News Release

Media Contacts:
Kristina Chang
Tel: (908) 927-2416
Mobile: (201) 213-4115
kchang12@its.jnj.com

Christina Chan
Tel: (908) 927-5769
Mobile: (908) 635-2406
cchan20@its.jnj.com

Investor Relations Contacts:
Johnson & Johnson
Louise Mehrotra
Tel: (732) 524-6491

Johnson & Johnson
Lesley Fishman
Tel: (732) 524-3922

Real-World Data on XARELTO® in Patients with Non-Valvular Atrial Fibrillation and Diabetes Among 14 Presentations at American College of Cardiology's 65th Annual Scientific Session

New data add to growing body of real-world evidence supporting physicians and hospitals in optimizing patient care for those at risk of stroke or blood clots

Raritan, NJ (March 21, 2016) — Janssen Pharmaceuticals, Inc., and its development partner, Bayer, today announced that 14 data presentations will be presented at the American College of Cardiology's 65th Annual Scientific Session (ACC.16), including real-world findings confirming the safety of XARELTO® (rivaroxaban) in a high-risk group of patients with non-valvular atrial fibrillation (NVAF) and concomitant diabetes. This real-world research complements the XARELTO® clinical trials by providing important insights to physicians on how the medicine is performing in patients seen in everyday practice.

Data from these 14 abstracts are generated from the XARELTO® EXPLORER program, which

has evaluated XARELTO® in more than 91,000 patients in real-world settings to date. Other topic areas that will be presented include adherence, hospitalization length of stay and hospital costs, including outcomes in patients undergoing treatment for venous thromboembolism (VTE).

Nearly six million Americans are living with atrial fibrillation, and based on data of Medicare beneficiaries, an estimated 34 percent of people with NVAF also have diabetes. The risk of stroke is 1.5 times higher in people with NVAF and concomitant diabetes than in those without diabetes. Adhering to dietary guidelines is important for people with diabetes, and warfarin, an older anticoagulant often prescribed to NVAF patients, carries dietary restrictions, making treatment challenging for people living with both conditions. XARELTO®, given once daily with no dietary restrictions or blood monitoring required, could be a proven treatment option for NVAF patients with diabetes.

"It is critically important that we continue to assess the performance of once-daily XARELTO® in high-risk NVAF patients seen in everyday practice, and at the ACC Annual Scientific Session we will show how the medicine is performing in patients with concomitant diabetes," said Paul Burton, MD, PhD, Vice President, Medical Affairs, Janssen. "Additionally, our research continues to evaluate the value that XARELTO® offers healthcare systems beyond the medicine's best-in-class access and affordability in the U.S., and we look forward to sharing further data on this important topic."

Below is a listing of the data presentations for XARELTO® at ACC.16:

High-Risk Populations

- (1118-361/361) Major Bleeding among Rivaroxaban Users with Non-Valvular Atrial Fibrillation and Diabetes. Poster presentation: Saturday, April 2, 10:00-10:45 a.m. CT. Location: South Hall A1.

- (1153-323/323) Efficacy and Safety of Rivaroxaban Compared with Warfarin in Patients with Carotid Artery Disease and Non-Valvular Atrial Fibrillation: Insights from the ROCKET AF Trial. Poster presentation: Saturday, April 2, 3:45-4:30 p.m. CT. Location: South Hall A1.

- (1233-327/327) Safety and Efficacy of Rivaroxaban in Patients with Cardiac Implantable Electronic Devices: Observations from the ROCKET AF Trial. Poster presentation: Sunday, April 3, 3:45-4:30 p.m. CT. Location: South Hall A1.

- (1268-358/358) Impact of Renal Function on Ischemic Stroke and Major Bleeding Rates in Non-Valvular Atrial Fibrillation Patients Treated with Warfarin and Rivaroxaban. Poster presentation: Monday, April 4, 9:45-10:30 a.m. CT. Location: South Hall A1.

Value/Adherence

- (1120-379/379) Impact of Dosing Frequency on Adherence to Chronic Cardiovascular Medications: A Meta-Regression Analysis. Poster presentation: Saturday, April 2, 10:00-10:45 a.m. CT. Location: South Hall A1.

- (1154-344/344) Adherence to Rivaroxaban and Dabigatran in Non-Valvular Atrial Fibrillation Patients in the United States. Poster presentation: Saturday, April 2, 3:45-4:30 p.m. CT. Location: South Hall A1.

- (1186-310/310) Comparison of Rivaroxaban or Warfarin Use for Venous Thromboembolism on Inpatient Length of Stay. Poster presentation: Sunday, April 3, 9:45-10:30 a.m. CT. Location: South Hall A1.

- (1265-314/314) Is Rivaroxaban Associated with Shorter Inpatient Stays and Lower Hospital Costs versus Heparin/Warfarin in Low-Risk Pulmonary Embolism Patients? Poster presentation: Monday, April 4, 9:45-10:30 a.m. CT. Location: South Hall A1.

Registry

- (1118-355/355) Management and Outcomes of Patients with Atrial Fibrillation and Cancer: the ORBIT-AF Registry. Poster presentation: Saturday, April 2, 10:00-10:45 a.m. CT. Location: South Hall A1.

- (1188-337/337) Treatment and Stroke Risk in Low-Risk CHA_2DS_2VASc Atrial Fibrillation Patients: Findings from the ORBIT-AF Registry. Poster presentation: Sunday, April 3, 9:45-10:30 a.m. CT. Location: South Hall A1.

- (1188-349/349) Adherence to Guideline Recommendations in Atrial Fibrillation: Findings from ORBIT-AF. Poster presentation: Sunday, April 3, 9:45-10:30 a.m. CT. Location: South Hall A1.

- (1268-352/352) Oral Anticoagulant Selection in Community Patients with New-Onset Atrial Fibrillation: Results from the ORBIT-AF II Registry. Poster presentation: Monday, April 4, 9:45-10:30 a.m. CT. Location: South Hall A1.

Measurement

- (1265-309/309) External Validation of Prognostic Rules for 30-Day Post-Pulmonary Embolism Mortality: Assessment of a Claims-Based and Three Clinical-Based Approaches. Poster presentation: Monday, April 4, 9:45-10:30 a.m. CT. Location: South Hall A1.

- (1186-311/311) External Validation of the In-Hospital Mortality for Pulmonary Embolism Using Claims Data (IMPACT) Prediction Rule. Poster presentation: Sunday, April 3, 9:45-10:30 a.m. CT. Location: South Hall A1.

For more information, including a complete list of abstract titles, visit the official website for ACC.16 here.

About the EXPLORER Clinical Development Program

A collaborative research effort with Bayer, EXPLORER evaluates the use of XARELTO® in a broad range of cardiovascular conditions. The focus of EXPLORER is two-fold: to research the potential role of XARELTO® in addressing additional critical needs; and, to generate important clinical evidence on the performance of XARELTO® in the real world. 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, which includes ongoing and completed studies, independent registries and non-interventional studies.

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 together are developing rivaroxaban.

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

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 Janssen.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 inherent in new product research and development, including uncertainty of clinical success and 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.