



News Release

Bayer Committed to Prevention of Arterial Thrombosis:

Bayer Completes Enrollment into Major Phase III Study with Rivaroxaban (ROCKET AF)

- ROCKET AF study compares rivaroxaban to warfarin in the prevention of stroke and non-CNS systemic embolism in patients with Atrial Fibrillation
- Bayer Schering Pharma supports Thrombosis Research Institute's launch of GARFIELD – a global patient Registry to evaluate 'real life' outcomes in the prevention of stroke in patients with Atrial Fibrillation
- Fast Track designation for rivaroxaban development program in the secondary prevention of cardiovascular events in patients with Acute Coronary Syndrome recognizes high unmet medical need.

Barcelona, August 30, 2009 – Bayer Schering Pharma has completed patient enrollment into the Phase III ROCKET AF study (Rivaroxaban Once daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation). The ROCKET AF study is assessing the efficacy and safety of rivaroxaban (Xarelto®) 20 mg once-daily, a novel oral, direct Factor Xa inhibitor, compared to the current standard of care, warfarin, a vitamin K antagonist (VKA) dose-adjusted, for the prevention of stroke and non-CNS systemic embolism in patients with Atrial Fibrillation (AF).

“We are most encouraged by the excellent progress of the ROCKET AF study in Atrial Fibrillation and look forward to the study results in 2010,” said Kemal Malik, M.D., member of the Bayer HealthCare Executive Committee and Chief Medical Officer.

ROCKET AF is a prospective, randomized, double-blind, double-dummy study including 14,269 patients from more than 1,100 centers across 45 countries, worldwide. The study

design and rationale will be presented at the European Society of Cardiology (ESC) Congress in Barcelona¹.

GARFIELD Patient Registry

GARFIELD (Global Anticoagulant Registry in the FIELD), a Registry of 50,000 newly diagnosed patients with AF, was also announced at the ESC Congress today by the Thrombosis Research Institute (TRI) – an independent charitable research foundation dedicated to improving care in patients with cardiovascular disease. The Registry will follow patients prospectively for up to six years to assess the global burden of AF and its launch is being supported by a research grant from Bayer Schering Pharma.

“The largest study of its kind to date, and involving unselected patients in randomly identified sites in up to 50 countries around the world, GARFIELD is unique in focusing on identifying real life outcomes. This includes the limitations of current interventions to prevent stroke, and how new opportunities in both AF management and the emerging novel anticoagulant agents might be used to improve clinical outcomes and reduce the potential burden of thromboembolic stroke for patients, healthcare systems and society more generally,” said Professor Ajay Kakkar Director of the Thrombosis Research Institute and Professor of Surgical Sciences at Queen Mary University of London.

“Our substantial research grant to the Thrombosis Research Institute for the initiation of GARFIELD supports an exceptional project and one which we hope will generate important new knowledge of great benefit to AF sufferers and those responsible for their care, helping to improve clinical outcome,” added Kemal Malik.

Unmet Medical Need in SPAF

AF affects over six million people in Europe². It causes the two upper chambers of the heart (the atria) to quiver instead of beating effectively; resulting in blood not being completely pumped out, which in turn causes pooling and can lead to clotting in the atria. If a blood clot leaves the atria, it can become lodged in an artery in the brain causing the patient to suffer from an ischemic stroke³. Approximately one in five ischemic strokes are due to AF⁴.

It is particularly important to prevent such events as AF-related strokes are more severe, cause greater disability and have a worse prognosis than strokes in patients without AF⁴. New treatments for SPAF are required as existing options, such as VKAs, have a narrow

therapeutic window and optimal dosing is difficult to achieve. Therefore, patients taking warfarin must be monitored frequently to ensure they receive the correct dose.

Fast Track Designation for Rivaroxaban in Acute Coronary Syndrome

The US Food and Drug Administration (FDA) grant of Fast Track designation for the rivaroxaban development program (ATLAS ACS TIMI 51) in the secondary prevention of cardiovascular events in patients with Acute Coronary Syndrome (ACS) recognizes the high unmet medical need. The trial is investigating the efficacy and safety of rivaroxaban in up to 16,000 patients. Data are expected in 2011.

About rivaroxaban

Rivaroxaban was invented in Bayer's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Rivaroxaban is approved in the European Union for the prevention of VTE in adult patients undergoing elective hip or knee replacement surgery.

Rivaroxaban is marketed under the brand name Xarelto[®]. Additional approvals have been granted in other countries, including Australia, Canada, China, Mexico and Singapore. To date, Xarelto[®] has been launched in more than 40 countries around the world by Bayer HealthCare.

The extensive clinical trial program supporting rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. More than 65,000 patients are expected to be enrolled into the rivaroxaban clinical development program, which will evaluate the product in the prevention and treatment of a broad range of acute and chronic blood-clotting disorders, including VTE treatment, stroke prevention in patients with atrial fibrillation, secondary prevention of acute coronary syndrome, and VTE prevention in hospitalized, medically ill patients.

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

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Forward-Looking Statements

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References

¹ Patel, M. Rationale and design of the ROCKET AF study: comparison of rivaroxaban with warfarin for the prevention of stroke and systemic embolism in patients with atrial fibrillation. (Poster 305) The European Society of Cardiology; 08.30-12.30, September 01 2009; Barcelona, Spain

² Kannel WB, Benjamin EJ. Status of the epidemiology of atrial fibrillation. *Med Clin North Am* 2008;92:17-40

³ NHS choices. Atrial fibrillation: introduction. 2007 www.nhs.uk/Conditions/Atrial-fibrillation. Accessed March 2009

⁴ Marini C, De Santis F, Sacco S, et al. Contribution of atrial fibrillation to incidence and outcome of ischemic stroke: results from a population-based study. *Stroke* 2005;36:1115-19