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Janssen Expands the EXPLORER Global Cardiovascular Research Program with Three New Studies Evaluating XARELTO® in Patients at Risk for Venous Thromboembolism

Raritan, NJ (March 31, 2014) - Janssen Research & Development, LLC (Janssen) announced today it is adding three new clinical trials to its EXPLORER global cardiovascular research program for XARELTO® (rivaroxaban), the most studied and broadly indicated oral Factor Xa inhibitor in the world today. The additional trials will evaluate rivaroxaban for the treatment or prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) in pediatric and other patient populations, including those at risk for DVT or PE due to a concurrent medical illness. The new studies will include more than 11,000 patients in over 30 countries.

With the addition of these studies, the EXPLORER global cardiovascular research program now encompasses eight clinical trials assessing the safety and efficacy of rivaroxaban in high-risk patient populations, including those with chronic heart failure, coronary artery disease and peripheral artery disease. EXPLORER is an integral part of the extensive clinical development program for rivaroxaban, evaluating its use in a broad range of cardiovascular conditions.

"Each year in the U.S., more people die from DVT and PE than from motor vehicle accidents, breast cancer and HIV combined," said Anne Hermanowski Vosatka, M.D., Ph.D., FACC, vice president and compound development team leader for XARELTO® at Janssen. "New trials added to the EXPLORER global cardiovascular research program will broaden our understanding of how rivaroxaban might help patients at risk for developing blood clots such as DVT or PE, addressing an urgent unmet need."

Specifically, Janssen and its development partner, Bayer HealthCare, will add the following new trials under the EXPLORER global cardiovascular research program:

- **MARINER** is a Phase 3 study designed to evaluate the efficacy and safety of rivaroxaban once-daily compared with placebo to reduce the risk of symptomatic DVT and/or PE due to a concurrent medical illness for up to 45 days after hospital discharge. This study will include approximately 8,000 patients in more than 15 countries.
- **EINSTEIN JUNIOR**, including Phase 1, 2a, 2b and 3 clinical trials, will evaluate rivaroxaban according to an age- and body weight-adjusted dosing schedule for the treatment and secondary prevention of DVT and/or PE in pediatric populations. The study program will include at least 150 patients in 20 countries, and is currently enrolling participants for Phase 2 trials. The Phase 3 study is expected to start in September 2014. Please click **here** for more information.
- **EINSTEIN CHOICE** is a Phase 3 study designed to evaluate whether once-daily rivaroxaban in doses of 10mg or 20mg is superior to aspirin for the prevention of symptomatic recurrent DVT and/or PE in patients who have completed between six and 12 months of anticoagulant therapy. The study will include approximately 2,850 patients in 31 countries and is currently enrolling participants. Please click **here** for more information.

In total, the global clinical development program for rivaroxaban will include 15 Phase 3 clinical trials, 10 of which are completed. By the time of its completion in 2018, more than 136,000 patients are expected to have participated in the global clinical development program, including those patients assessed in EXPLORER.

In addition, Janssen and Bayer recently entered into an agreement with Portola Pharmaceuticals, Inc. to initiate Phase 3 studies evaluating Portola's investigational Factor Xa inhibitor reversal agent, andexanet alpha, for use with XARELTO® in emergency situations, such as for patients with major bleeding or those requiring emergency surgery. The clinical collaboration will be in effect through completion of Phase 3 studies with XARELTO® and any potential U.S. and EU regulatory approval of andexanet alfa. Phase 3 studies are expected to start in the first half of 2014.

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 travels to the lung, via the heart, where it can partially or completely block a branch of the pulmonary artery. When PE occurs with large clots, multiple clots or when the patient already has pre-existing heart or lung disease, the event may be fatal. Each year up to 900,000 Americans experience a DVT or PE, resulting in up to 300,000 deaths.

About EXPLORER Global Cardiovascular Research Program
The EXPLORER global cardiovascular research program is an integral part of the extensive clinical development program for rivaroxaban, evaluating its use in a broad range of cardiovascular conditions, making it the most studied and broadly indicated oral Factor Xa inhibitor in the world today. Additional studies within the EXPLORER program include:

- **COMMANDER-HF** is evaluating rivaroxaban in patients with chronic heart failure and significant coronary artery disease

who are receiving standard care. The study will include 5,000 patients in 12 countries. Please click **here** for more information.
- **COMPASS** is evaluating rivaroxaban in patients with coronary artery disease or peripheral artery disease. This study includes 20,000 patients across 25 countries and will be conducted in collaboration with the Population Health Research Institute (PHRI) at McMaster University in Hamilton, Ontario, Canada. Please click **here** for more information.
- **PIONEER AF-PCI** is evaluating rivaroxaban in 2,100 patients who have non-valvular atrial fibrillation (NVAF) and are undergoing percutaneous coronary intervention (PCI) with stent placement. The trial is assessing rivaroxaban in combination with dual antiplatelet therapy and when aspirin is not used. Please click **here** for more information.
- **VENTURE-AF** is evaluating the use of rivaroxaban in patients with NVAF undergoing catheter ablation, a procedure that uses energy delivered through catheters to eliminate the abnormal tissue that is causing the arrhythmia. The study will include up to 250 patients in four countries. Please click **here** for more information.
- **X-VeRT** is evaluating patients with atrial fibrillation scheduled for cardioversion - a medical procedure to convert abnormally fast heart rate to a normal rhythm, using electricity or antiarrhythmic medications. The study includes 1,500 patients across 17 countries and will compare rivaroxaban to dose-adjusted vitamin K antagonist. Please click **here** for more information.

About XARELTO® (rivaroxaban)
XARELTO® works by blocking the blood clotting Factor Xa and 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.

Eight million patients have received XARELTO® worldwide, and more than five million prescriptions have been written for XARELTO® in the U.S. XARELTO® has earned a strong reimbursement profile among oral anticoagulants, with 90 percent of patients on Medicare Part D and 90 percent of commercial patients covered at the lowest branded co-pay.

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 resourc 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.

WHAT IS XARELTO®?

XARELTO® is a prescription medicine used to reduce the risk of stroke and blood clots in people 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.

XARELTO® is also a prescription medicine used to treat deep vein thrombosis and pulmonary embolism, and to help reduce the risk of these conditions occurring again.

XARELTO® is also a prescription medicine used to reduce the risk of forming a blood clot in the legs and lungs of people who have just had knee or hip replacement surgery.

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 back pain, tingling, numbness, muscle weakness (especially in your legs and feet), or loss of control of the bowels or bladder (incontinence).

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®?" above.

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 call 1-800-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 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.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; 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; general industry conditions including 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 Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

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