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Investor News

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Bayer Initiates Xarelto® (Rivaroxaban) Study in Patients with Non-Valvular Atrial Fibrillation Undergoing Percutaneous Coronary Intervention with Stent Placement

Leverkusen, Germany, March 8, 2013 – Bayer HealthCare announced today the initiation of the PIONEER AF-PCI study, a Phase IIIb clinical study of its oral anticoagulant Xarelto® (rivaroxaban) to investigate how best to treat patients with non-valvular atrial fibrillation (AF) who undergo percutaneous coronary intervention (PCI) with stent placement.

The PIONEER AF-PCI study will enroll approximately 2,100 patients worldwide. The trial will assess the safety of two rivaroxaban treatment strategies and a dose-adjusted vitamin K antagonist (VKA) treatment strategy. Patients will be treated for 12 months.

“There are limited data available on how best to treat those patients with atrial fibrillation who require anticoagulant therapy for stroke prevention and also have a coronary stent implanted requiring dual antiplatelet therapy,” said C. Michael Gibson, M.S., M.D., Chairman of the PERFUSE Study Group, Harvard Medical School, and the Principal Investigator of the PIONEER AF-PCI study. “This study will help to address a clinically important question and provide physicians with information needed to make treatment decisions for this high-risk patient population.”

“We heard the excitement from physicians when Xarelto was approved for use in patients with non-valvular atrial fibrillation and we also listened to the questions they asked us about what to do for patients with overlapping risk factors,” said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The PIONEER AF-PCI study is part of our ongoing commitment to improve patient outcomes across a broad range of venous and arterial thromboembolic conditions.”

The PIONEER AF-PCI trial is part of the global clinical development program for rivaroxaban, which will - by the time of its completion – have involved more than 100,000 patients worldwide.

About PIONEER AF-PCI

The PIONEER AF-PCI study (an open-label, randomized, controlled, multicentre study exploring two treatment strategies of rivaroxaban and a dose-adjusted oral vitamin K antagonist treatment strategy in patients with atrial fibrillation who undergo percutaneous coronary intervention) will include approximately 2,100 patients worldwide. Patients with documented AF following PCI will be enrolled into the study. The primary endpoint is the composite of TIMI major bleeding, minor bleeding and bleeding requiring medical attention (known collectively as clinically significant bleeding). In the study, patients will be randomized into three arms:

- Rivaroxaban 15 mg once daily and a P2Y12 inhibitor (such as clopidogrel 75 mg daily)
- Rivaroxaban 2.5 mg twice daily, a P2Y12 inhibitor (such as clopidogrel 75 mg daily) and ASA 75-100 mg daily
- Dose-adjusted VKA, a P2Y12 inhibitor (such as clopidogrel 75 mg daily) and ASA 75-100 mg daily

About Venous and Arterial Thromboembolism (VAT)

Thrombosis is the formation of a blood clot inside a blood vessel, blocking a vein (venous thrombosis) or artery (arterial thrombosis). Venous and Arterial Thromboembolism (VAT) is caused when some or all of a clot detaches and is moved within the blood stream until it obstructs a smaller vessel. This can result in damage to vital organs, because the tissue beyond the blockage no longer receives nutrients and oxygen.

VAT is responsible for a number of serious and life threatening conditions:

- Venous Thromboembolism (VTE) occurs when part of a clot formed in a deep vein, for example in the leg (known as deep vein thrombosis, or DVT), is carried to the lung, via the heart, preventing the uptake of oxygen. This is known as a pulmonary embolism (PE), an event which can be rapidly fatal

- Arterial Thromboembolism (ATE) occurs when oxygenated blood flow from the heart to another part of the body (via an artery) is interrupted by a blood clot. If this occurs in a vessel supplying blood to the brain, it can lead to a stroke, an event that can be severely debilitating or fatal. If it occurs in a coronary artery, it can lead to acute coronary syndrome (ACS), a complication of coronary heart disease which
  includes conditions such as myocardial infarction (heart attack), and unstable angina

VAT is responsible for significant morbidity and mortality, and requires active or preventative treatment to avoid potentially serious or fatal patient outcomes.

To learn more about VAT, please visit www.VATspace.com

About Xarelto® (Rivaroxaban)
Rivaroxaban is the most broadly indicated new oral anticoagulant and is marketed under the brand name Xarelto®. To date, Xarelto is approved for six distinct uses in the venous arterial thromboembolic (VAT) space:

- 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 deep vein thrombosis (DVT) in adults
- The treatment of pulmonary embolism (PE) 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 venous thromboembolism (VTE) in adult patients undergoing elective knee replacement surgery

Whilst licences may differ from country to country, across all indications Xarelto is approved in more than 120 countries.

Rivaroxaban was discovered by Bayer HealthCare, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

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 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

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.6 billion (2012), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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