



FOR IMMEDIATE RELEASE

**XARELTO® APPROVED AS FIRST ONCE-DAILY, ORAL ANTICOAGULANT
FOR STROKE PREVENTION IN ATRIAL FIBRILLATION THAT DOES NOT REQUIRE
ROUTINE COAGULATION MONITORING**

Toronto, ON (January 17, 2012) – Bayer Inc. announced today the Health Canada approval of Xarelto® (rivaroxaban tablet) in the prevention of stroke and systemic embolism in patients with atrial fibrillation (AF) in whom anticoagulation is appropriate. ⁽¹⁾ Xarelto® is the first once-daily oral anticoagulant for this indication that does not require routine coagulation monitoring. Xarelto® is also approved for the prevention of venous thromboembolic events (VTE), or blood clots, in patients who have undergone elective total hip or total knee replacement surgery and has become the number one dispensed anticoagulant prescribed by Canadian orthopedic surgeons in this indication. ⁽²⁾

“This important new approval supports the safety and efficacy of Xarelto® in the prevention of potentially fatal blood clots in patients with atrial fibrillation, a condition that affects almost 350,000 Canadians,” said Dr. Jean Grégoire, a cardiologist at the Montreal Heart Institute and Assistant Professor of Medicine at the University of Montreal. “Xarelto® is an effective, safe, well-tolerated and convenient option that will enable healthcare professionals to reduce the risk of stroke in their patients.”

A New Alternative in Stroke Prevention in Atrial Fibrillation

The approval of Xarelto® for the prevention of stroke and systemic embolism in AF patients is based on the clinical benefits demonstrated in ROCKET AF, a randomized, double-blind global Phase III study that compared once-daily Xarelto® with warfarin in more than 14,000 patients, including 750 from Canada. The results from the ROCKET AF trial were published in the *New England Journal of Medicine* in August 2011. ⁽³⁾

In ROCKET AF, once-daily Xarelto® successfully met the primary efficacy outcome of non-inferiority while patients were on study medication; results demonstrated a 21 per cent relative risk reduction in stroke and systemic embolism compared to warfarin. In addition, although major and clinically significant non-major bleeding rates were comparable to warfarin, Xarelto® reduced the risk of critical bleeds, such as fatal bleeds and intra-cranial haemorrhages. ⁽³⁾

“AF exposes patients to the serious risk of stroke - so safe, effective and less complex treatment should encourage improved compliance and lead to potentially better stroke prevention,” said Dr. Shaun Goodman, a cardiologist at St. Michael’s Hospital and Professor of Medicine at the University of Toronto who served as a ROCKET AF Steering Committee member and Canadian National Leader for the trial. “Patients with AF have a five-fold increase in the risk of stroke, and these strokes are often more severe and disabling in this patient population.”

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“Xarelto® is patient-friendly as it is the only once-daily medication that does not require frequent coagulation monitoring and dose adjustments. We’re hopeful that a new alternative like Xarelto® will offer greater convenience to our patients,” added Dr. Goodman.

About Atrial Fibrillation (AF)

Atrial fibrillation (AF), the most common form of cardiac arrhythmia in clinical practice, affects approximately 350,000 Canadians ⁽⁴⁾ and is an established risk factor for stroke and premature death. It is estimated that after age 60, one-third of all strokes are caused by AF. ⁽⁴⁾

In patients with AF, the irregular heartbeat makes them vulnerable to the formation of a blood clot in the atria, which can travel to the brain, potentially resulting in a stroke. Strokes cause damage to the brain, and can lead to physical and behavioural impairment, significant disability, or even death. About a third of people with AF have no symptoms whatsoever. The danger of AF being undetected is that it puts people at risk of serious complications, including stroke.

About Xarelto®

Xarelto® (rivaroxaban tablet) is a fixed-dose oral anticoagulant that has a rapid onset of action with a predictable dose response, does not require routine coagulation monitoring and dose adjustments, and has limited potential for food and drug interactions. ⁽⁵⁾

In addition to the new indication, Xarelto® is approved in Canada for VTE prevention in patients following elective total hip or knee replacement surgery. To date, Xarelto® is approved in more than 110 countries worldwide and has been successfully launched in more than 85 countries by Bayer HealthCare in this VTE indication.

The extensive clinical trial program supporting Xarelto® makes it one of the most studied and widely published oral, direct Factor Xa inhibitors. The studies, reported and ongoing, involve over 75,000 patients for the prevention and treatment of venous and arterial thromboembolic disorders across a broad range of acute and chronic conditions, including the secondary prevention of acute coronary syndrome and treatment of pulmonary embolism.

Xarelto®, like other anticoagulants, should be used with caution in patients with an increased risk of bleeding. Bleeding can occur at any site during therapy with Xarelto®. The possibility of a hemorrhage should be considered in evaluating the condition of any anticoagulated patient. Any unexplained fall in hemoglobin or blood pressure should lead to a search for a bleeding site.

Patients at high risk of bleeding should not be prescribed Xarelto®. Should severe bleeding occur, treatment with Xarelto® must be discontinued and the source of bleeding investigated promptly. The use of Xarelto® is not recommended in patients with severe renal impairment.

Physicians should refer to the Xarelto® Product Monograph for complete information.

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About Bayer Inc.

Bayer Inc. (Bayer) is a Canadian subsidiary of Bayer AG, an international research-based group with core businesses in health care, crop science and innovative materials. Headquartered in Toronto, Ontario, Bayer Inc. operates the Bayer Group's HealthCare and MaterialScience businesses in Canada. Bayer CropScience Inc., headquartered in Calgary, Alberta operates as a separate legal entity in Canada. Together, the companies play a vital role in improving the quality of life for Canadians - producing products that fight diseases, protecting crops and animals, and developing high-performance materials for applications in numerous areas of daily life. Canadian Bayer facilities include the Toronto headquarters and offices in Montréal and Calgary.

Bayer Inc. has approximately 800 employees across Canada and had sales of \$827 million CDN in 2010. Globally, the Bayer Group had sales of over 35 billion Euro in 2010. Bayer Inc. invested approximately \$36 million CDN in research and development in 2010. Worldwide, the Bayer Group spent the equivalent of over 3.1 billion Euro in 2010 in R&D. For more information, go to www.bayer.ca.

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For more information including the updated Xarelto® Product Monograph, or to arrange an interview with a Canadian professional, please contact:

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- (3) Patel MH, Mahaffey KW, Garg J et al. Rivaroxaban versus Warfarin in Non-valvular Atrial Fibrillation. *New England Journal of Medicine* 2011; 365:883-891.
- (4) Heart and Stroke Foundation of Canada.
http://www.heartandstroke.on.ca/site/c.pvl3leNWJwE/b.5052981/k.17A/Atrial_fibrillation.htm?src=report
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