Arrhythmia Alliance
The Heart Rhythm Charity
www.heartrhythmcharity.org.uk

P O Box 3697
Stratford Upon Avon
Warwickshire
CV37 8YL

T: +44 (0) 1789 450787
F: +44 (0) 1789 450682

Promoting better understanding, diagnosis, treatment and quality of life for individuals suffering with cardiac arrhythmia

Embargoed until 00.01 on Thursday 27th May 2010

News Release

First warfarin comparison study to enrol 90% of atrial fibrillation patients with high risk of stroke[1]

Comparison of five anticoagulation trials for the prevention of stroke in patients with non-valvular atrial fibrillation (AF) demonstrates that those enrolled on Bayer's ROCKET AF trial clearly reflects patients most at risk of stroke.[1]

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)

Newbury, Berkshire, Thursday 27th May, 2010 – new data from a warfarin comparison study shows that the health characteristics of the patients enrolled on the ROCKET AF trial more closely reflect the typical AF patient population than four other recent major trials in this category*.[1] The baseline demographic data, from Bayer Schering Pharma's study, were presented today at the 19th European Stroke Conference, Barcelona; the study is designed to assess the safety and efficacy of once-daily oral rivaroxaban (Xarelto®) against warfarin in 14,269 AF patients.[2]

Healthcare professionals widely use the $CHADS_2$ tool to assess stroke-risk and subsequent need for anticoagulation therapy in patients with AF.[3] A high $CHADS_2$ score (three and above) corresponds to a greater risk of stroke, while a low score corresponds to a lower risk of stroke. The ROCKET AF study specifically targeted AF patients with the greatest need for a stroke-preventing anticoagulant.[2] Of those enrolled, 90% have a $CHADS_2$ score of three or higher[2] – whilst the four comparable studies only had between 27 and 44% of patients with a $CHADS_2$ score of at least three.[1]

Arrhythmia Alliance
The Heart Rhythm Charity
www.heartrhythmcharity.org.uk

P O Box 3697
Stratford Upon Avon
Warwickshire
CV37 8YL
T: +44 (0) 1789 450787
F: +44 (0) 1789 450682

Due to the carefully chosen patient population and study design of ROCKET AF, investigators have been able to gather data consistent with the types of AF patients who need anticoagulation therapy, which healthcare professionals see in a real life setting.[2] Professor Keith Fox, Co-Chair of the Steering Committee of the ROCKET AF and Professor of Cardiology at the University of Edinburgh, is eagerly anticipating final outcomes of the trial and commented, "With this trial design, I anticipate that ROCKET AF is likely to provide a realistic picture of how warfarin alternatives can effectively prevent stroke in those AF patients at an increased risk." He continued, "Dosing difficulties and continuous coagulation monitoring have always plagued the use of warfarin and clinicians should be excited by the prospect of new, effective, therapeutic alternatives to help protect their patients from the debilitating effects of stroke."

In the UK, AF affects approximately 740,000 people, increases the risk of stroke by five times, and is responsible for 15% of the 150,000 strokes per year.[4,5,6,7] Of those affected by AF, up to 80% have a moderate to high risk of suffering a stroke and should receive anticoagulation treatment to reduce this risk, as advised by the National Institute of Health and Clinical Excellence (NICE).[3,8] At present vitamin K antagonists (VKAs), such as warfarin, are the only oral anticoagulants recommended for these patients.[8] However, despite clear guidelines, only 15 to 44% of eligible patients receive a VKA.[9] Those aged 75 or over are usually eligible, as they are at increased risk of stroke, but are less likely to receive appropriate treatment due to a variety of factors.[3,4] Frequent monitoring, dose adjustments, and drug and food interactions may contribute to a healthcare professional's possible reluctance to prescribe warfarin to the elderly population, as do dementia related compliance issues, and bleeding risks associated with fall related injuries.[4,10]

Without appropriate treatment patients are at continued risk of stroke which results in a significant economic burden to the NHS. The direct cost of stroke to the NHS is estimated to be £2.8 billion.[7] These drawbacks have led to the growing need for clinical studies, like ROCKET AF, into alternative anticoagulation therapies that offer favourable benefit-risk profiles.

"ROCKET AF is a study with a patient population that reflects clinical practice advocated in current guidelines," said Dr Luis Felipe Graterol, Medical Director, Bayer Schering Pharma. "We are looking

P O Box 3697
Stratford Upon Avon
Warwickshire
CV37 8YL
T: +44 (0) 1789 450787
F: +44 (0) 1789 450682

forward to the results of the study and hope that this trial provides us with much needed information on how to effectively reduce the risk of stroke for patients with atrial fibrillation."

Enrolment to the ROCKET AF trial is complete, the first patient was enrolled in December 2006 and the maximum observation period is expected to be four years.[2] Results are anticipated late Q4 2010.

Rivaroxaban is currently licensed for use in the UK for VTE prevention following elective hip or knee replacement surgery.

The abstract is available online at the European Stroke Conference website: http://www.eurostroke.eu/pub_ongoings.asp

- Ends -

*The four comparable studies are ACTIVE W, AMADEUS, RE-LY, SPORTIF V

UK.PH.GM.XAR.2010.107
Date of preparation: May 2010

Contact(s) for further information:

Athena

Sarah Avent
Tel: 020 8956 2227
Mobile: 07795 236448
sarah.avent@athenamedcomms.com

Hannah Stacey
Tel: 020 8956 2289
Mobile: 07984 496441
hannah.stacey@athenamedcomms.com

Note to Editors:

Please find attached two backgrounders containing further details about the ROCKET AF study design and additional information about stroke prevention in atrial fibrillation.

The $CHADS_2$ scoring table

Arrhythmia Alliance
The Heart Rhythm Charity
www.heartrhythmcharity.org.uk

P O Box 3697
Stratford Upon Avon
Warwickshire
CV37 8YL
T: +44 (0) 1789 450787
F: +44 (0) 1789 450682

	Condition	Points
C	Congestive heart failure	1
H	Hypertension: blood pressure consistently above 140/90 mmHg (or treated hypertension on medication)	1
A	Age >75 years	1
D	Diabetes Mellitus	1
S_2	Prior Stroke or TIA	2

Adding together the points that correspond to the conditions that a patient has will result in the $CHADS_2$ score. This score is used to estimate stroke risk.

About Rivaroxaban
Rivaroxaban was invented in Bayer's Wuppertal laboratories in Germany and is being marketed in Europe by Bayer Schering Pharma. It is approved in the European Union for the prevention of VTE in adult patients undergoing elective hip or knee replacement surgery. Additional approvals have been granted in other countries, including Australia, Canada, China, Mexico and Singapore. To date, rivaroxaban has been launched in more than 25 countries around the world by Bayer Schering Pharma.

The extensive clinical trial programme supporting rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. More than 60,000 patients are expected to be enrolled into the rivaroxaban clinical development programme, which will evaluate the product in a broad range of acute and chronic blood clotting conditions.

To learn more about thrombosis, please visit www.thrombosisadviser.co.uk

About Bayer Schering Pharma
Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Haematology & Neurology, Oncology and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialised markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of patients' lives.

Further information can be found at www.bayerscheringpharma.co.uk

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by 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.

References

Arrhythmia Alliance
The Heart Rhythm Charity
www.heartrhythmcharity.org.uk

P O Box 3697
Stratford Upon Avon
Warwickshire
CV37 8YL

T: +44 (0) 1789 450787
F: +44 (0) 1789 450682

1. Patel M. Baseline characteristics of the ROCKET AF study: comparison with recent atrial fibrillation studies. European Stroke Conference 2010. Poster OAID:5 .

2. The Executive Steering Committee, on behalf of the ROCKET AF Study Investigators. Rivaroxaban—Once daily, oral, direct factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation: Rationale and Design of the ROCKET AF study. *American Heart Journal*. 159:3:340-347.e1, March 2010

3. Lip GYH, Nieuwlaat R, Pisters R, et al. Refining Clinical Risk Stratification for Predicting Stroke and Thromboembolism in Atrial Fibrillation Using a Novel Risk Factor-Based Approach: The Euro Heart Survey on Atrial Fibrillation. *Chest*. February 2010 137:263-272

4. Lane DA et al. Barriers to anticoagulation in patients with atrial fibrillation: Changing Physician-Related Factors. *American Heart Association*. Stroke. 2008;39:7-9

5. 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

6. NHS Improvement. Heart Improvement Atrial Fibrillation in Primary Care National Priority Project. 2008. Available online at http://www.heart.nhs.uk/priority_projects/summary_documents/af_summary.pdf Last accessed: 24 May 2010

7. The Stroke Association. Facts and figures about stroke. Available online at http://www.stroke.org.uk/media_centre/facts_and_figures/index.html. Last accessed: 18 May 2010

8. National Institute for Health and Clinical Excellence (NICE). Atrial Fibrillation: A quick reference guide. Available at http://guidance.nice.org.uk/CG36/QuickRefGuide/pdf/English. Last accessed 18 May 2010

9. Kakar P, Lane D, Lip G. Y. H. Bleeding risk stratification models in deciding on anticoagulation in patients with atrial fibrillation: a useful complement to stroke risk stratification schema. *Chest*. 2006; 130: 1296-1299

10. Wensley S, Keir S, Caine S et al. Additional risk factors in atrial fibrillation patients not receiving warfarin. British Geriatrics Society. *Age and Ageing*. 1999; 28: 355-357