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# Investor News

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## Xarelto® to be Studied with Factor Xa Inhibitor Antidote

Bayer and Janssen announce clinical collaboration agreement with Portola

**Leverkusen, Germany, February 5, 2013** – Bayer HealthCare and Janssen Pharmaceuticals, Inc. today announced a clinical collaboration agreement with Portola Pharmaceuticals, Inc., San Francisco / USA, to evaluate the safety of PRT4445, an investigational antidote for Factor Xa inhibitors, in healthy volunteers who have been administered the oral anticoagulant Xarelto® (rivaroxaban). This proof-of-concept study, comprising multiple cohorts with different anticoagulants being tested, is expected to be completed in the second half of 2013.

The study is designed to evaluate the safety of multiple dosage strengths of PRT4445 in combination with Xarelto in order to determine the dose of PRT4445 that would be required to reverse the anticoagulant activity of Xarelto in emergency situations. Standard clinical measures are currently employed to manage these patients and events.

“Although when normalization of blood clotting is necessary, stopping the intake of Xarelto is usually effective, we understand the desire of doctors to have a specific antidote to reverse the anticoagulation effects of the product,” said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We are addressing this request both through in-house research as well as through this external collaboration with Portola.”

Bayer and Janssen will make an undisclosed payment to Portola and will provide development and regulatory guidance for the study. Portola retains all global development and commercialization rights for PRT4445.

**About PRT4445**

Portola Pharmaceutical's PRT4445 is a novel recombinant protein designed to reverse the anticoagulant activity in Factor Xa inhibitor-treated patients suffering from an uncontrolled bleeding episode or undergoing emergency surgery. It is similar to native Factor Xa but has structural modifications intended to restrict its biological activity to reverse the effects of Factor Xa inhibitors. PRT4445 works by acting as a decoy for Factor Xa inhibitors in the blood, thereby preventing them from inhibiting the activity of native Factor Xa. As a result, the native Factor Xa is available to participate in the coagulation process and restore normal clotting.

Results of a Phase I single ascending dose safety and tolerability study, conducted by Portola in 32 healthy volunteers in the United States, showed that PRT4445 was generally well tolerated with no apparent safety signals.

**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 use in the following venous arterial thromboembolic (VAT) indications:

- 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) and prevention of recurrent DVT and pulmonary embolism (PE) in adults
- The treatment of PE and prevention of recurrent PE and DVT in adults
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or 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 17.2 billion (2011), 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 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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