Important Global Data from XARELTO® EXPLORER Cardiovascular Research Program Highlighted in 17 Presentations at the American Heart Association Scientific Sessions 2015

The EXPLORER program is unmatched by any non-vitamin K oral anticoagulant (NOAC) in its size, scope and ambition and continues to generate important clinical evidence on XARELTO® (rivaroxaban)

* Key research in areas of critical medical need, including studies in high-risk populations and safety in real-world settings will be presented

* Results of ANNEXA™-R evaluating a potential reversal agent for XARELTO® to be presented during late-breaking clinical trial session

* Additional insights will be shared on key patient safety topics, including XARELTO® use in patients with renal disease and real-world persistence rates compared to selected oral anticoagulants

RARITAN, N.J., Nov. 6, 2015 - Janssen Pharmaceuticals, Inc., and its development partner, Bayer HealthCare, today announced that 17 data presentations, generated from the EXPLORER cardiovascular research program for XARELTO® (rivaroxaban), will be presented at this year's American Heart Association Scientific Sessions 2015. Notably, the performance of XARELTO® in core areas that impact patient safety will be highlighted at the congress, including patients with renal disease and real-world persistence rates compared to selected oral anticoagulants. Additionally, full results from the second part of the Phase 3 ANNEXA-R (Andexanet Alfa a Novel Antidote to the Anticoagulant Effects of FXa Inhibitors – Rivaroxaban) study will be presented during a late-breaking clinical trial session.

"We look forward to sharing new research from our global EXPLORER cardiovascular research program, including important data on the safety and efficacy of XARELTO® in non-valvular atrial fibrillation patients with renal disease and insights from real-world observational studies on the safety of our medicine," said Hayes Dansky, M.D., Therapeutic Area Leader, Cardiovascular, Janssen. "XARELTO® continues to lead the way with the most published data in the Factor Xa class examining critical aspects of treatment in the real-world setting, including safety, efficacy and adherence. Our work continues to equip physicians with important data that can help inform the care of their patients."

The EXPLORER program evaluates the use of XARELTO® in a broad range of cardiovascular conditions, addressing critical medical needs and generating important clinical evidence on the real-world safety performance of the medicine. By the time of its completion, more than 275,000 patients will have participated in the XARELTO® EXPLORER clinical development program, which includes ongoing and completed studies, independent registries and non-interventional studies.

EXPLORER is a collaborative research effort with Bayer HealthCare and is a blend of completed and ongoing studies that includes six additional indication-seeking programs.

EXPLORER continues to assess the safety and efficacy of XARELTO® in high-risk patient populations, such as those with chronic heart failure and coronary artery disease, peripheral artery disease, acute coronary syndrome, embolic stroke of undetermined source, active cancer or who are medically ill. Three of the studies look at different non-valvular atrial fibrillation (NVAF) populations:

- **X-VeRT** was the first prospective, exploratory trial comparing the safety and efficacy of XARELTO® to vitamin K antagonists (VKA), such as warfarin, in NVAF patients undergoing cardioversion, a common procedure that uses electrical stimulation to return the heart to normal rate and rhythm. Results were presented at ESC Congress 2014 and published last year in the *European Heart Journal*.
- **VENTURE-AF** was the first prospective, exploratory trial examining XARELTO® as an alternative to VKA in NVAF patients undergoing catheter ablation, a frequently used interventional procedure to remove abnormal tissue in the heart that is causing the irregular heartbeat or if cardioversion is unsuccessful. Results were published in the *European Heart Journal* in May of this year.
- **PIONEER AF-PCI** is an ongoing study evaluating XARELTO® in NVAF patients following percutaneous coronary intervention, also known as angioplasty, with stent placement, a common procedure used to open blocked coronary arteries and restore blood flow to the heart.

A listing of the data presentations is included below:

Late-Breaking Clinical Trial

(LBCT 04) ANNEXA-R Part 2: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial Demonstrating Sustained Reversal of Rivaroxaban-Induced Anticoagulation in Older Subjects by Andexanet Alfa, a Universal Antidote for Factor XA Inhibitors. Oral presentation: Wednesday, Nov. 11, 11:21-11:30 a.m. ET. Location: Chapin Theater.

Phase 3 Clinical Trial Sub-Analyses

(316) On-Treatment Outcomes in Patients with Worsening Renal Function with Rivaroxaban Compared to Warfarin: Insights from ROCKET AF. Oral presentation: Monday, Nov. 9, 2:00-2:15 p.m. ET. Location: W312C.

(S 4081) Efficacy and Safety of Rivaroxaban versus Warfarin in Patients Taking Non-dihydropyridine Calcium Channel Blockers: Results from the ROCKET AF Trial. Poster presentation: Sunday, Nov. 8, 9:00-10:15 a.m. ET. Location: A2, Clinical Science.

Real-World Data Analyses

(M 2074) Incidence and Characteristics of Major Bleeding Among Rivaroxaban Users with Renal Disease and Non-Valvular Atrial Fibrillation. Poster presentation: Monday, Nov. 9, 9:00-10:15 a.m. ET. Location: A2, Population Science.

(M 2077) Treatment Persistence and Discontinuation with Rivaroxaban, Dabigatran and Warfarin for Stroke Prevention in Patients with Non-Valvular Atrial Fibrillation. Poster presentation: Monday, Nov. 9, 9:00-10:15 a.m. ET. Location: A2, Population Science.

(M 2155) Adherence to Non-VKA Oral Anticoagulant Medications Based on the Pharmacy Quality Alliance Measure. Poster presentation: Monday, Nov. 9, 2:00-3:15 p.m. ET. Location: A2, Population Science.

(QCOR09) Evaluation of U.S. Prescription Patterns: Are Treatment Guidelines for Cancer-associated Venous Thromboembolism (VTE) Followed? Poster presentation: Monday, Nov. 9, 9:30-11:00 a.m. ET. Location: A2, Best of AHA Specialty Conferences.

(S 2123) Real-Life Evidence of Stroke Prevention in Patients with Atrial Fibrillation: The RELIEF Study. Poster presentation: Sunday, Nov. 8, 2:00-3:15 p.m. ET. Location: A2, Population Science.

(840) Risk Factors for Major Bleeding Events in Rivaroxaban Users with Atrial Fibrillation: A Nested Case-Control Study. Oral presentation: Tuesday, Nov. 10, 9:30-9:40 a.m. ET. Location: A2, Population Science Theater.

Registry Data

(S 4088) Frequency and Management of Major Bleeding in Atrial Fibrillation Patients Treated with Warfarin and Non-Vitamin K Oral Anticoagulants in Community Practice: Results from the ORBIT-AF II Registry. Poster presentation: Sunday, Nov. 8, 9:00-10:15 a.m. ET. Location: A2, Clinical Science.

(M 4058) Comparative Performance of the R_2CHADS_2, $CHADS_2$, and CHA_2DS_2–VASc Scores in Atrial Fibrillation. Poster presentation: Monday, Nov. 9, 9:00-10:15 a.m. ET. Location: A2, Clinical Science.

(M 2076) Therapeutic Strategies Following Major Bleeding in Atrial Fibrillation: Findings from ORBIT-AF. Poster presentation: Monday, Nov. 9, 9:00-10:15 a.m. ET. Location: A2, Population Science.

Clinical Characteristics and Treatment Patterns of Medicaid Patients with Atrial Fibrillation: Insights from the ORBIT-AF I Registry. Oral presentation: Tuesday, Nov. 10, 11:15-11:30 a.m. ET. Location: W414CD.

(T 4046) Rhythm Control Versus Rate Control and Clinical Outcomes in Patients with Atrial Fibrillation: Results from ORBIT-AF. Poster presentation: Tuesday, Nov. 10, 9:00-10:15 a.m. ET. Location: A2, Clinical Science.

(T 4051) Patterns of Discontinuation for Non-Vitamin K Oral Anticoagulants in Atrial Fibrillation: Results from the ORBIT-AF II Registry. Poster presentation: Tuesday, Nov. 10, 9:00-10:15 a.m. ET. Location: A2, Clinical Science.

(T 4266) Factors Associated with Quality of Life in Atrial Fibrillation: Results from the ORBIT-AF Registry. Poster presentation: Tuesday, Nov. 10, 2:00-3:15 p.m. ET. Location: A2, Clinical Science.

Association of Body Mass Index with Outcomes in Patients with Atrial Fibrillation: Results from the ORBIT-AF Registry. Poster presentation: Tuesday, Nov. 10, 2:00-3:30 p.m. ET. Location: Valencia Ballroom (W415AB).

Persistence on Dabigatran vs. Warfarin in Patients with Atrial Fibrillation: Results from the ORBIT-AF Registry. Poster presentation: Tuesday, Nov. 10, 2:00-3:30 p.m. Location: Valencia Ballroom (W415AB).

For more information, including a complete list of abstract titles, visit the American Heart Association Scientific Sessions website at http://www.abstractsonline.com/pp8/#!/3795/.

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.

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 www.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 Biotech, Inc., Janssen Research & Development, LLC 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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