News Release

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New Data from U.S. Post-Approval Study Assess Ischemic Stroke and Intracranial Hemorrhage Rates in People with Non-Valvular Atrial Fibrillation Comparing Both Rivaroxaban with Warfarin and Apixaban with Warfarin

Real-world findings show balance of benefit and risk of XARELTO® (rivaroxaban) with respect to ischemic stroke and a reduction in intracranial hemorrhage in routine clinical practice, further confirming the efficacy and safety profile observed in ROCKET AF

Raritan, NJ (April 18, 2016) — Results of the REVISIT-US study, an analysis including 30,988 patients that evaluated the real-world occurrence of ischemic stroke and intracranial hemorrhage (ICH) in people with non-valvular atrial fibrillation (NVAF), comparing both XARELTO® (rivaroxaban) with warfarin and apixaban with warfarin, were presented at the 12th Annual Congress of the European Cardiac Arrhythmia Society. The effect on the important endpoints of ischemic stroke and ICH for XARELTO® versus warfarin in the real world was generally consistent with what was seen in ROCKET AF, the Phase 3 registration trial for XARELTO® and other real-world studies such as XANTUS and PMSS.

The Real-world EVIdence on Stroke prevention In patients with aTrial Fibrillation in the United States (REVISIT-US) study was a retrospective claims analysis performed using U.S. MarketScan claims data and was sponsored by Janssen Pharmaceuticals, Inc. and its development partner, Bayer. According to the study authors, results of REVISIT-US showed XARELTO® (n=11,411) was associated with a nonsignificant 29 percent decrease in ischemic stroke (HR=0.71; 95% CI 0.47-1.07) and a significant 47 percent reduction in ICH

(HR=0.53; 95% CI 0.35-0.79) versus warfarin (n=11,411). The rate of ischemic stroke observed for rivaroxaban was 0.54 percent per year versus 0.83 percent per year for warfarin. The rate of ICH observed for rivaroxaban was 0.49 percent per year versus 0.96 percent per year for warfarin.

In ROCKET AF, the rate of ischemic stroke was 1.6 per 100 person-years[1] with XARELTO® versus 1.6 per 100 person-years with warfarin, and the rate of ICH was significantly lower in the XARELTO® group at 0.5 percent per year than in the warfarin group at 0.7 percent per year (HR=0.67; 95% CI 0.47-0.93).

"It's essential we continue real-world research to ensure oral anticoagulants are striking an appropriate balance of safety and efficacy in patients with NVAF," said Craig Coleman, PharmD, Professor of Pharmacy Practice, University of Connecticut. "Based on the findings from the REVISIT-US study, we are seeing that rivaroxaban is performing as expected in real-world practice, providing a necessary balance of benefit and risk with respect to both ischemic stroke and a significant reduction in intracranial hemorrhage."

Nearly six million Americans have atrial fibrillation, a major risk factor for stroke. Atrial fibrillation increases the risk of stroke by five times and accounts for 15 to 20 percent of all strokes.[2,3] Current clinical practice guidelines recommend people with NVAF and a CHA_2DS_2-VASc score of greater than or equal to two be considered for anticoagulation therapy to reduce their risk of stroke.[4]

"The REVISIT-US study is an important complement to existing real-world research of XARELTO® because it specifically looked at ischemic stroke and intracranial hemorrhage, two of the most serious types of events physicians work the hardest with their patients to avoid, given their potential for irreversible harm," said Paul Burton, MD, PhD, Vice President, Medical Affairs, Janssen. "Finding the right balance of efficacy and safety is critically important, but avoiding bleeding should not come at the cost of a stroke. We are pleased that, time and time again, real-world studies in more than 91,000 patients across

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[1] Incidence rate was calculated using a person-time approach: the total number of people experiencing ischemic stroke divided by the number of years of all people receiving XARELTO® (expressed in 100-year increments).
[2] Colilla S et al. Estimates of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. Adult Population. *Am J Cardiol* 2013;112(8):1142-1147.
[3] American Heart Association (2014, April 16). Prevention Strategies for Atrial Fibrillation. Retrieved from: http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/Prevention-Strategies-for-Atrial-Fibrillation-AFib-or-AF_UCM_423784_Article.jsp#.VvRBcuIrKUk
[4] January CT et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation. *J Am Coll Cardiol* 2014;64(21):e1-e76.

our six indications in the U.S. continue to confirm the positive benefit-risk profile of XARELTO®."

About REVISIT-US

The REVISIT-US study assessed the real-world effectiveness and safety of newly initiated XARELTO® compared with warfarin and apixaban compared with warfarin among adult patients with NVAF. The study was designed to show consistency between hazard ratios in Phase 3 trials and real-world analyses, not head-to-head comparisons of non-vitamin K antagonist oral anticoagulants (NOAC). A total of 11,411 warfarin patients were matched to 11,411 XARELTO® patients, and a total of 4,083 warfarin patients were matched to 4,083 apixaban patients using U.S. MarketScan claims data from January 1, 2012, to October 31, 2014. REVISIT-US included XARELTO® and apixaban patients starting on the individual FDA approval dates and were only matched to warfarin patients initiated during the same time frame. Using the matched cohorts, Cox regression was performed for the ischemic stroke and ICH endpoints.

Patients in REVISIT-US had a CHA_2DS_2-VASC score of greater than or equal to two, 180 days or more of continuous medical coverage, and an International Classification of Diseases 9th Edition (ICD-9) diagnosis code for NVAF on at least two occasions. Exclusion criteria included prior history of stroke, systemic embolism or ICH. Using the matched cohorts, Cox regression was performed for the ischemic stroke and ICH endpoints (identified using primary ICD-9 codes only) and reported as hazard ratios and 95 percent confidence intervals.

More than 91,000 patients have been evaluated in real-world research since the approval of XARELTO®, across all six indications in the U.S. Study after study, including XANTUS and PMSS, the ongoing post-marketing safety surveillance study program, continue to confirm the benefit-risk profile of XARELTO®, as observed in the ROCKET AF trial. Real-world research is an integral part of EXPLORER, the overall clinical development program for XARELTO®. A collaborative research effort with Bayer, EXPLORER evaluates the potential role of XARELTO® in addressing additional critical medical needs and generates important clinical evidence on the performance of the medicine in routine clinical practice. EXPLORER includes six additional indication-seeking trials beyond the currently approved six indications in the U.S. By the time of its completion, more than 275,000 patients will have participated in the XARELTO® EXPLORER clinical development program.

Delivering Value to Patients, Physicians and Healthcare Systems

XARELTO® leads the NOAC class by having the strongest affordability and access position in the U.S. For qualifying people with commercial insurance using the XARELTO® CarePath™ saving card, XARELTO® has no cost.[5] For people with Medicare and commercial insurance, XARELTO® is broadly reimbursed, with more than 93 percent of commercial patients and more than 95 percent of patients on Medicare Part D covered at the lowest branded co-pay. XARELTO® also has the lowest average out-of-pocket cost of any NOAC available in the U.S. today. More than 19 million prescriptions have been written for XARELTO® in the U.S. since its launch.

About XARELTO® (rivaroxaban)

XARELTO® works by blocking the blood clotting Factor Xa. XARELTO® does not require routine blood monitoring. XARELTO® has a broad indication profile 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.

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.

[5] Subject to a maximum annual program benefit of $3,400.

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.

Janssen and Bayer together are developing rivaroxaban.

For more information about XARELTO®, visit www.xarelto.com.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at @JanssenUS.

Cautions Concerning Forward-Looking Statement
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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Pharmaceuticals, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product development, including the uncertainty of clinical success and of obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. 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 January 3, 2016, including in Exhibit 99 thereto, and the company's 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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