael – The Hub

A further 13 oral and poster presentations will provide new real-world insights on venous and arterial blood clot management:

In patients with atrial fibrillation:

- [\*Major bleeding among patients with atrial fibrillation treated with rivaroxaban or warfarin in Sweden. Interim results from an on-going post-authorization study\*](#)
  - Oral Session: Are you still afraid about bleeding risk of antithrombotic therapy in atrial fibrillation?
  - Sunday 28 August, 14:54-15:12, Minsk – Village 4
- [\*The CHA<sub>2</sub>DS<sub>2</sub>-VASc score strongly correlates with glomerular filtration rate and predicts decline in renal function over time in patients with atrial fibrillation and chronic kidney disease\*](#)
  - Rapid Fire Abstract: Clinical features and management of atrial fibrillation
  - Monday 29 August, 09:33-09:42, Agora 1 – Poster Area
- [\*Real-world evidence of stroke prevention in patients with non-valvular atrial fibrillation in the United States: the REVISIT-US study\*](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation II
  - Sunday 28 August, 14:00-18:00, Poster Area
- [\*Real-world evidence of stroke prevention in patients with non-valvular atrial fibrillation\*](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation II
  - Sunday 28 August, 14:00-18:00, Poster Area
- [\*Economic Evaluation of Rivaroxaban versus Acenocoumarol in the Prevention of Stroke in Patients with Non-valvular Atrial Fibrillation in Spain\*](#)
  - Poster Session 3: Stroke and more
  - Sunday 28 August, 14:00-18:00, Poster Area
- [\*Predictors of major bleeding in patients with atrial fibrillation treated with rivaroxaban in XANTUS: findings from a real-world prospective study\*](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation III
  - Sunday 28 August, 14:00-18:00, Poster Area
- [\*Oral anticoagulant prescribing patterns for stroke prevention in atrial fibrillation among general practitioners and cardiologists in three European countries\*](#)

- Poster Session 3: Anticoagulation in atrial fibrillation III
- Sunday 28 August, 14:00-18:00, Poster Area

In patients with a pulmonary embolism and / or deep vein thrombosis:

- [\*Is Rivaroxaban Associated with Shorter Hospital Stays and Reduced Costs vs. Parenteral Bridging to Warfarin Among Pulmonary Embolism Patients?\*](#)
  - Oral Session: Optimizing the treatment of pulmonary embolism
  - Sunday 28 August, 17:24-17:42, Vienne – Village 9
- [\*Subgroup analysis of patients with concomitant pulmonary embolism in XALIA, a non-interventional study of rivaroxaban in routine treatment of deep vein thrombosis\*](#)
  - Moderated Poster Session: Advances in pulmonary embolism
  - Monday 29 August, 15:35-15:42, Moderated Poster Station, Poster Area
- [\*Risk of Venous Thromboembolism Recurrences in Patients who Continued versus Discontinued Rivaroxaban Therapy After an Initial Six-month Therapy\*](#)
  - Rapid Fire Abstract: Antithrombotics in daily clinical practice
  - Tuesday 30 August, 16:39-16:48, Galileo – The Hub
- [\*Outcomes Associated with Observation Versus Inpatient Stays for Pulmonary Embolism\*](#)
  - Poster Session 4: Acute pulmonary embolism
  - Monday 29 August, 08:30-12:30, Poster Area
- [\*Hospitalizations and Other Healthcare Resource Utilization among Patients with Deep Vein Thrombosis Treated with Rivaroxaban versus Low-Molecular-Weight Heparin and Warfarin in the Outpatient Setting\*](#)
  - Poster Session 4: Thrombosis and coagulation
  - Monday 29 August, 08:30-12:30, Poster Area
- [\*External Validation of a Multivariable Claims-Based Prediction Rule for In-Hospital Pulmonary Embolism Mortality\*](#)
  - Poster Session 4: Acute pulmonary embolism
  - Monday 29 August, 08:30-12:30, Poster Area

Additionally, six presentations from the independent GARFIELD-AF (Global Anticoagulant Registry in the FIELD) and ORBIT-AF (Outcomes Registry for Better Informed Treatment of Atrial Fibrillation) Registries will provide new real-world insights on diagnosis and treatment patterns in patients with non-valvular AF:

- [Identifying patients with atrial fibrillation and "truly low" thromboembolic risk who are poorly characterized by CHA<sub>2</sub>DS<sub>2</sub>-VASc: Superior performance of a novel machine learning tool in GARFIELD-AF](#)
  - Late-Breaking Oral Session: Registries atrial fibrillation
  - Monday 29 August, 08:30-08:45, Raphael – The Hub
- [Association of Inappropriate Dosing of Non-Vitamin K Oral Anticoagulants and Risk of Adverse Events: Results from the ORBIT-AF II Registry](#)
  - Late-Breaking Oral Session: Registries atrial fibrillation
  - Monday 29 August, 09:30-09:45, Raphael – The Hub
- [Patterns of Amiodarone Use and Outcomes in Clinical Practice for Atrial Fibrillation: insights from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation \(ORBIT-AF\)](#)
  - Poster Session 4: Miscellaneous in arrhythmia
  - Monday 29 August, 08:30-12:30, Poster Area
- [Pharmacotherapy for atrial fibrillation in patients with chronic kidney disease: insights from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation \(ORBIT-AF\)](#)
  - Poster Session 4: Miscellaneous in arrhythmia
  - Monday 29 August, 08:30-12:30, Poster Area
- [Do baseline characteristics account for geographical variations in event rates in patients with newly diagnosed atrial fibrillation? The GARFIELD-AF registry](#)
  - Moderated Poster Session: Antithrombotic therapy in atrial fibrillation 1
  - Monday 29 August, 15:56-16:03, Moderated Poster Station, Poster Area
- [Vitamin K antagonist control for patients with nonvalvular atrial fibrillation in Eastern and Southeastern Asia: An analysis of event rates from GARFIELD-AF](#)
  - Moderated Poster Session: Antithrombotic therapy in atrial fibrillation 2
  - Tuesday 30 August, 10:35-10:45, Moderated Poster Station, Poster Area

## **Sub-Analyses of Phase III Studies Offer Clinical Insights on Rivaroxaban in Patients with non-valvular AF**

Sub-analyses of the Phase III ROCKET AF and X-TRA studies will provide clinical insights on the use of rivaroxaban in patients with non-valvular AF, including:

- [Systemic embolization in patients with atrial fibrillation: results from ROCKET AF](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation III
  - Sunday 28 August, 14:00-18:00, Poster Area
- [Left atrial thrombus resolution in atrial fibrillation or flutter: results of a prospective study with rivaroxaban \(X-TRA\) and a retrospective observational registry providing baseline data \(CLOT-AF\)](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation II
  - Sunday 28 August, 14:00-18:00, Poster Area
- [Left atrial thrombus resolution in non-valvular atrial fibrillation or flutter: results of a prospective study with rivaroxaban \(X-TRA\) – biomarker substudy](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation II
  - Sunday 28 August, 14:00-18:00, Poster Area
- [Net clinical benefit of rivaroxaban compared with warfarin in patients with atrial fibrillation](#)
  - Poster Session 3: Anticoagulation in atrial fibrillation II
  - Sunday 28 August, 14:00-18:00, Poster Area

## **New Study on Rivaroxaban Addresses Area of Unmet Medical Need**

An oral presentation of the GALILEO study, which will investigate the clinical utility of rivaroxaban in patients following transcatheter aortic valve replacement (TAVR):

- [GALILEO: Rivaroxaban in TAVR patients](#)
  - Special Session: The future is in the pipeline
  - Tuesday 30 August, 10:30-10:40, Agora 1 – Poster Area

## **About Xarelto<sup>®</sup> (Rivaroxaban)**

Rivaroxaban is the most broadly indicated non-vitamin K antagonist oral anticoagulant (NOAC) and is marketed under the brand name Xarelto<sup>®</sup>. 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 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 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](http://www.thrombosisadviser.com)

To learn more about Xarelto, please visit [www.xarelto.com](http://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](http://www.bayer.com).

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### **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](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.