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FDA Advisory Committee Recommends Against Approval of the Use of Oral Anticoagulant XARELTO® to Reduce the Risk of Thrombotic Cardiovascular Events in Patients with Acute Coronary Syndrome

Raritan, NJ (January 16, 2014) - Janssen Research & Development, LLC (Janssen) announced today the U.S. Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee has voted against the approval of the use of XARELTO® (rivaroxaban), an oral anticoagulant, to reduce the risk of thrombotic cardiovascular events in patients with Acute Coronary Syndrome (ACS) in combination with standard antiplatelet therapy. Janssen is seeking approval of rivaroxaban at a proposed dose of 2.5 mg twice daily (BID) for a 90 day treatment duration.

"We appreciate the thoroughness of the committee's review and continue to believe rivaroxaban, in addition to the current standard of care, may help provide patients with ACS additional protection against life-threatening cardiovascular events such as death, heart attack and stroke," said Paul Burton, M.D., Ph.D., Vice President, Clinical Development, Janssen Research & Development. "We will work with the FDA to address questions raised today."

ACS is a complication of coronary heart disease, which is the leading cause of death in the U.S. and one of the most prevalent non-communicable diseases in the world. ACS occurs when a blood clot blocks a coronary artery, reducing blood supply to the heart. This disruption of blood flow can cause a heart attack or unstable angina, a condition signifying that a heart attack may soon occur. Each year, an estimated 1.2 million patients in the U.S. are discharged from the hospital with a diagnosis of ACS.

The advisory committee's recommendation was based on review of the 15,526-patient pivotal Phase 3 ATLAS ACS 2 TIMI 51 (**A**nti-Xa **T**herapy to **L**ower cardiovascular events in **A**ddition to aspirin with/without thienopyridine therapy in **S**ubjects with Acute Coronary Syndrome) clinical trial of rivaroxaban.

In August 2013, Janssen issued a resubmission to the complete response from the FDA for rivaroxaban 2.5 mg twice daily (BID) to reduce the risk of secondary cardiovascular events in patients with ACS for a 90 day treatment duration. Recommendations from the advisory committee today will be considered by the FDA in its review of the supplemental New Drug Application (sNDA) for rivaroxaban in this indication, but the recommendation of the advisory committee panel is not binding. If approved by the FDA, rivaroxaban will be commercialized for this additional indication in the U.S. by Janssen Pharmaceuticals, Inc.

Results from the ATLAS ACS 2 TIMI 51 study showed that rivaroxaban, given in combination with standard antiplatelet therapy, was superior to standard therapy alone in preventing secondary cardiovascular events in patients with ACS. In patients receiving rivaroxaban and standard therapy, rates of Thrombolysis In Myocardial Infarction (TIMI) major bleeding events not associated with coronary artery bypass graft (CABG) surgery were low overall, yet statistically significantly increased versus those treated with standard therapy plus a placebo. Importantly, these differences were not associated with an excess risk of fatal bleeding.

About XARELTO® (rivaroxaban)
XARELTO® works by blocking the blood clotting Factor Xa. XARELTO® does not require routine blood monitoring. XARELTO® has the broadest indication profile of any novel oral anticoagulant and is approved for six indications that include:

1. To reduce the risk of strokes and blood clots in patients with atrial fibrillation not caused by a heart valve problem. For patients currently well managed on warfarin, there is limited information on how XARELTO® and warfarin compare in reducing the risk of stroke.
2. To treat patients with deep vein thrombosis (DVT).
3. To treat patients with pulmonary embolism (PE).
4. To reduce the risk of recurrence of DVT or PE following an initial six-month treatment for acute venous thromboembolism.
5. To reduce the risk of blood clots in the legs and lungs of patients who have just had knee replacement surgery.
6. To reduce the risk of blood clots in the legs and lungs of patients who have just had hip replacement surgery.

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 in 2018, approximately 100,000 patients will have participated in the rivaroxaban clinical development program.

Janssen Research & Development, LLC, and Bayer HealthCare together are developing rivaroxaban.

For more information about XARELTO®, visit www.xarelto-us.com. The XARELTO® CarePath™ Support Program is a resource

designed for healthcare providers, patients and caregivers. Visit www.xareltocarepath.com or call 1-888-XARELTO to learn more about the XARELTO® CarePath™ resources focused on access, education and adherence.

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 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.

  If you have to stop taking XARELTO®, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.
- **XARELTO® can cause bleeding**, which can be serious, and rarely may lead to death. This is because XARELTO® is a blood thinner medicine 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®)
- Other medicines to prevent or treat blood clots

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:

- Unexpected bleeding or bleeding that lasts a long time, such as:
  - Nosebleeds that happen often
  - Unusual bleeding from gums
  - 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 (looks 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

Spinal or epidural blood clots (hematoma): People who take a blood thinner medicine (anticoagulant) like XARELTO®, and have medicine injected into their spinal and epidural area, or have a spinal puncture, have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:

- A thin tube called an epidural catheter is placed in your back to give you certain medicine
- You take NSAIDs or a medicine to prevent blood from clotting
- You have a history of difficult or repeated epidural or spinal punctures
- You have a history of problems with your spine or have had surgery on your spine

If you take XARELTO® and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have tingling, numbness, or muscle weakness, especially in your legs and feet.

XARELTO® is not for patients with artificial heart valves.

WHO SHOULD NOT TAKE XARELTO®?
Do not take XARELTO® if you:

- Currently have certain types of abnormal bleeding. Talk to your doctor before taking XARELTO® if you currently have 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 plan to become pregnant. It is not known if XARELTO® will harm your unborn baby. Tell your doctor right away if you become pregnant while taking XARELTO®. If you take XARELTO® during pregnancy, tell your doctor right away if you have bleeding or symptoms of blood loss.
- Are breastfeeding or plan to breastfeed. It is not known if XARELTO® passes into your breast milk. You and your doctor should decide if you will take XARELTO® or 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. **See "What is the most important information I should know about XARELTO®?"**

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.

- Your doctor will tell you how much XARELTO® to take and when to take it.
- Your doctor may change your dose if needed.

If you take XARELTO® for:

- **Atrial Fibrillation:** Take XARELTO® 1 time a day with your evening meal.
  If you miss a dose of XARELTO®, take it as soon as you remember on the same day.
  Take your next dose at your regularly scheduled time.
- **Blood clots in the veins of your legs or lungs:**
  - Take XARELTO® once or twice a day as prescribed by your doctor.
  - Take XARELTO® with food at the same time each day.
  - If you miss a dose of XARELTO®:
    - **and take XARELTO® 2 times a day:** Take XARELTO® as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your

regularly scheduled time.
        - **and take XARELTO® 1 time a day:** Take XARELTO® as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
    - **Hip or knee replacement surgery:** Take XARELTO® 1 time a day with or without food. If you miss a dose of XARELTO®, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take XARELTO®.
- Your doctor will decide how long you should take XARELTO®. Do not stop taking XARELTO® without talking to your doctor first.
- 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 have XARELTO® available to avoid missing any doses.
- 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®?

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.

Call your doctor for medical advice about side effects. You are also encouraged to report side effects to the FDA: visit *http://www.fda.gov/medwatch* or call1-800-FDA-1088. You may also report side effects to Janssen Pharmaceuticals, Inc., at 1-800-JANSSEN (1-800-526-7736).

Please click here for full Prescribing Information, including Boxed Warnings, and Medication Guide.

About Janssen

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.

(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 December 30, 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. None of the Janssen Pharmaceutical Companies 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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