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Investor News

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Secondary Prevention of Acute Coronary Syndrome (ACS):

Bayer's Xarelto® (Rivaroxaban) Meets Primary Efficacy Endpoint and Shows Significant Reduction in Mortality in Major ACS Study

- Rivaroxaban Meets Primary Efficacy Endpoint, Significantly Reducing the Composite of Cardiovascular Death, Myocardial Infarction and Stroke
- Rivaroxaban 2.5 mg twice daily Significantly Reduced Both the Rate of Cardiovascular Death and the Incidence of All-Cause Mortality by more than 30%
- Major Bleeding in Patients Receiving Rivaroxaban was Significantly Increased but there was no Increase in the Risk of Fatal Bleeding
- Study Results Presented as a Late-Breaker at the Scientific Sessions of the American Heart Association and Published by the New England Journal of Medicine

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Leverkusen, November 13, 2011 – Bayer HealthCare announced today that the combination of oral Xarelto® (Rivaroxaban) twice daily with standard antiplatelet therapy significantly reduced the composite primary efficacy endpoint of cardiovascular death, myocardial infarction and stroke in patients with acute coronary syndrome (ACS) compared to those receiving standard antiplatelet therapy alone. In addition, rivaroxaban 2.5 mg in combination with standard therapy significantly reduced mortality over standard therapy alone. Results from the pivotal Phase III ATLAS ACS 2-TIMI 51 study presented today at the American Heart Association Scientific Sessions and published by the New England Journal of Medicine also showed that rivaroxaban significantly increased the rate of major bleeding, but did not increase the risk of fatal bleeding over standard therapy alone.

ACS occurs when a blood clot blocks a coronary artery, which can lead to heart attacks or chest pain known as unstable angina.

“The clinical benefit of giving rivaroxaban in combination with standard antiplatelet therapy seen in the ATLAS ACS 2-TIMI 51 study is welcome, and could lead to significant improvement in the management of patients with acute coronary syndrome,” said Eugene Braunwald, M.D., Distinguished Hersey Professor of Medicine at Harvard Medical School and Founding Chairman of the Thrombolysis In Myocardial Infarction (TIMI) Study Group, Brigham and Women’s Hospital.

“For more than a decade ACS patients have been effectively treated with a low-dose aspirin given in combination with a thienopyridine to help reduce their risk of a recurrent cardiovascular event. This study showed that by adding the oral Factor Xa inhibitor rivaroxaban to standard therapy, this risk is greatly reduced, resulting in a significant reduction in mortality,” said C. Michael Gibson, M.D., senior investigator of the TIMI Study Group, Harvard Medical School, and the Principal Investigator in the ATLAS ACS studies of rivaroxaban. “If the data from ATLAS ACS 2-TIMI 51 were extrapolated into clinical practice, we could potentially see one life saved for every 56 patients treated with this combination of therapies over a two year period.”

The results of the ATLAS ACS 2-TIMI 51 study showed that both 2.5 and 5 mg of rivaroxaban dosed twice daily (BID) in addition to standard therapy — low-dose aspirin with or without a thienopyridine such as clopidogrel — were superior to standard therapy plus placebo in both study arms in the primary efficacy endpoint of preventing recurrent major cardiovascular events (cardiovascular death, myocardial infarction and stroke) in patients with ACS [combined doses 8.9% vs. 10.7%[1] (P=0.008), Relative Risk Reduction (RRR)=16%]. Additionally and importantly, rivaroxaban significantly reduced stent thrombosis compared with placebo [2.3% vs. 2.9% (P=0.016)].

Patients dosed with 2.5 mg BID of rivaroxaban showed a significant reduction in risk of the composite primary endpoint [9.1% vs. 10.7% (P=0.020)], driven by a significant 34% RRR in the rate of cardiovascular death [2.7% vs. 4.1% (P=0.002)]. There was also a significant reduction in deaths from any cause [2.9% vs. 4.5% (P=0.002)]. The 5 mg BID dose of rivaroxaban also significantly reduced the rate of the primary efficacy endpoint in the study [8.8% vs. 10.7% (P=0.028)].

The principal safety endpoint for the study was TIMI major bleeding not associated with coronary artery bypass graft (CABG) surgery. In patients receiving rivaroxaban in

[1] All event rates are reported as KM estimates through 24 months

combination with standard therapy, bleeding rates were statistically significantly increased versus those treated with standard therapy plus placebo [2.1% vs. 0.6% (P<0.001)]. Similarly, rivaroxaban resulted in higher rates of TIMI major bleeding events not associated with CABG surgery at both the 2.5 mg and 5 mg BID doses compared to placebo [1.8% vs. 0.6% (P<0.001) and 2.4% vs. 0.6% (P<0.001), respectively]. Importantly, rivaroxaban did not increase the risk of fatal bleeding. Other treatment-emergent adverse events were generally balanced across treatment groups.

The U.S. Food and Drug Administration (FDA) has granted rivaroxaban “fast track” designation for this indication, given the seriousness of ACS as a medical condition and the potential clinical benefit of rivaroxaban.

“These important results demonstrate that rivaroxaban can help patients with acute coronary syndrome,” said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer. “Acute coronary syndrome is a chronic, life-threatening condition, and we believe, based on these data, that rivaroxaban could greatly improve the current standard of care.”

It is intended to submit an application for marketing authorization by the end of this year.

About ACS

ACS is a complication of coronary heart disease, which is the leading cause of death in the U.S. and one of the most prevalent non-communicable diseases in the world. ACS occurs when a blood clot blocks a coronary artery, reducing blood supply to the heart. This disruption of blood flow can directly cause a heart attack, or cause severe pain in the chest (unstable angina) indicating that a heart attack may soon occur.

About ATLAS ACS 2-TIMI 51

The ATLAS ACS 2-TIMI 51 (**A**nti-Xa **T**herapy to **L**ower cardiovascular events in **A**ddition to aspirin with/without thienopyridine therapy in **S**ubjects with **A**cute **C**oronary **S**yndrome) study was designed to test the efficacy of rivaroxaban compared to placebo in preventing cardiovascular death, myocardial infarction and stroke in patients with ACS. Patients were given standard antiplatelet therapy plus rivaroxaban dosed at 2.5 mg or 5 mg BID, or a placebo. Of the 15,526 patients randomized into the study, 93% received aspirin and

thienopyridine in addition to rivaroxaban or placebo, and the balance were treated with aspirin plus rivaroxaban or placebo.

The double blind, randomized, placebo-controlled study was coordinated by the TIMI Study Group and Brigham and Women's Hospital and Harvard Medical School, and was funded and led by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

About Rivaroxaban (Xarelto®)

Rivaroxaban is an oral anticoagulant that was discovered in Bayer HealthCare's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for routine coagulation monitoring, and a limited potential for food and drug interactions.

Rivaroxaban is marketed under the brand name Xarelto® for VTE prevention in adult patients following elective hip or knee replacement surgery, and it is the only oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin in this indication. Rivaroxaban is approved in more than 110 countries worldwide and marketed outside the U.S. by Bayer HealthCare in this indication.

In the U.S., where rivaroxaban has been available since July 2011 for VTE prevention in adult patients following elective hip or knee replacement surgery, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. The Bayer HealthCare sales force is supporting Janssen Pharmaceuticals, Inc. in designated hospital accounts. On November 5, Xarelto® received further marketing approval in the U.S. for the prevention of stroke in patients with Atrial Fibrillation.

The extensive clinical trial program supporting rivaroxaban makes it the most studied and widely published oral, direct Factor Xa inhibitor. The studies, reported and ongoing, involve over 75,000 patients for the prevention and treatment of venous and arterial thromboembolic (VAT) disorders across a broad range of acute and chronic conditions, including stroke prevention in patients with Atrial Fibrillation, DVT treatment and the prevention of recurrent DVT or PE, and the secondary prevention of Acute Coronary Syndrome.

To learn more about thrombosis, please visit www.thrombosisadviser.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 16.913 billion (2010), 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, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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