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Investor News

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Phase III J-ROCKET AF Study of Bayer's Xarelto® (rivaroxaban) Meets Primary Endpoint

- Safety of once-daily Xarelto comparable to warfarin in Japanese patients with atrial fibrillation
- Results presented in the late breaking clinical trials session at the 23rd Congress of the International Society on Thrombosis and Haemostasis in Kyoto, Japan
- As communicated in April 2011, Xarelto has been submitted for marketing approval in the prevention of stroke in patients with atrial fibrillation to the Japanese Ministry of Health, Labor and Welfare

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Leverkusen, July 25, 2011 – Conducted in Japan, the Phase III J-ROCKET AF study of Bayer's once-daily Xarelto® (rivaroxaban) in Japanese patients with non-valvular atrial fibrillation at risk of stroke met its primary endpoint, demonstrating non-inferiority versus warfarin for the principal safety outcome – the composite of major and non-major clinically relevant bleeding. In addition, J-ROCKET AF showed a 51% reduction of stroke and non-CNS systemic embolism in the Xarelto group compared with patients receiving warfarin. This was not statistically significant, as the trial was not powered for efficacy.

"The J-ROCKET AF study of rivaroxaban is the first and only pivotal, randomized, double-blind, double-dummy trial that has been undertaken in Japanese patients with atrial fibrillation, conducted with a Japan-specific dose and in full recognition of the Japanese Guideline environment. It is important that rivaroxaban demonstrated non-inferior safety and that there were numerically fewer intracranial hemorrhages versus warfarin. Since the J-ROCKET AF data are supportive of the results of the global ROCKET AF trial, I expect rivaroxaban to become an alternative to warfarin for Japanese patients suffering from non-valvular atrial fibrillation", said Masatsugu Hori, M.D., Steering Committee Chairman and President of Osaka Medical Center for Cancer and Cardiovascular Diseases.

On April 14, 2011, Bayer communicated that Xarelto had been submitted for marketing approval in the prevention of stroke in patients with atrial fibrillation to the Japanese Ministry of Health, Labor and Welfare (MHLW).

Detailed Study Results

Event rates for the principal safety endpoint, the composite of major and non-major clinically relevant bleeding, were similar between the treatment groups: 18.0% and 16.4% per year for Xarelto and warfarin, respectively (hazard ratio [HR]=1.11; 95% Confidence Interval [CI] 0.87–1.42). Event rates for major bleeding were 3.0% and 3.6% per year (HR=0.85; 95% CI 0.50–1.43) and for non-major clinically relevant bleeding were 15.4% and 13.0% per year for Xarelto and warfarin, respectively (HR=1.20; 95% CI 0.92–1.56). Importantly, there was a trend toward lower rates of intracranial hemorrhages and bleeding-related death with Xarelto. These data are consistent with the results of the global ROCKET AF trial, which were reported at the Scientific Sessions of the American Heart Association (AHA) 2010 and showed similar rates of major and non-major clinically relevant bleeding in a diverse population of patients treated with once-daily Xarelto compared with dose-adjusted warfarin.

The relative reduction in the risk of stroke and non-CNS systemic embolism observed with Xarelto was 51% compared with warfarin (1.3% and 2.6% per year, respectively, HR=0.49; 95% CI 0.24–1.00). As the trial was powered for safety, not efficacy, this result did not reach statistical significance. This result is supported by the statistically significant reduction in stroke and non-CNS systemic embolism seen in the global ROCKET AF study in patients receiving active treatment with Xarelto, as well as the non-inferior efficacy demonstrated in the ITT population.

About J-ROCKET AF

In Japan, there are more than 800,000 individuals affected by atrial fibrillation. J-ROCKET AF (**J**apanese **R**ivaroxaban **O**nce daily oral direct Factor Xa inhibition **C**ompared with vitamin **K** antagonism for prevention of stroke and **E**mbolism **T**rial in **A**trial **F**ibrillation) is part of the large global clinical development program for Xarelto, which includes the global ROCKET AF Phase III trial involving 14,264 patients randomized, the results of which were reported at AHA (Chicago, 2010). J-ROCKET AF was a smaller study (1,280 patients randomized) that was performed to evaluate the safety of Xarelto versus warfarin in patients with non-valvular atrial fibrillation living in Japan.

J-ROCKET AF was a prospective, randomized, double-blind Phase III study in which Japanese patients were enrolled from over 160 centres across Japan. Mean on-treatment exposure to study drugs was 499 days and 481 days for Xarelto and warfarin, respectively. The study was led by Masatsugu Hori, M.D., President of Osaka Medical Center for Cancer and Cardiovascular Diseases, Japan, and an academic Steering Committee of leading Japanese experts.

The primary objective of the study was to evaluate the safety of Xarelto, one tablet, once-daily versus dose-adjusted warfarin in patients with non-valvular atrial fibrillation in Japan. Non-inferiority was shown with respect to on-treatment bleeding, assessed as the composite of major and non-major clinically relevant bleeding events – the primary safety outcome. The primary efficacy endpoint was the composite of all-cause stroke and non-CNS systemic embolism.

Patients were randomized to 15 mg Xarelto once daily (10 mg in patients with moderate renal impairment at screening) or to warfarin with a target INR of 2.0–3.0 for patients aged <70, or 1.6–2.6 for those aged ≥70. The doses of Xarelto and warfarin were selected to reflect the prevailing Anticoagulant Guidelines in Japan – reflecting the specific characteristics of the patient population in Japan and local medical practices – and hence were lower than those evaluated in the global ROCKET AF trial (20 mg Xarelto once daily, or 15 mg Xarelto once daily for patients with moderate renal impairment).

About Xarelto® (Rivaroxaban)

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 coagulation monitoring, as well as a limited potential for food and drug interactions.

Xarelto® is marketed 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 for this indication. To date, Xarelto is approved in more than 110 countries worldwide and has been successfully launched in more than 85 countries by Bayer HealthCare in this indication. In the U.S., where Xarelto has been successfully launched in July 2011, Janssen Pharmaceuticals, Inc. (a Johnson

& Johnson Company) holds marketing rights for Xarelto. Bayer HealthCare sales force is supporting the Janssen Pharmaceuticals, Inc. sales force in designated hospital accounts.

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 disorders across a broad range of acute and chronic conditions, including stroke prevention in patients with Atrial Fibrillation, VTE treatment, 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 and manufacture 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.

Find more information at www.bayerpharma.com.

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