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Janssen Research & Development Submits Supplemental New Drug Application to U.S. FDA for XARELTO® (rivaroxaban) to Reduce the Risk of Stent Thrombosis in Patients with Acute Coronary Syndrome

RARITAN, May 9, 2012 - Janssen Research & Development, LLC (Janssen) announced today that it has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the use of XARELTO® (rivaroxaban), an oral anticoagulant, to reduce the risk of stent thrombosis in patients with Acute Coronary Syndrome (ACS). XARELTO® currently is under review with the U.S. FDA to reduce the risk of secondary cardiovascular events in patients with ACS. XARELTO® already is approved in the U.S. to reduce the risk of blood clots in the legs and lungs of people who have just had knee or hip replacement surgery, and to reduce the risk of both hemorrhagic and thrombotic strokes as well as other blood clots in people with atrial fibrillation not caused by a heart valve problem.

The filing is supported by data from the pivotal Phase 3 ATLAS ACS 2 TIMI 51 (**Anti-Xa Therapy to Lower cardiovascular events in Addition to aspirin with/without thienopyridine therapy in Subjects with Acute Coronary Syndrome**) trial, which was presented in November 2011 at the American Heart Association Scientific Sessions and published in the *New England Journal of Medicine* ([10.1056/NEJMoa1112277](http://dx.doi.org/10.1056/NEJMoa1112277)). In the trial, the 2.5 mg twice-daily (BID) dose of rivaroxaban was associated with a 35% Relative Risk Reduction in the rate of stent thrombosis compared to placebo [2.2% vs. 2.9% (Hazard Ratio: 0.65; Confidence Interval: 0.45-0.94)]*. Rates of TIMI (**Thrombolysis In Myocardial Infarction**) major bleeding events not associated with coronary artery bypass graft surgery were low overall in the trial, but rivaroxaban was associated with higher rates of these bleeds in the 2.5 mg BID dose compared to placebo [1.8% vs. 0.6% (Hazard Ratio: 3.46; Confidence Interval: 2.08-5.77)]. Importantly, these differences were not associated with an excess risk of fatal bleeding. Additional data on stent thrombosis, from the ATLAS ACS 2 TIMI 51 trial, will be presented later this year.

Coronary stents are implanted in more than 1.5 million patients each year. Stent thrombosis is an uncommon, but catastrophic complication that may occur after a stent has been inserted into a patient's coronary artery. Stent thrombosis can result in a heart attack or even death.

About XARELTO® (rivaroxaban)

XARELTO® belongs to a group of medicines called anticoagulants, and works by blocking the blood clotting Factor Xa, thereby reducing the tendency to form clots. In the U.S., XARELTO® is a prescription medication used to reduce the risk of blood clots in the legs and lungs of people who have just had knee or hip replacement surgery, and to reduce the risk of both hemorrhagic and thrombotic strokes as well as other blood clots in people with atrial fibrillation not caused by a heart valve problem. There is limited information on how XARELTO® compares to a medicine called warfarin in reducing the risk of stroke when the blood levels of warfarin are well-controlled. The blood levels of warfarin often vary in patients.

The extensive program of clinical trials evaluating rivaroxaban makes the compound the most studied oral, Factor Xa inhibitor in the world today. Rivaroxaban is being developed jointly by Janssen Research & Development, LLC and Bayer HealthCare. U.S. marketing rights for XARELTO® are held by Janssen Pharmaceuticals, Inc.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development, LLC and Janssen Pharmaceuticals, Inc., are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssenrnd.com for more information.

*Based on modified ITT population. Mega JL, Braunwald E, Wiviott SD, et al. Rivaroxaban in patients with a recent acute coronary syndrome. *N Engl J Med.* 2011;366(1):9-19.

Important Safety Information

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

For people taking XARELTO® for atrial fibrillation:

People with atrial fibrillation (an irregular heart beat) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. XARELTO® lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking XARELTO®, you may have an increased risk of forming a clot in your blood.

- **Do not stop taking XARELTO® without talking to the doctor who prescribes it for you. Stopping XARELTO® increases your risk of having a stroke or forming blood clots in other parts of your body.**

If you have to stop taking XARELTO®, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

For all people taking XARELTO®:

- XARELTO® can cause bleeding which can be serious, and rarely may lead to death. This is because XARELTO® is a blood thinner that reduces blood clotting. While you take XARELTO® you are likely to bruise more easily and it may take longer for bleeding to stop.

You may have a higher risk of bleeding if you take XARELTO® and take other medicines that increase your risk of bleeding including:

- aspirin or aspirin containing products,
- non-steroidal anti-inflammatory drugs (NSAIDs)
- warfarin sodium (Coumadin®, Jantoven®)
- any medicine that contains heparin
- clopidogrel (Plavix®)
- prasugrel (Effient®)
- ticagrelor (Brilinta®)

Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:

- 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 during surgery.
- any unexpected bleeding, or bleeding that lasts a long time (such as nose bleeds that happen often, unusual bleeding from gums, or menstrual bleeding that is heavier than normal or vaginal bleeding)
- bleeding that is severe or that you cannot control
- red, pink or brown urine
- bright red or black stools (look like tar)
- cough up blood or blood clots
- vomit blood or your vomit looks like "coffee grounds"
- headaches, feeling dizzy or weak
- pain, swelling, or new drainage at wound sites

WHO SHOULD NOT TAKE XARELTO®?

Do not take XARELTO® if you:

- currently have abnormal or unusual bleeding
- are allergic to rivaroxaban or any of the ingredients of XARELTO®

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

Before taking XARELTO® tell your doctor if you:

- Have ever had bleeding problems
- Have liver or kidney problems
- Have any other medical condition
- Are pregnant or planning to become pregnant
- Are breastfeeding or plan to breastfeed

Tell all of your doctors and dentists that you are taking XARELTO®. They should talk to the doctor who prescribed XARELTO® for you before you have any surgery, medical or dental procedure.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way XARELTO® works. Certain medicines may increase your risk of bleeding. Especially tell your doctor if you take:

- ketoconazole (Nizoral®)

- itraconazole (Onmel™, Sporan®)
- ritonavir (Norvir®)
- lopinavir/ritonavir (Kaletra®)
- indinavir (Crixivan®)
- carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol®-XR, Teril™, Epi®)
- phenytoin (Dilantin-125®, Dilantin®, Phenobarbital, Solfoton™)
- rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®)
- St. John's wort (Hypericum perforatum)

Ask your doctor if you are not sure if your medicine is one listed above. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

HOW SHOULD I TAKE XARELTO®?

Take XARELTO® exactly as prescribed by your doctor. **Do not change your dose or stop taking XARELTO® unless your doctor tells you to.**

For people who have:

- **atrial fibrillation:** Take XARELTO® 1 time a day **with your evening meal. Stopping XARELTO® may increase your risk of having a stroke or forming blood clots in other parts of your body.**
- **hip or knee replacement surgery:** Take XARELTO® 1 time a day with or without food.
- Your doctor may stop XARELTO® for a short time before any surgery, medical or dental procedure. Your doctor will tell you when to start taking XARELTO® again after your surgery or procedure.
- Do not run out of XARELTO®. Refill your prescription for XARELTO® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have XARELTO® available to avoid missing any doses.
- If you miss a dose of XARELTO®, take it as soon as you remember on the same day.
- If you take too much XARELTO®, go to the nearest hospital emergency room or call your doctor right away.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?

XARELTO® can cause bleeding which can be serious, and rarely may lead to death. Please see "What is the most important information I should know about XARELTO®?"

Tell your doctor if you have any side effect that bothers you or that does not go away.

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).

Please click [here](#) for full prescribing information, **including Boxed Warnings** and the Medication Guide.

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(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Research & Development, LLC nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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