NEWS RELEASE

New Data on XARELTO® Versus Vitamin K Antagonists in Atrial Fibrillation Patients Undergoing Catheter Ablation Presented at Heart Rhythm 2015

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Raritan, NJ (May 14, 2015) - Janssen Pharmaceuticals, Inc. and its development partner, Bayer HealthCare, today announced results from the VENTURE-AF trial. The study explored the potential of once-daily XARELTO® (rivaroxaban) as an alternative to vitamin K antagonists (VKA), used to reduce the risk of blood clots, in people with non-valvular atrial fibrillation (NVAF) undergoing catheter ablation, a frequently used interventional procedure to remove abnormal tissue in the heart that is causing the irregular heartbeat. The results were presented at Heart Rhythm 2015, the Heart Rhythm Society's 36th Annual Scientific Sessions, and published in the **European Heart Journal**.

Over the past decade, the number of catheter ablation procedures has risen dramatically in the United States, with more than 93,000 procedures performed from 2000-2010. Current guidelines recommend uninterrupted anticoagulation before, during and after the procedure to help prevent life-threatening blood clots. The VENTURE-AF study is the first global, prospective, randomized trial of any novel oral anticoagulant (NOAC) in this high-risk patient population.

VENTURE-AF was a 248-patient, Phase 3b trial. For patients treated during or after the catheter ablation procedure, there was one major bleed in the VKA group, as defined by the ISTH scale, compared to zero for rivaroxaban. There were no major bleeds in either group using GUSTO- and TIMI-defined scales. The majority of bleeding that occurred in the study was mild or insignificant. There was one ischemic stroke and one vascular death in the VKA arm compared to none for rivaroxaban. Serious adverse events were comparable between both treatment strategies

with 17 in the rivaroxaban group and 20 in the VKA group. VENTURE-AF was intentionally designed as an exploratory study and thus no formal statistical superiority or non-inferiority analysis was planned.
"The VENTURE-AF study results provide physicians with additional insights that may help them manage non-valvular atrial fibrillation patients who are scheduled for catheter ablation," said Andrea Natale, M.D., F.A.C.C., F.H.R.S., F.E.S.C., Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center, Austin, TX, and lead investigator of VENTURE-AF. "Given the dose adjustments often needed for patients on vitamin K antagonists, such as warfarin, to ensure the medicine is working effectively, rivaroxaban may offer a simpler approach in this setting."

VENTURE-AF is a part of the EXPLORER global cardiovascular research program for XARELTO®. The EXPLORER program includes 11 trials assessing the safety and efficacy of XARELTO® in high-risk patient populations, including those with chronic heart failure, coronary artery disease, peripheral artery disease, acute coronary syndrome and embolic stroke of undetermined source. By the time of its completion, more than 275,000 patients will have participated in the XARELTO® clinical development program, other completed and ongoing clinical trials, investigative registries, and non-interventional studies.

"The VENTURE-AF results build on the promising data observed in a sub-analysis of the landmark ROCKET-AF trial," said Paul Burton, M.D., Ph.D., Vice President, Medical Affairs, Janssen. "Through our work on the EXPLORER global cardiovascular research program, that includes six indication-seeking programs currently underway, we will continue to evaluate the full potential of XARELTO® in addressing unmet medical needs for patients."

About Atrial Fibrillation Management

An irregular heartbeat caused by atrial fibrillation can put patients at five-fold increased risk for a stroke. Reducing that stroke risk with anticoagulants is a component of atrial fibrillation management. Additionally, physicians may use measures that can return the heart rate and rhythm back to normal. Most often, medications that address heart rate and rhythm will be used first, and in situations where those are not effective, a patient may undergo a procedure. This can include cardioversion, a common medical procedure that uses electrical stimulation to return the heart to normal rate and rhythm. If this is not successful, or the irregular heartbeat returns frequently, catheter ablation may be performed in order to remove abnormal tissue in the heart that is causing the irregular heartbeat. Clinical guidelines for either procedure recommend stable, uninterrupted anticoagulation before, during and after the procedure.

About the VENTURE-AF Study

VENTURE-AF (Acti**V**e-Controlled Multi-C**ENT**er St**U**dy with Blind-Adjudication Designed to Evaluate the Safety of Uninterrupted **R**ivaroxaban and Uninterrupted Vitamin K Antagonists in Subjects Undergoing Cath**E**ter Ablation for Non-Valvular **A**trial **F**ibrillation) was a prospective, randomized, open-label, active-controlled, Phase 3b study

involving 248 patients with occasional or persistent NVAF scheduled for catheter ablation who received uninterrupted XARELTO® or uninterrupted VKA therapy. Patients were recruited from 37 centers in five countries worldwide.

In this study, XARELTO® 20 mg once daily, taken orally, or dose-adjusted VKA therapy, also taken orally, was randomly assigned to patients in a 1:1 ratio. Patients received the assigned treatment for at least four weeks prior to the catheter ablation procedure, and continued with treatment after the procedure for four weeks. The primary endpoint was the occurrence of major bleeding events within 30 days from the procedure, defined using one of three commonly used scales (GUSTO, ISTH and TIMI). Secondary endpoints included the occurrence of myocardial infarction (heart attack), stroke, systemic embolization, vascular death and other adverse events.

VENTURE-AF was intentionally designed as an exploratory study and thus no formal statistical superiority or non-inferiority analysis was planned. Of note, a traditional estimation of sample size indicated an unfeasibly large number of patients would be needed to show a significant difference for efficacy and safety. Accordingly, a descriptive comparison was used for a population size that was intended to generate clinically meaningful information (approximately 250 patients).

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:

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.
To treat patients with deep vein thrombosis (DVT).
To treat patients with pulmonary embolism (PE).
To reduce the risk of recurrence of DVT or PE following an initial six-month treatment for acute venous thromboembolism.
To reduce the risk of blood clots in the legs and lungs of patients who have just had knee replacement surgery.
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.

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 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.

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 Pharmaceuticals, Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit **JanssenPharmaceuticalsInc.com** for more information.

Cautions Concerning Forward-Looking Statements

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 new 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 December 28, 2014, 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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