

Consumer News Release

Bayer's Xarelto[®] (Rivaroxaban) First Oral Anticoagulant to Show Significant Benefit in the Chronic Setting

- Over 13,000^{1,2,3} patients suffer from recurrent blood clots every year in the UK
- Xarelto[®], Bayer's oral anticoagulant, reduces relative risk of potentially fatal clots by 82%⁴

Newbury, Berkshire, 6th December 2009 – Data from a Phase III trial of an oral anticoagulant in the chronic setting demonstrates that Bayer's oral anticoagulant Xarelto reduces the risk of potentially fatal recurring venous blood clots by 82%.⁴

Results from the EINSTEIN-Extension study, presented today at the 51st Annual meeting of the American Society of Haematology in New Orleans, demonstrate that Xarelto, when compared to placebo, reduced the risk of a recurrent venous blood clot by 82% (RRR) [1.3% (n=8) vs. 7.1% (n=42), respectively] in patients who had been previously treated for a deep vein thrombosis (DVT) or pulmonary embolism (PE).⁴

Recurring venous blood clots occur in approximately 21.5%¹ of the 61,000^{2,3} people that suffer from a DVT each year in the UK. Following an initial blood clot, up to 10% of patients who are treated adequately with anticoagulants, still experience an additional blood clot within 12 months.⁵

Dr Alexander Cohen, Consultant in Vascular Medicine, King's College Hospital, London said; "The results from the EINSTEIN-Extension study provide compelling evidence for extending prophylaxis for an additional 6-12 months beyond the currently recommended 3-6 months of treatment. VTE is a major public health concern, and costs the NHS millions each year; these results will help shape its treatment, giving physicians and

patients the best chance of reducing its reoccurrence and providing the health service with considerable savings.”

Venous blood clots account for 10% of hospital mortality and cost the NHS an estimated £640 million per year;⁶ it is estimated that a further £19 million of NHS money has been spent on litigation from patients who have developed blood clots as a result of a hospital stay or procedure.⁷

Xarelto requires no routine monitoring (such as clotting, liver function etc)⁸ and is well tolerated, with results from the study demonstrating that the rates of major bleeding, the primary safety endpoint, were low and not statistically significantly different ($p=0.11$) to placebo [0.7% (n=4) vs. 0.0% (n=0) for Xarelto and placebo, respectively].⁴

A second safety endpoint of clinically relevant, non-major bleeding showed a statistical difference ($p<0.001$) between the two groups [5.4% (n=32) vs. 1.2% (n=7) in the Xarelto and placebo arms, respectively].⁴

Xarelto has been studied in an extensive clinical trial programme and demonstrated no evidence of compromised liver function. No cases of serious liver injury were reported in either group of the EINSTEIN-Extension study.⁹

Xarelto is approved in the European Union for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

For further information, the abstract (Iba-2) is available online at the ASH website:

<http://ash.confex.com/ash/2009/webprogram/Paper25669.html>

Contact(s) for further information:

Athena Medical PR

Rawaa Abdalla

Tel: 020 8956 2870

Mobile: 07853 349 792

rawaa@athenamedicalpr.com

Danielle Smith

Tel: 020 8956 2296

Mobile: 07786 078745

danielle@athenamedicalpr.com

Notes to editors

About the EINSTEIN Programme

EINSTEIN is a global clinical development programme composed of three clinical studies in approximately 8,000 patients. Two of these studies enrolled patients with acute, symptomatic deep vein thrombosis (EINSTEIN-DVT, enrollment complete) or pulmonary embolism (EINSTEIN-PE). In these two trials, patients received oral rivaroxaban 15 mg twice-daily for the first three weeks, followed by oral rivaroxaban 20 mg once-daily, compared with initial enoxaparin treatment followed by a vitamin K antagonist. The third study, EINSTEIN-EXT, compared the efficacy and safety of rivaroxaban to placebo in the secondary prevention of recurrent symptomatic venous blood clots in patients who had previously suffered a symptomatic DVT or PE, by extending preventative treatment by 6 or 12 months beyond a previously completed regimen of 6 to 12 months of therapy. 1,200 patients from 28 countries around the world were enrolled in the EINSTEIN-EXT study.

About Xarelto (Rivaroxaban)

Xarelto 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, Xarelto 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 the prevention and treatment of a broad range of acute and chronic 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:

1. Hansson PO, Sorbo J, Eriksson H. Recurrent Venous Thromboembolism After Deep Vein Thrombosis. *Archive of International Medicine*. 2000;160:769-774
2. Deep Vein Thrombosis. *Patient UK*. Available at: <http://www.patient.co.uk/health/Deep-Vein-Thrombosis.htm> Last Accessed: 30 November 2009
3. UK Population. *National Statistics Online*. Available at: <http://www.statistics.gov.uk/cci/nugget.asp?id=1352> Last Accessed: 30 November 2009
4. Buller. HR. Iba-2 Once-Daily Oral Rivaroxaban Versus Placebo in the Long-Term Prevention of Recurrent Symptomatic Venous Thromboembolism. The Einstein-Extension Study. Late-breaking Abstract Session; LBA--2. 51st Annual Meeting of the American Society of Haematology. 8 December 2009. Available at: <http://ash.confex.com/ash/2009/webprogram/Paper25669.html> Last Accessed: 30 November 2009
5. Kearon C. Natural History of Venous Thromboembolism. *Circulation* 2003; 107;I-22-I-30
6. The House of Commons Health Committee. 2005. The Prevention of Venous Thromboembolism in Hospitalised Patients. Available at: <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/99/99.pdf>. Last Accessed: 30 November 2009
7. Scurr JHR et al. Is failure to provide venous thromboprophylaxis negligent? *Phlebology*. 2007; 22: 186 – 191
8. Xarelto SmPC, May 2009
9. Data on file, December 2009