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# Investor News

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## New Pivotal Phase III Study Initiated with Bayer's Xarelto® (Rivaroxaban) in Patients with Chronic Heart Failure and Significant Coronary Artery Disease

Low-dose rivaroxaban given fast track designation by U.S. FDA as first novel oral anticoagulant to be evaluated in this high-risk patient group

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**Leverkusen, Germany, March 8, 2013** – Bayer HealthCare and its cooperation partner Janssen Research & Development, LLC announced today the initiation of COMMANDER-HF, a pivotal Phase III clinical trial that will evaluate Xarelto® (rivaroxaban) 2.5 mg twice daily in patients with chronic heart failure (HF) and significant coronary artery disease (CAD). Rivaroxaban is the first novel oral anticoagulant to be evaluated in this patient group who remain at high-risk for complications following hospitalization for exacerbation of their HF.

Heart failure poses a major public health problem worldwide.[i] It is one of the most common reasons for hospitalization in the developed world and places a major burden on hospital staff and resources.[ii] In the U.S. and Europe, three-quarters of all patients hospitalized with heart failure for the first time will die within five years.[iii]

"COMMANDER-HF will assess whether the addition of low-dose rivaroxaban on top of standard therapy can help reduce the risk of death, heart attack or stroke in this high-risk patient group following hospitalization," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The U.S. Food and Drug Administration granted a fast track designation process for the COMMANDER-HF study to help facilitate the development process, and expedite the review of rivaroxaban in this indication.

The trial will assess the safety and efficacy of 2.5 mg twice daily rivaroxaban compared to placebo (on a background of standard treatment) in reducing the risk of death, myocardial infarction (MI) or stroke in 5,000 patients with chronic HF and significant CAD following hospitalization. The primary efficacy outcome is the composite of all-cause mortality, MI, or stroke. The principal safety outcome is the composite of fatal bleeding or bleeding into a critical space with a potential for permanent disability.

Xarelto has the broadest indication profile of any of the newer oral anticoagulants. To date, Xarelto is approved for six distinct uses in the venous arterial thromboembolic (VAT) space.

**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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[i] McMurray JJV, et al. The burden of heart failure. European Heart Journal Supplements (2002) 4 (Supplement D), D50-D58.
[ii] Cowie MR, et al. Hospitalization of patients with heart failure. European Heart Journal (2002) 23, 877–885,
[iii] McMurray JJV, et al. The burden of heart failure. European Heart Journal Supplements (2002) 4 (Supplement D), D50-D58.