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Investor News

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American College of Cardiology 66th Annual Scientific Session (ACC.17):

EINSTEIN CHOICE Study with Bayer's Rivaroxaban Accepted for Late-Breaking Clinical Trial Presentation at ACC.17

Leverkusen, Germany, March 6, 2017 – Bayer AG and its development partner Janssen Pharmaceuticals, Inc. announced today that results from the Phase III EINSTEIN CHOICE study with the oral Factor Xa inhibitor rivaroxaban (Xarelto®) will be presented as part of a Late-Breaking Clinical Trial Session on Saturday, March 18th as part of the upcoming American College of Cardiology 66th Annual Scientific Session, which will take place in Washington, D.C., USA, from March 17 to 19.

The Phase III EINSTEIN CHOICE study investigated the efficacy and safety of two doses of rivaroxaban (10 mg once daily and 20 mg once daily) versus aspirin (100 mg once daily) for the extended treatment of patients with a venous thromboembolism (VTE), who had previously completed 6 to 12 months of anticoagulation therapy.[1] VTE includes pulmonary embolism and deep vein thrombosis and is the third most common cause of cardiovascular death after heart attack and stroke.[2] Existing Guidelines recommend anticoagulation therapy for three months or longer for patients with an initial VTE.[3] However, the risk for patients with unprovoked VTE or with ongoing risk factors experiencing a second event is up to 10 percent in the first year if treatment is stopped.[4] In clinical practice physicians need to carefully assess how long to provide anticoagulation therapy for the individual patient following the initial treatment phase and also which treatment regimen may best align with the benefit-risk profile of the individual patient.

Additionally, results from the Phase II GEMINI ACS 1 study will be presented as part of the same Late-Breaking Clinical Trial session at ACC.17. GEMINI ACS 1 assessed the safety of dual antithrombotic therapy of rivaroxaban 2.5 mg twice daily in combination with clopidogrel or ticagrelor compared with dual antiplatelet therapy of aspirin 100 mg

once daily in combination with clopidogrel or ticagrelor in patients with a recent acute coronary syndrome (ACS).

Late-Breaking Clinical Trial Data on Rivaroxaban:

Late-Breaking Clinical Trial Session 404
Saturday 18 March, 08:00-08:25 EDT, Main Tent, Hall D

- *EINSTEIN CHOICE: Rivaroxaban or Aspirin for Extended Treatment of Venous Thromboembolism*
- *GEMINI ACS 1: A Randomized Trial Evaluating Clinically Significant Bleeding With Low-Dose Rivaroxaban Versus Aspirin, in Addition to P2Y12 Inhibition, for Patients After Acute Coronary Syndromes*

Furthermore, new clinical and real-world insights on rivaroxaban will be presented in oral and poster sessions at ACC.17:

- *Rates of Oral Anticoagulant Use, While Improving Over Time, Remain Low Among Hospitalized Patients with Atrial Fibrillation*
    - Poster Session 1110 - Fibrillatory Arrhythmias: Outcomes With Contemporary Practice
    - Friday 17 March, 10:00-10:45 EDT, Poster Hall, Hall C

- *Incremental Risk of Ischemic Stroke Over Time in Newly Diagnosed Heart Failure Patients without Atrial Fibrillation*
    - Poster Session 1123 - Making Progress in Understanding Heart Failure
    - Friday 17 March, 10:00-10:45 EDT, Poster Hall, Hall C

- *A Benefit-Risk Analysis of Recurrent Venous Thromboembolism in Patients Who Continued Versus Discontinued Rivaroxaban Therapy After an Initial Six-Month Therapy*
    - Oral Session 904 - Highlighted Original Research: Pulmonary Hypertension and Venous Thromboembolic Disease and the Year in Review
    - Saturday 18 March, 08:12-08:22 EDT, Room 147B

- *Thrombolytic Therapy in Anticoagulated Patients: Case Series From Rivaroxaban Versus Warfarin in Nonvalvular Atrial Fibrillation (ROCKET AF)*
    - Poster Session 1189 - Arrhythmias and Clinical EP: Anticoagulation Issues
    - Saturday 18 March, 09:45-10:30 EDT, Poster Hall, Hall C

- *Real-World Versus Randomized Trial Outcomes in Similar Populations of Rivaroxaban-Treated Patients with Nonvalvular Atrial Fibrillation in ROCKET AF and XANTUS*
    - Poster Session 1189 - Arrhythmias and Clinical EP: Anticoagulation Issues
    - Saturday 18 March, 09:45-10:30 EDT, Poster Hall, Hall C

- *Effectiveness and Safety of Apixaban and Rivaroxaban Versus Warfarin for the Secondary Prevention of Stroke or Systemic Embolism Among Nonvalvular Atrial Fibrillation Patients*
    - Poster Session 1190 - Atrial Fibrillation and VT: Specific Situations and Newer Outcome Measures
    - Saturday 18 March, 09:45-10:30 EDT, Poster Hall, Hall C

- *Rivaroxaban Users Have Significantly Less Treatment Discontinuation Compared with Users of Other Oral Anticoagulants in Non-Valvular Atrial Fibrillation*
    - Poster Session 1252 - Antithrombotic Therapy in Ischemic Heart Disease
    - Saturday 18 March, 15:45-16:30 EDT, Poster Hall, Hall C

- *Impact of Comorbid Coronary Artery Disease and Severe Peripheral Artery Disease on Major Adverse Cardiovascular Events*
    - Poster Session 1287 - Interventional Cardiology: PCI in Complex Patients
    - Sunday 19 March, 09:45-10:30 EDT, Poster Hall, Hall C

Separately, an investigator-initiated study, as well as independent studies from the GARFIELD-AF (Global Anticoagulant Registry in the FIELD-Atrial Fibrillation) 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 atrial fibrillation:

- *Treatment And Outcomes of Patients With Nonvalvular Atrial Fibrillation According to Guideline-Defined Anticoagulation Thresholds: Results From the GARFIELD-AF Registry*
    - Poster Session 1110 - Fibrillatory Arrhythmias: Outcomes With Contemporary Practice
    - Friday 17 March, 10:00-10:45 EDT, Poster Hall, Hall C

- *Designing Tailored Health Messaging To Enhance Patient-Centred Care in Non-Valvular Atrial Fibrillation*
    - Poster Session 1130 - Innovations in Practice Management and Social Media
    - Friday 17 March, 10:00-10:45 EDT, Poster Hall, Hall C

- *Early Mortality in Patients With New Onset Atrial Fibrillation: Results From the GARFIELD-AF Registry*
    - Moderated Poster Session 1134M - Atrial Fibrillation, Anticoagulation and Novel Device Therapies
    - Friday 17 March, 11:00-11:10 EDT, Arrhythmias and Clinical EP Moderated Poster Theater, Poster Hall, Hall C

- *Does Frailty Alter the Benefits of Oral Anticoagulation in Patients With Atrial Fibrillation?*
    - Poster Session 1190 - Atrial Fibrillation and VT: Specific Situations and Newer Outcome Measures
    - Saturday 18 March, 09:45-10:30 EDT, Poster Hall, Hall C

- *The Prescribing of Antiplatelet Therapy Only in Patients With Nonvalvular Atrial Fibrillation: Results From the GARFIELD-AF Registry*
    - Moderated Poster Session 1223M - Stroke and AF: Thinking About the Heart
    - Saturday 18 March, 12:45-12:55 EDT, Arrhythmias and Clinical EP Moderated Poster Theater, Poster Hall, Hall C

- *Nuisance Bleeding in Anticoagulated Patients With Atrial Fibrillation: Insights From the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF)*
    - Poster Session 1280 - Atrial Fibrillation and VT: Incorporating Novel Risks Toward Decision Making
    - Sunday 19 March, 09:45-10:30 EDT, Poster Hall, Hall C

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 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
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 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 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.

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Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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.

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[1] Weitz JI, Bauersachs R, Beyer-Westendorf J, et al. Two doses of rivaroxaban versus aspirin for prevention of recurrent venous thromboembolism. Thromb Haemostasis 2015;114(3):645-50
[2] Galioto N, Danley DL, Van Maanen RJ. Recurrent Venous Thromboembolism. American Academy of Family Physicians 2011
[3] Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease CHEST Guideline and Expert Panel Report. CHEST 2017;149(2):315-52
[4] Prandoni P, Noventa F, Ghirarduzzi A, et al. The risk of recurrent venous thromboembolism after discontinuing anticoagulation in patients with acute proximal deep vein thrombosis or pulmonary embolism. A prospective cohort study in 1,626 patients. Haematologica, The Hematology Journal 2007, 92(02), 199-205