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U.S. FDA Grants Priority Review for XARELTO® (rivaroxaban) Supplemental NDAs for the Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and the Long-Term Prevention of Recurrent DVT and PE

Company Also Provides Update on Stent Thrombosis sNDA

RARITAN, N.J., July 9, 2012 - Janssen Research & Development, LLC (Janssen R&D) announced today the U.S. Food and Drug Administration (FDA) has assigned a priority review designation to the supplemental New Drug Applications (sNDAs) filed on May 2, 2012 for XARELTO® (rivaroxaban), an oral anticoagulant, seeking new indications to treat patients with deep vein thrombosis (DVT), pulmonary embolism (PE), and to prevent recurrent DVT and PE.

DVT is a condition in which blood clots form in one of the large, deep veins, usually in the legs. PE is a serious condition that most commonly occurs when part or all of a DVT dislodges and is carried to the lung, via the heart, where it can partially or completely block a branch of the pulmonary artery.

"We are delighted to have received a priority review designation for XARELTO® for the treatment of PE and DVT, and also to prevent the recurrence of these conditions. Each year an estimated 900,000 Americans experience a DVT or PE, and one third of those events are fatal. If approved for these indications, XARELTO® has the potential to address critical unmet needs in treating patients with these serious medical conditions," said Paul Burton, M.D., Ph.D., Vice President, Cardiovascular Franchise Medical Leader at Janssen R&D.

The FDA grants priority review to medicines that offer major advances in care or provide a treatment where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), FDA will aim to complete its review within six months from the receipt of the sNDA submission, rather than the standard 10 month review cycle.

The submissions are supported by data from the global EINSTEIN program, which includes two Phase 3 studies evaluating the safety and efficacy of rivaroxaban in the treatment of patients with acute symptomatic DVT or PE and the prevention of recurrent events in these patients. A third Phase 3 study evaluated the safety and efficacy of rivaroxaban in the long-term prevention of recurrent DVT and PE. In total, these Phase 3 studies included more than 9,400 patients.

Separately, Janssen R&D announced it is withdrawing the sNDA for the use of XARELTO® to reduce the risk of stent thrombosis in patients with Acute Coronary Syndrome (ACS). The company is withdrawing this sNDA because it is contingent on a separate sNDA, for XARELTO® to reduce of the risk of secondary cardiovascular events in patients with ACS, which Janssen R&D received a complete response letter from the FDA on June 21, 2012. Data from the ATLAS ACS 2 TIMI 51 trial support both sNDAs.

"We remain confident in the overall study results from the ATLAS ACS 2 TIMI 51 trial, including the observed reduction in stent thrombosis that formed the basis for this separate sNDA," said Dr. Burton. "Our top priority is to work with FDA on our original sNDA for ACS and submit our reply to the complete response letter as soon as possible. We plan to resubmit the sNDA for stent thrombosis at the same time."

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

About XARELTO® (rivaroxaban)
Unlike other oral anticoagulants on the U.S. market, only XARELTO® works by blocking the blood clotting Factor Xa. XARELTO® does not require routine blood monitoring, and is approved for three uses: to reduce the risk of blood clots in the legs and lungs of people who have just had knee replacement surgery, to reduce this risk in people who have just had 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.

XARELTO® has the broadest indication profile of any of the newer oral anticoagulants either in market today or coming to the U.S. market in the foreseeable future, and is broadly available for more than 90% of commercial and Medicare health plan members. To date, more than 1.5 million patients have received XARELTO® worldwide and more than 387,000 prescriptions

have been written for XARELTO® in the U.S. alone.

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 75,000 patients will have participated in the rivaroxaban clinical development program. There are four filings currently submitted to the FDA. Three are under review and the fourth, for the ACS indication, is pending reply to the complete response letter. Rivaroxaban is being developed jointly by Janssen R&D 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 http://www.janssenrnd.com for more information.

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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 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™, Sporanox®)
- ritonavir (Norvir®)
- lopinavir/ritonavir (Kaletra®)
- indinavir (Crixivan®)
- carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol®-XR, Teril™, Epitol®)
- 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, any of the other Janssen Pharmaceutical Companies 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; increased scrutiny of the health care industry by government agencies; and product efficacy or safety concerns resulting in product recalls or regulatory action. 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.)