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

Investor News

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Two abstracts on Phase III COMPASS study with Bayer's Rivaroxaban accepted for presentation in Hot Line sessions at ESC Congress 2017

- Results from COMPASS, the largest clinical study of rivaroxaban to date, will provide new insights into the management of patients with chronic coronary and peripheral artery disease
- COMPASS study was stopped early because of overwhelming efficacy
- A total of 17 rivaroxaban abstracts accepted for presentation covering both clinical and real-world studies in venous and arterial thromboembolism

Leverkusen, Germany, August 21, 2017 – Bayer AG and its development partner Janssen Research & Development, LLC, announced today that two abstracts featuring new clinical data from the Phase III COMPASS study[1] have been accepted for Hot Line presentations at ESC Congress 2017. The congress will take place in Barcelona, Spain from 26-30 August, 2017. The COMPASS study evaluated the efficacy and safety of 2.5 and 5 mg vascular dose of rivaroxaban (Xarelto®) for the prevention of major adverse cardiac events (MACE) including stroke, cardiovascular death and heart attack in patients with chronic coronary artery disease (CAD) and / or peripheral artery disease (PAD) including those with prior heart conditions. In February this year, as part of a planned interim analysis, the COMPASS study was found to have met its primary endpoint early and was stopped because of overwhelming efficacy.

Cardiovascular disease, which includes CAD and PAD, is responsible for approximately 17.7 million deaths per year[2]. Specifically, CAD led to 8.8 million deaths in 2015[3], and around 202 million people worldwide are estimated to be living with PAD[4]. The current guideline-recommended antithrombotic treatment for these patients is antiplatelet therapy, which is generally not considered sufficient as event rates remain high[5]. Consequently, there is a need to improve outcomes by establishing new or add-on treatments, which have the potential to reduce the risk of MACE in patients with

atherosclerotic disease. Rivaroxaban is the first and only non-vitamin K antagonist oral anticoagulant (NOAC) investigated in these high-risk patient populations.

Note: Per ESC Embargo Policy, all below mentioned abstracts are under embargo until the time of presentation.

Full data from the Phase III COMPASS Study will be featured in the following Hot Line presentations:

- *Cardiovascular Outcomes for People using Anticoagulation Strategies (COMPASS) trial: primary results*
  - Hot Line: Late Breaking Clinical Trials 1; Abstract number 1154
  - Sunday 27 August, 11:36-11:51, Barcelona – Main Auditorium

- *Cardiovascular Outcomes for People using Anticoagulation Strategies (COMPASS) trial: Results in patients with Peripheral Artery Disease*
  - Hot Line: Late Breaking Clinical Trials 1; Abstract number 1157
  - Sunday 27 August, 11:54-12:09, Barcelona – Main Auditorium

The COMPASS study was conducted in collaboration with the Population Health Research Institute (PHRI) in Canada and enrolled 27,395 patients from more than 600 sites across more than 30 countries worldwide. In the study, patients were randomized to receive either rivaroxaban 2.5 mg twice daily in addition to aspirin 100 mg once daily, rivaroxaban 5 mg twice daily alone, or aspirin 100 mg once daily alone.

A further 15 abstracts on rivaroxaban have been accepted for presentation from clinical trials, as well as real-world studies, in the areas of stroke prevention and venous clot protection. This includes presentations from the PIONEER AF-PCI study, and results from the real-world XANTUS study as follows:

- *Rivaroxaban strategies improve the number of days patients remain out of the hospital and event free: A PIONEER substudy*
  - Poster Session 4: Stroke Prevention; Abstract number P3590
  - Monday 28 August, 08:30-12:30, Poster Area

- *Safety analysis of rivaroxaban: a pooled analysis of the global XANTUS programme (real-world, prospective, observational studies for stroke prevention in patients with atrial fibrillation)*

- Poster Session 4: Stroke Prevention; Abstract number P3592
- Monday 28 August, 08:30-12:30, Poster Area

Separately, 8 independent data presentations on the use of NOACs in real-world settings have been accepted for presentation, including a Hot Line presentation from the IMPACT-AF study and presentations from the GARFIELD-AF Registry, including on the burden of atrial fibrillation across Europe.

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 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

Bayer AG, Investor Relations contacts:

Oliver Maier (+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)

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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.

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[1] Clinicaltrial.gov NCT01776424
[2] WHO Fact Sheet. Cardiovascular Diseases, 2017. http://www.who.int/mediacentre/factsheets/fs317/en/ [accessed 01 June 2017]
[3] WHO Fact Sheet. The Top 10 Causes of Death, 2017. http://www.who.int/mediacentre/factsheets/fs310/en/ [accessed 01 June 2017]
[4] Fowkes FG, Rudan D, Rudan I et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet. 2013 Oct 19;382(9901):1329-40
[5] Di Manno MND, Guida A, Camera M et al. Overcoming limitations of current antiplatelet drugs: A concerted effort for more profitable strategies of intervention. Annals of Medicine 2011 Nov; 43(7): 531–544.