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Investor News

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Phase III COMPASS study with Bayer's Rivaroxaban in Patients with Coronary or Peripheral Artery Disease Shows Overwhelming Efficacy and Meets Primary Endpoint Early

- Coronary or peripheral artery disease patients carry significant risk of fatal or debilitating myocardial infarction and stroke
- Rivaroxaban is the only non-vitamin K antagonist oral anticoagulant currently under assessment in this high risk patient population

Leverkusen, February 8, 2017 – Bayer AG and its cooperation partner Janssen Research & Development, LLC today announced that the Phase III trial COMPASS evaluating the efficacy and safety of rivaroxaban (Xarelto®) for the prevention of major adverse cardiac events (MACE) including cardiovascular death, myocardial infarction and stroke in patients with coronary artery disease (CAD) or peripheral artery disease (PAD) has met its primary endpoint ahead of time. Following a planned interim analysis conducted by the independent Data Monitoring Committee (DMC), the DMC recommended to stop the trial early as the primary MACE endpoint has reached its prespecified criteria for superiority. Owing to the magnitude of effect and the confirmation of the existing safety profile of rivaroxaban, Bayer, Janssen and the Population Health Research Institute (PHRI) will offer rivaroxaban to study participants in an open-label extension trial. The COMPASS study is the largest clinical study of rivaroxaban to date.

The Phase III COMPASS study was conducted in collaboration with the PHRI and has enrolled 27,402 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 complete data analysis from this study is expected to be presented at an upcoming medical meeting in 2017.

“Despite established and effective treatments, an unmet medical need in this patient population still exists with rates of CAD and PAD rising globally,” said Dr Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “Bayer is committed to an ongoing clinical development programme that addresses such unmet medical needs. We are excited about these results and look forward to making rivaroxaban available to patients with CAD and PAD to reduce their risk of major adverse cardiac events.”

Coronary artery disease (CAD) is the most common cause of cardiovascular disease and is responsible for approximately 7.3 million deaths worldwide every year. One-third to one-half of all middle-aged men and women in high income countries are at risk of developing CAD during their lifetime, and the number of people with CAD is rising globally. By 2020, the burden of coronary artery disease is projected to reach 82 million disability-adjusted life years (DALYs) or “healthy years of life lost”.

Peripheral artery disease (PAD), while often undiagnosed, affects over 27 million people in Europe and North America and is an important risk marker of cardiovascular disease. Globally, screening studies suggest that approximately 20% of adults older than 55 years have evidence of PAD. The disease prevalence is strongly age-related and, like CAD, the numbers of affected patients is rising, because of the aging of the population.

COMPASS is part of 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 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 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.

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.

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