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Investor News

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Portola Pharmaceuticals Announces Initial Phase II Results Demonstrating Dose-Dependent Reversal of Bayer's Xarelto® Anticoagulation Activity with Andexanet Alfa (PRT4445)

Data set with additional dosing cohorts to be presented at 55th American Society of Hematology (ASH) Annual Meeting and Exposition

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Leverkusen, Germany, November 11, 2013 – Bayer HealthCare announced today that initial results from a Phase II proof-of-concept study of Portola Pharmaceuticals' andexanet alfa, an investigational Factor Xa inhibitor antidote, in healthy volunteers who were administered Bayer's novel oral anticoagulant Xarelto® (rivaroxaban) have been accepted for presentation at the 55th American Society of Hematology (ASH) Annual Meeting and Exposition, which is being held in New Orleans, LA, USA, from December 7-10, 2013.

Initial results from the first two dosing cohorts of the study, submitted by Portola Pharmaceuticals and now published online on the ASH website, demonstrated that andexanet alfa is able to dose-dependently reverse the anticoagulant effects of Xarelto. In addition, no serious adverse events were reported. These data, as well as data from additional cohorts evaluating higher doses of andexanet alfa, will be presented in a poster session on December 9.

"Xarelto is a highly effective anticoagulant, and in previous Phase III studies has been shown to significantly reduce the risk of the most concerning bleeding events compared to warfarin. In rare emergency situations when the normalization of blood clotting becomes necessary, stopping Xarelto would allow for normalization of coagulation parameters within one day – this is as effective as giving Vitamin K to patients receiving warfarin," said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee

and Head of Global Development. “While there are several clinical measures currently available to manage such events, we are committed to meeting the interest to have a specific antidote.”

About the Phase II Proof-of-Concept Study

The randomized, placebo-controlled, double-blind, cohort dose-escalation Phase II proof-of-concept study treated healthy volunteers with an oral dose of Xarelto at 20 mg once-daily (qd) for 6 days and then randomized them in a 6:3 ratio (with 6 patients on drug and 3 on placebo) to andexanet alfa in the different dosing cohorts. Cohorts one and two received a single IV bolus of andexanet alfa at either 210 mg or 420 mg respectively. Within two minutes following completion of the 210 mg and 420 mg bolus of andexanet alfa, anti Factor Xa activity decreased dose-dependently by 20 percent and 53 percent respectively. Xarelto-induced inhibition of thrombin generation and prolongation of both prothrombin time and activated clotting time were also partially reversed by andexanet alfa in a dose-dependent manner. Interim safety data showed that andexanet alfa was well tolerated, with no thrombotic events, serious, or severe adverse events reported.

About Andexanet Alfa (PRT4445)

Portola Pharmaceuticals’ andexanet alfa is a novel recombinant, modified Factor Xa molecule that has the potential to be the first specific antidote to reverse the effects of Factor Xa inhibitors in patients who suffer an uncontrolled bleeding episode or require emergency surgery. Andexanet alfa is similar to native Factor Xa, but has been modified to restrict its biological activity, such as its ability to cleave thrombin, an enzyme involved in the clotting cascade. Andexanet alfa acts as a Factor Xa decoy that binds and sequesters direct Factor Xa inhibitors in the blood. Once bound to andexanet alfa, the Factor Xa inhibitors are unable to bind to and inhibit native Factor Xa. The native Factor Xa should then be available to participate in the coagulation process and restore hemostasis.

About Xarelto® (Rivaroxaban)

Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto®. Xarelto is approved for five indications across seven distinct areas of use, protecting patients across more venous and arterial thromboembolic (VAT) conditions than any other novel OAC:

- 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 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 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 125 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 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, 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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