

Bayer's Xarelto® Approved in Canada

Last Updated Thursday, 20 November 2008

Health

Canada has just approved Xarelto® (rivaroxaban) for the prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip or total knee replacement surgery. This marks the first approval for Xarelto worldwide.

- For the first time in the world, the new oral, once-daily anticoagulant Xarelto is to be made commercially available to patients in Canada

- In July 2008, the CHMP issued a positive opinion and recommended approval of rivaroxaban in the EU for the prevention of venous blood clots in patients undergoing elective total hip or total knee replacement surgery. A final decision is expected very soon

- Xarelto is the most studied oral, direct Factor Xa inhibitor in the world today

Xarelto

is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Leverkusen, Germany / Toronto, Canada, September 16, 2008 - Health Canada has granted Bayer HealthCare marketing authorization for the anticoagulant Xarelto® (rivaroxaban), taken as one tablet, once-daily, for the prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip or total knee replacement surgery. This decision marks the first approval for Xarelto worldwide. Bayer will start marketing the product immediately.

"Xarelto, discovered in Bayer's Wuppertal laboratories in Germany, is a first-in-class product and the only oral anticoagulant to demonstrate superior efficacy over the standard of care, enoxaparin," said Arthur Higgins, CEO of Bayer HealthCare. "The approval in Canada marks an important milestone for the most

extensively studied product of its class and Bayer HealthCare has achieved a major step forward in establishing a new era in antithrombosis therapy."

"Xarelto has the potential to revolutionize how we prevent dangerous blood clots after elective total hip or knee replacement surgery in Canada," said Dr. A.G.G. Turpie, Professor of Medicine, McMaster University, Canada, and Principal Investigator for the RECORD program. "The existing treatment standards have limitations, so new therapies such as Xarelto can help doctors to prevent the potentially lethal effects of venous blood clots."

The approval from Health Canada was based on data from the extensive RECORD clinical program that included three Phase III trials of Xarelto involving nearly 10,000 patients undergoing elective hip or knee replacement surgery (RECORD1, 2 and 3 trials). Results from these three studies demonstrated the superior efficacy of Xarelto, both in head-to-head comparisons with enoxaparin (RECORD1 and 3), and when comparing extended-duration (5 weeks) Xarelto with short-duration (2 weeks) enoxaparin (RECORD2). In all three trials, Xarelto and enoxaparin had similar safety profiles including low rates of major bleeding.

Xarelto has also been recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) and Bayer expects the marketing authorization across all EU-member states very soon.

About Venous Thromboembolism

Venous thromboembolism (VTE) is a serious life-threatening condition which kills more people each year than breast cancer, AIDS, prostate cancer and traffic accidents combined. Overall, it is estimated that there are 15,000 to 20,000 VTE cases in Canada annually.

During hip or knee replacement procedures, the large veins of the leg that carry blood back to the heart are damaged which significantly increases the risk of VTE for patients undergoing such major orthopedic surgery. In fact, venous blood clots occur in 40-60% of patients undergoing major orthopedic surgery who do not receive preventative care. In 2005-2006, there were nearly 69,000 hospitalizations for hip and knee replacements in Canada alone.

To learn more about VTE please visit www.thrombosisadviser.com.

About Xarelto® (rivaroxaban)

The extensive clinical trial program supporting Xarelto makes it the most studied oral, direct Factor Xa inhibitor in the world today. Almost 50,000 patients are expected to be enrolled into the Xarelto 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, VTE prevention in hospitalized, medically ill patients and secondary prevention of acute coronary syndrome.

Xarelto

was recently submitted to the U.S. Food and Drug Administration (FDA). On approval, Ortho-McNeil, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., will market the drug in the United States. In addition to the FDA submission, filings are under review with regulatory agencies in more than 10 other countries.

Xarelto

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.

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 subsidiary of Bayer AG, 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, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

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, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

Contact:

Dr. Jost Reinhard, Tel.: +49 30-468-15062

E-mail: jost.reinhard@bayerhealthcare.com

Contact (US and Canada media):

Doug Grant, Tel.: +1 416 246 5001

E-mail: doug.grant.b@bayer.com

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.