



## **FDA Approves XARELTO® (rivaroxaban tablets) to Help Prevent Deep Vein Thrombosis in Patients Undergoing Knee or Hip Replacement Surgery**

XARELTO® is the only new oral anticoagulant with FDA approval in this indication

**Raritan, NJ (July 1, 2011)** — Janssen Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved XARELTO® (rivaroxaban tablets), a novel, once-daily, oral anticoagulant for the prevention (prophylaxis) of deep vein thrombosis (DVT) which may lead to a pulmonary embolism (PE) in people undergoing knee or hip replacement surgery.

“The approval of once-daily XARELTO® tablets will provide a new option to help protect patients from developing venous blood clots following knee or hip replacement surgery,” said Louis M. Kwong, M.D., Professor of Orthopedic Surgery at Harbor-UCLA Medical Center, who was involved with the rivaroxaban clinical trials program in this indication. “XARELTO® has a proven clinical benefit over one of today’s most widely used options in preventing these potentially life-threatening blood clots, and the use of a once-daily pill may play an essential role in helping to simplify clinical practice.”

According to the American Academy of Orthopedic Surgeons, more than 800,000 Americans undergo knee or hip replacement surgery each year. These procedures are associated with an increased risk for DVT, a blood clot that forms in a deep vein, usually in the leg. If all or part of a DVT breaks off, it can travel to the lungs and become a PE, where it may impact the flow of oxygenated blood and lead to potentially life-threatening consequences.

The American College of Chest Physicians recommends the use of blood thinners (anticoagulants) immediately following major orthopedic replacement surgery and extended use post-discharge (at least 10 days for knee replacement, and up to 35 days for hip replacement) to help reduce such risks; however, full compliance with these guidelines using previously available options has not been widely observed. DVT and PE are the leading causes of re-hospitalization following joint replacement surgery.



"The use of blood thinners has been shown to safely and effectively help keep people from developing preventable blood clots," said Alan Brownstein, Chief Executive Officer of the National Blood Clot Alliance. "The FDA approval of a new blood thinner, XARELTO<sup>®</sup>, offers a new option for patients seeking knee or hip replacement surgery, and we encourage people to discuss with their physicians the risk of blood clots and which blood thinner offers optimal protection as part of their pre-surgical consultation."

Pivotal data from the XARELTO<sup>®</sup> Phase 3 clinical development program reflected in the approved label showed significantly greater efficacy of rivaroxaban, both in head-to-head comparison with enoxaparin and when comparing extended-duration (5 weeks) rivaroxaban with short-duration (2 weeks) enoxaparin, followed by placebo. In these trials, rivaroxaban and enoxaparin demonstrated similar safety profiles including low rates of major bleeding.

XARELTO<sup>®</sup> is approved for use at a 10 mg dose, once-daily for 35 days following hip replacement and for 12 days following knee replacement surgery. To date, XARELTO<sup>®</sup> is approved in more than 110 countries worldwide and has been successfully launched in more than 80 countries by Bayer HealthCare. Janssen Pharmaceuticals, Inc. holds marketing rights for XARELTO<sup>®</sup> in the U.S. The U.S. Bayer HealthCare sales force will support the Janssen Pharmaceuticals, Inc. sales force by detailing XARELTO<sup>®</sup> in designated hospital accounts.

"Shorter hospital stays following hip and knee replacement surgeries have made the prevention of venous blood clots an outpatient issue, and XARELTO<sup>®</sup> provides a safe and effective oral treatment option that can be easily transitioned from use in hospital to home," said Paul Chang, M.D., Vice President, Medical Affairs, Internal Medicine, Janssen Pharmaceuticals, Inc. "We're pleased to make XARELTO<sup>®</sup> tablets available to physicians to help them better protect their patients from these highly preventable surgical complications."

#### **About XARELTO<sup>®</sup> (rivaroxaban tablets)**

XARELTO<sup>®</sup> is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in people undergoing knee or hip replacement surgery. XARELTO<sup>®</sup> belongs to a group of medicines called anticoagulants. It works by blocking the blood clotting Factor Xa and thereby reduces the tendency of the blood to form clots.



XARELTO® is the third New Drug Application the U.S. FDA has approved from the Janssen Pharmaceutical Companies this year.

Additionally, XARELTO® is being evaluated for the prevention and treatment of a broad range of disorders in which blood clotting plays a major role. The extensive program of clinical trials evaluating rivaroxaban makes the compound the most studied oral, Factor Xa inhibitor in the world today. By the time of its completion, more than 65,000 patients will have participated in the rivaroxaban clinical development program. Rivaroxaban is being developed jointly by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Bayer HealthCare.

## **Important Safety Information**

### **WHAT IS XARELTO®?**

XARELTO® (rivaroxaban tablets) is a prescription medicine used to help prevent blood clots from forming in patients after hip or knee replacement surgery.

### **WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT XARELTO®?**

- You should take XARELTO® exactly as directed by your doctor
- Do not skip a dose or stop taking XARELTO® unless you are advised to do so by your doctor. Stopping may increase your risk of a blood clot
- If a dose is missed, take XARELTO as soon as possible and continue on the following day, taking XARELTO® as directed by your doctor. Do not take two doses at the same time
- XARELTO® can cause bleeding, which can sometimes be serious, even life-threatening. You may find you bruise or bleed more easily while you take it. It might take longer than usual to stop bleeding
- Alert your doctor right away if you develop any:
  - Tingling, numbness or muscle weakness, especially in your legs. This is particularly important if you had a procedure called spinal or epidural puncture as part of your anesthesia for your hip or knee replacement surgery.
  - Unusual bleeding or bruising (bruises that develop without an injury or grow in size)
  - New bleeding (for example, nose bleeds, bleeding gums, red urine, bright red blood in your stool, coughing up or vomiting blood)
  - Bleeding that is heavier than usual (for example, from cuts or menstruation)
  - Dizziness, weakness, or tiredness, all of which could indicate a loss of blood
  - Pain, swelling, or new fluid leakage in or around the surgical incision

## WHO SHOULD NOT TAKE XARELTO®?

Tell your doctor if you have:

- Unusual bleeding
- Ever had an allergic-type (hypersensitivity) reaction to XARELTO®

## WHAT SHOULD I TELL MY DOCTOR BEFORE OR WHILE TAKING XARELTO®?

- Tell your doctor or dentist about all the medicines you take.
  - This includes XARELTO®, any other prescription and nonprescription medicines, over-the-counter medications, and herbal supplements.
- Tell your doctor if you:
  - Have a bleeding disorder or have problems with unusual bleeding
  - Have any problems with your kidneys or liver
  - Are pregnant or planning to become pregnant
  - Are breast-feeding or are planning to breast-feed

## WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?

- XARELTO® may increase your chance of bleeding. This bleeding can sometimes be serious (and even life-threatening)
- In studies side effects with XARELTO® included fluid leakage from a wound, itching, pain in arms or legs, blisters, fainting, and muscle spasm.
- **Discuss any side effects with your doctor. You are also encouraged to report side effects to the FDA: visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.** You may also report side effects to Janssen Pharmaceuticals, Inc. at 1-800-JANSSEN (526-7736)

This is a summary of important information about XARELTO®. If you would like more information, talk with your doctor.

Please see full [Product Information](#), or visit [www.XARELTOhcp.com](http://www.XARELTOhcp.com).

### About Janssen Pharmaceuticals, Inc.

As a member of the Janssen Pharmaceutical Companies of Johnson & Johnson, Janssen Pharmaceuticals, Inc., is dedicated to addressing and solving some of the most important unmet medical needs in pain management, infectious diseases and cardiovascular and metabolic diseases. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to individuals with serious conditions, and to physicians throughout the world.

For more information on Janssen Pharmaceuticals, Inc., visit us at [www.janssenpharmaceuticalsinc.com](http://www.janssenpharmaceuticalsinc.com) or follow us on Twitter at [www.twitter.com/JanssenUS](http://www.twitter.com/JanssenUS).

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Dr. Kwong is a paid consultant to Janssen Pharmaceuticals, Inc.

Janssen Pharmaceuticals, Inc. provides support to the National Blood Clot Alliance for initiatives benefitting patients.

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