



Bayer HealthCare
Bayer Schering Pharma



News release for medical and consumer media, regional London press and national newspapers

Bayer's Novel Oral Anticoagulant Xarelto[®] (rivaroxaban) Gets European Licence

New drug Xarelto[®] (rivaroxaban), which has been shown to be significantly more effective than current standard, gets UK licence

1st October 2008 - A new drug launched today could help in the fight against what experts and campaigners are calling a 'major patient safety issue'¹ – the prevention of hospital-acquired DVT (deep vein thrombosis). Xarelto, a once-daily tablet which has been shown to be significantly more effective than the existing standard treatment, injectable enoxaparin²⁻³, could help prevent unnecessary deaths from hospital-acquired DVT in patients undergoing elective hip or knee replacement surgery – one of the groups at highest risk¹.

In the UK 160,000 hip and knee replacement procedures are performed annually.⁴ Due to the invasive nature of this surgery and lack of mobility it causes, up to half of these patients would go on to develop a hospital-acquired DVT if preventative treatment (thromboprophylaxis) is not given.⁵ However, despite continued calls for more priority to be given to hospital-acquired DVT and for government investment in its prevention to reflect that of hospital-acquired infections (£50 million annually)⁶, the limitations of commonly used treatments and lack of compulsory patient risk assessment mean that many patients are still being put at risk by not receiving preventative treatment.¹

In clinical trials, such preventative treatment with new drug Xarelto has shown that patients undergoing elective hip or knee replacement surgery have a significantly lower risk of developing blood clots following their procedure than patients treated with the current

mainstay of therapy, enoxaparin (70% and 49% relative risk reductions and 2.6% and 9.2% absolute risk reductions respectively)*, whilst maintaining comparable rates of bleeding.²⁻³

Beverley Hunt, Medical Director of Lifeblood: The Thrombosis Charity, comments: “Despite the clear evidence of benefit and the existence of national guidelines, current provision of thromboprophylaxis for hospitalised patients is suboptimal, and hospital-acquired DVTs continue to cause unnecessary suffering and death. As a health professional and campaigner for improved patient care, I hope the introduction of new, effective and convenient anticoagulants such as Xarelto will mean more patients, especially those in high risk groups, will benefit in the future.”

The cost to the NHS of treating patients who develop hospital-acquired DVT from all causes is thought to be as high as £222.8 million per year¹, much higher than the cost of treating MRSA (£45 million).⁷ A further £19 million of the NHS’ money is spent on litigation from patients and their families who have developed blood clots as a result of a hospital stay or procedure.⁸ Despite this evidence suggests that hospital trusts are still failing to implement NICE’s recommendations for preventative treatment to be provided to all high risk patients for up to four weeks following surgery.⁹

Commenting on the impact that Xarelto could have on the uptake of thromboprophylaxis, Mr Richard Field, an orthopaedic surgeon working at the South West London Elective Orthopaedic Centre (the EOC), the highest volume centre for joint replacement in the UK, said: “The most important thing for me as an orthopaedic surgeon, is to provide our patients with the safest possible route through their surgery. The possibility of offering a simple, one tablet, once-a-day medication which is highly effective and easy for patients to take should help us to meet this challenge.”

Xarelto is currently undergoing appraisal by NICE, which is expected to publish its recommendations in June 2009.

-Ends-

* Absolute risk is used to describe the risk of developing a disease over a time period

Relative risk is used to compare the risk of one group developing a disease in comparison to the risk of another group.

CONTACT FOR FURTHER INFORMATION:

Athena Medical PR

Emma Keeling
Tel: 020 8956 2299
Mobile: 07884 311982
emmak@athenamedicalpr.com

Natalie Bennett
Tel: 020 8956 2299
Mobile: 07786 078745
natalie@athenamedicalpr.com

NOTES FOR EDITORS

About hospital-acquired DVT

- Venous blood clots, (also known as venous thromboembolism or VTE) can take the form of either:
 - A deep vein thrombosis (DVT) - a blood clot in a deep vein (usually in the leg) that partially or totally blocks the flow of blood¹⁰
 - A pulmonary embolism (PE) - a blood clot blocking an artery in the lungs¹⁰
- Each year an estimated 25,000 to 32,000 people in the UK die from venous blood clots as a result of a hospital stay or surgical procedure (sometimes referred to as 'hospital-acquired DVT'). This is more people than die from breast cancer, prostate cancer, HIV/AIDS and road traffic accidents combined¹
- Many of these deaths could be prevented¹
- Effective prevention and treatment of hospital-acquired DVT is a major national public health issue¹
- People at risk of hospital-acquired DVT include people undergoing major orthopaedic surgery and those who are hospitalised or immobilised over long periods^{11,12}
- The majority (74%) of hospital-acquired DVT cause symptoms after the patient has left hospital¹²
- Hospital-acquired DVT occur in up to 50% of patients undergoing major orthopaedic surgery who do not receive preventative care⁵
- In November 2007, the All Party Parliamentary Thrombosis Group (APPTG) published a report following an audit of acute hospital trusts which found that only 32% of hospital trusts are taking steps to risk assess patients (for hospital-acquired DVT) and bring their practices in line with NICE and government recommendations⁹ which are as follows:
 - Current NICE recommendations state that:¹³
 - All patients undergoing major surgery should be assessed to identify their individual risk of developing VTE after the procedure

- All patients undergoing major orthopaedic surgery of the lower limbs should receive anticoagulant therapy, LMWH (low molecular weight heparin) for up to 28 days after surgery in combination with pressure stockings, to reduce the risk of VTE

About Xarelto (rivaroxaban)

Xarelto is the first of a new class of oral anticoagulant specifically inhibiting (blocking) Factor Xa, a pivotal step in the coagulation (blood clotting) process¹⁴

Unlike low weight molecular heparins such as enoxaparin, which are administered daily by injection, Xarelto is an oral, once-daily tablet which is administered six to ten hours after surgery.² It is licensed for two weeks following elective knee replacement surgery or five weeks following elective hip replacement surgery. An oral tablet such as Xarelto offers a more convenient, patient orientated treatment option than an injection as it enables patients to more easily continue their anticoagulant therapy at home, providing ongoing protection against the continued risk of developing clots. Further, there are no coagulation monitoring requirements with Xarelto, which is an advantage over traditional oral anticoagulants such as Warfarin.

Almost 50,000 people are expected to be enrolled into the overall development programme for Xarelto. Clinical trials are underway evaluating its use in a wide range of conditions.

About Bayer Schering Pharma UK

Bayer Schering Pharma is a leading, worldwide speciality pharmaceutical company. Its research and business activities are focussed on the fields of haematology & cardiology, oncology, diagnostic imaging, primary care, specialised therapeutics and women's healthcare. With innovative products and using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life of patients.

References:

1. The Commons Health Committee. 2005. The Prevention of Venous Thromboembolism in Hospitalised Patients.
<http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/99/99.pdf>
2. Eriksson BI et al. Rivaroxaban versus enoxaparin for thromboprophylaxis after hip arthroplasty. *N Engl J Med* 2008;358:-2765-75
3. Lassen MR et al. Rivaroxaban versus enoxaparin after total knee arthroplasty. *N Engl J Med* 2008; 358:2776 – 86
4. The National Joint Registry.
<http://www.njrcentre.org.uk/njrcentre/Patients/Jointreplacementstatistics/tabid/99/Default.aspx>.
(Last accessed 08.09.08)
5. Choi BY et al. Venous Thromboembolism Following Total Knee Replacement. *J Surg Orthop Adv* 2007; 16: 31-5.
6. The Department of Health.
<http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=296735&NewsAreaID=2&NavigatedFromDepartment=True>. (Last accessed on 08.09.08)
7. The Daily Telegraph. <http://www.telegraph.co.uk/news/uknews/2194132/Every-MRSA-case-costs-NHS-an-extra-9000.html>. (Last accessed on 08.09.09)
8. Scurr JHR et al. Is failure to provide venous thromboprophylaxis negligent? *Phlebology* 2007; 22: 186 – 191
9. All-Party Parliamentary Thrombosis Group (APPTG) VTE Research Report, April 19 2007

10. Lifeblood: The Thrombosis Charity. Ten questions about thrombosis. 2008. http://www.thrombosis-charity.org.uk/cms/index.php?option=com_content&task=category§ionid=9&id=21&Itemid=83 (Last accessed on 28.08.08)
11. Heit JA. The Epidemiology of Venous Thromboembolism in the Community: Implications for Prevention and Management.
J Thromb Thrombolysis 2006; 21: 23-9.
12. Spencer FA et al. Venous Thromboembolism in the Outpatient Setting. *Arch Intern Med* 2007; 167: 1471-5.
13. NICE Clinical Guideline 46. Quick Reference Guide. Venous Thromboembolism: Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery. April 2007
14. Turpie A et al. Comparison of rivaroxaban—an oral, direct factor Xa inhibitor—and subcutaneous enoxaparin for thromboprophylaxis after total knee replacement (RECORD4: a phase 3 study). European Federation of National Associations of Orthopaedics and Traumatology 2008 Annual Meeting; May 29-June 1, 2008; Nice, France. Abstract F85.