Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

Not intended for U.S. and UK media

ROCKET AF, the landmark double-blind study of rivaroxaban versus warfarin:

Major Subgroup Analysis Shows Bayer's Rivaroxaban is Highly Effective in the Prevention of Recurrent Strokes

Positive benefit-risk profile of rivaroxaban in secondary prevention patients, a group who are difficult to manage and who experience the greatest complications from current anticoagulation therapy, including intra-cranial haemorrhage (ICH)

Leverkusen, May 25, 2011 – A pre-planned subgroup analysis of the ROCKET AF Phase III clinical study confirms that rivaroxaban is highly effective in the prevention of recurrent strokes in patients with atrial fibrillation (AF) who have experienced a prior stroke or transient ischemic attack (TIA). These findings were presented today at the 20th European Stroke Conference by Professor Werner Hacke, Chair of the Department of Neurology at the University of Heidelberg, Germany, and member of the ROCKET AF Executive Steering Committee.

AF-related stroke is a leading cause of serious long-term disability and death globally. The current standard of care, warfarin, is a highly effective stroke prevention treatment, but its use is limited by side-effects including intra-cranial haemorrhage, numerous food and drug interactions, as well as the need for regular INR monitoring. Therefore, there is a large medical need for other highly effective prevention options with fewer limitations.

The ROCKET AF secondary prevention sub-analysis examined the benefits of rivaroxaban and warfarin in the highest number of prior-stroke AF patients studied to date (7,468 total patients). Rivaroxaban showed a numerically lower (13%) risk compared with warfarin in the combined endpoint of stroke and systemic embolism in this subgroup of patients, this being in line with the results of the main ROCKET AF trial. Overall bleeding rates were similar between both treatment arms, although fatal bleeding events, as well as ICH events, were less frequent in those receiving rivaroxaban. Overall, the benefit-risk profile favours rivaroxaban in these difficult to manage secondary prevention patients.

These differences did not reach statistical significance as this subgroup analysis was not powered for these endpoints.

The investigators concluded that rivaroxaban is an effective alternative to warfarin for the protection of patients from both a first and recurrent strokes.

“The results are particularly significant for patients who have suffered a prior stroke and who are more difficult to manage when on current standard of care, as they have a higher stroke risk than those without prior history of an event.” said Professor Werner Hacke. “The ROCKET AF study has given us a unique opportunity to compare existing care with a new generation medicine that does not have the same limitations as warfarin.”

“AF increases stroke risk fivefold, and for many patients the burden of required routine INR monitoring can have a negative impact on the quality of daily life,” said Trudie Lobban, MBE, Founder and CEO of the Atrial Fibrillation Association (AFA). “The impact of secondary stroke can be devastating for patients and their families, who are already coping with the joint challenge of both AF and a prior, disabling event. For this reason alone, prevention of further stroke events is a critically important treatment goal.”

About the ROCKET AF Secondary Analysis Findings

The secondary prevention subgroup of the ROCKET AF study, consisting of patients with a prior history of stroke or TIA (representing 55 per cent of the total study population), received either 20mg once daily rivaroxaban (or 15 mg for patients with moderate renal impairment), or dose-adjusted warfarin. The ROCKET AF principal safety outcome was major and non-major clinically relevant bleeding. Rivaroxaban showed a numerically lower (13%) risk compared to warfarin in the prevention of recurrent strokes or non-CNS embolism in the safety population while on-treatment (2.26 events per 100 patient-years for rivaroxaban and 2.60 events per 100 patient-years for warfarin, HR 0.87, 95% CI [0.69, 1.10]). Similar rates of overall bleeding to those seen in the primary ROCKET AF analysis were found, with no difference between the treatment groups (13.31 safety outcome-related events per 100 patient-years for rivaroxaban and 13.87 events per 100 patient-years for warfarin, HR 0.96, 95% CI [0.87, 1.07]). Rates of ICH were numerically lower in the rivaroxaban arm (0.59 events per 100 patient-years for rivaroxaban and 0.8 events per 100 patient-years for warfarin, HR 0.74, 95% CI [0.47, 1.15]).

About the ROCKET AF Primary Study

ROCKET AF (Rivaroxaban Once daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation) was an event-driven, prospective, randomized, double-blind Phase III study in which more than 14,000 patients were enrolled from more than 1,100 centers across 45 countries worldwide. The study's primary goal was to assess the benefits of rivaroxaban 20mg once daily (or 15mg in patients with moderate renal impairment) in comparison with dose-adjusted warfarin in the protection of patients with non-valvular AF from stroke and non-CNS systemic embolism. The primary efficacy endpoint was a composite of all-cause stroke and non-CNS systemic embolism. The principal safety outcome was a composite of major and non-major clinically relevant bleeding events. The study met its primary endpoint of establishing non-inferiority of once-daily rivaroxaban versus warfarin whilst demonstrating a comparable safety profile. In the pre-specified primary efficacy analysis in the safety population while on treatment, rivaroxaban was superior to warfarin for prevention of stroke and systemic embolism. In an additional analysis in the intent-to-treat population to site notification, following all patients randomized in the trial whether or not they completed the course of therapy until the end of the trial was announced, rivaroxaban showed comparable efficacy to warfarin.

About 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.

Rivaroxaban is marketed under the brand name Xarelto® for the prevention of venous thromboembolism (VTE) in adult patients following elective hip or knee replacement surgery. Xarelto® is approved in more than 100 countries worldwide and has been successfully launched in more than 80 countries by Bayer HealthCare.

The extensive clinical trial program supporting rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. In total, more than 65,000 patients are expected to participate in the rivaroxaban clinical development program evaluating the product in the prevention and treatment of a broad range of venous and arterial thromboembolic diseases, including VTE treatment and secondary prevention of acute coronary syndrome (ACS).

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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)
Ute Menke (+49-214-30-33021)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by the Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.