Media Contacts:
Sarah Freeman
Mobile: (215) 510-4758
sfreem21@its.jnj.com

Investor Relations Contacts:
Johnson & Johnson
Joseph J. Wolk
Tel: (732) 524-1142

Lesley Fishman
Tel: (732) 524-3922

New XARELTO® (rivaroxaban) Data at ESC Congress 2017
Includes Late-Breaking Results from Landmark Phase 3 COMPASS Study

XARELTO® is the only Factor Xa inhibitor currently under investigation in patients with coronary and peripheral artery disease

Data from PIONEER AF-PCI examining the value of XARELTO® in patients with non-valvular atrial fibrillation following percutaneous coronary intervention with stenting among 25 studies being presented

TITUSVILLE, NJ (August 21, 2017) – New data from the landmark Phase 3 COMPASS study evaluating the use of XARELTO® (rivaroxaban) in coronary and peripheral artery disease (CAD and PAD) are among the 25 presentations from Janssen Research & Development, LLC (Janssen) and its development partner Bayer to be featured at the ESC Congress 2017 in Barcelona, Spain. In addition to two late-breaking presentations from the COMPASS study, the companies will present sub-analyses from PIONEER AF-PCI, a study of XARELTO® in patients with non-valvular atrial fibrillation (NVAF) following percutaneous coronary intervention (PCI) with stenting.

***Click to Tweet*: @JanssenUS to present 25 studies at #ESCCongress addressing #CAD, #PAD, #AFib and #PCI #JanssenCV http://po.st/gbV8rG**

Both COMPASS and PIONEER AF-PCI are part of the EXPLORER clinical research program for XARELTO®. Janssen announced earlier this year that COMPASS was being stopped early due

to efficacy based on the recommendation of the study's independent Data Monitoring Committee (DMC), as the primary efficacy endpoint had reached its pre-specified criteria for superiority.

"People living with CAD and/or PAD are at high risk for cardiovascular death, heart attack or stroke, and have limited treatment opportunities," said James F. List, MD, PhD, Global Therapeutic Area Head, Cardiovascular & Metabolism, Janssen. "We are excited to share the results of the very important COMPASS study as they provide new insights into the prevention of cardiovascular events in patients treated with XARELTO®, the only Factor Xa inhibitor currently under investigation in this population."

CAD and PAD affect 16.5 million and 10 million Americans, respectively. Globally, screening studies suggest approximately 20 percent of adults older than 55 years show evidence of PAD. Importantly, cardiovascular disease is estimated to account for one-third of deaths in people over age 35.

About COMPASS

COMPASS is a Phase 3 clinical study examining the use of XARELTO®, alone or in combination with aspirin, in the long-term prevention of major adverse cardiovascular (CV) events, including heart attack, stroke or CV-related death in people with CAD and/or PAD. A total of 27,395 patients with stable CAD and/or PAD from 33 countries were enrolled.

Both CAD and PAD are the result of atherosclerosis and occur when arteries become hardened or narrowed due to a buildup of cholesterol and plaque, limiting blood flow to parts of the body. When atherosclerosis occurs in the vessels that feed the heart, it is called CAD; it is called PAD when it occurs in other blood vessels in the body – most often in the legs, but also in the brain, arms and abdomen. People with CAD and/or PAD are at significant risk of experiencing a major CV event. While long-term aspirin helps prevent CV events, it is only modestly effective.

About PIONEER AF-PCI

Presented and published in 2016, the Phase 3b PIONEER AF-PCI study met its primary endpoint, showing XARELTO® significantly reduced the risk of bleeding compared to warfarin, the standard of care, in patients with NVAF who received background antiplatelet therapy following PCI with stenting. Although the study was not powered to make conclusions on efficacy, XARELTO® showed similar rates of major adverse CV events

compared to warfarin. A separate post-hoc sub-analysis of PIONEER AF-PCI showed a reduction in the risk of re-hospitalization for XARELTO® compared to warfarin.

"As PIONEER AF-PCI addresses a common situation in clinical practice, we wanted to better understand the value of XARELTO® in these patients," said Dr. List. "We look forward to sharing research on the number of clinically significant bleeding events, costs associated with re-hospitalization and the number of event-free days out of the hospital for patients both on XARELTO® and warfarin."

About EXPLORER

The EXPLORER program is unmatched by any oral anticoagulant in the Factor Xa inhibitor class in its size, scope and ambition. A collaborative effort between Janssen and Bayer, EXPLORER seeks to generate important clinical evidence on the safety and efficacy of XARELTO® and its potential role in addressing critical unmet medical needs. A number of the studies, including COMPASS, are designed to seek additional indications or expand the label for XARELTO® to benefit more patients in need of additional therapies for their cardiovascular disease. By the time of its completion, more than 275,000 patients will have participated in the EXPLORER clinical development program, other completed and ongoing clinical trials, investigative registries and non-interventional studies.

Following is a list of abstracts to be presented at the ESC Congress 2017:

Abstract #	**Title**	**Date/Time/Location**
XARELTO®: Vascular Protection		
1154 - 1155	Cardiovascular OutcoMes for People using Anticoagulation StrategieS (COMPASS) trial: primary results	Hot Line: Late-Breaking Clinical Trials 1 Sunday, August 27 11:36-11:51 a.m. CEST Barcelona - Main Auditorium
1157 - 1158	Cardiovascular OutcoMes for People using Anticoagulation StrategieS (COMPASS) trial: results in patients with coronary artery disease and in patients with peripheral artery disease	Hot Line: Late-Breaking Clinical Trials 1 Sunday, August 27 11:54 a.m.-12:09 p.m. CEST Barcelona - Main Auditorium
P4565	Rivaroxaban treatment strategies reduce not only the first bleeding event, but all (including multiple) bleeding events: a PIONEER substudy	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
P6112	Effect of procedure and lesion characteristics on bleeding and ischemic outcomes among atrial fibrillation patients	Poster Presentation Tuesday, August 29 2:00-6:00 p.m. CEST Poster Area

	undergoing percutaneous coronary intervention: results from the PIONEER AF-PCI trial	
2872	Association between sociodemographic factors and choice of direct oral anticoagulants versus warfarin in atrial fibrillation: a population based cross-sectional study using Swedish Registers	Rapid Fire Abstract Monday, August 28 8:30-8:39 a.m. CEST Agora 2 - Agora
P2642	Effect of rivaroxaban on coagulation and inflammation biomarkers: results from an X-VeRT substudy	Poster Presentation Sunday, August 27 2:00-6:00 p.m. CEST Poster Area
XARELTO®: Venous Protection		
P1617	Clinical and economic outcomes in low-risk pulmonary embolism patients treated with rivaroxaban vs. standard of care	Poster Presentation Sunday, August 27 8:30 a.m.-12:30 p.m. CEST Poster Area
P4925	Recurrent venous thromboembolism and major bleeding in patients treated with rivaroxaban or warfarin for venous thromboembolism in routine practice	Poster Presentation Tuesday, August 29 10:05-10:55 a.m. CEST Moderated Poster Station - Poster Area
XARELTO®: Stroke Prevention		
P3592	Safety analysis of rivaroxaban: a pooled analysis of the global XANTUS programme (real-world, prospective, observational studies for stroke prevention in patients with atrial fibrillation)	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
P3622	Timing of trial stoppage for non-inferiority trials and interpretation: lessons from ROCKET AF	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
XARELTO®: Value		
P3590	Rivaroxaban strategies improve the number of days patients remain out of the hospital and event free: A PIONEER sub-study	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
P4569	Rivaroxaban treatment strategies reduce costs associated with rehospitalizations due to bleeding and cardiovascular events: results from the PIONEER AF-PCI trial	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
Independent Studies/Registries		
P1078	Short and intermediate term all-cause mortality among newly-diagnosed heart failure patients in the U.S. Medicare population	Poster Presentation Sunday, August 27 10:05-10:55 a.m. CEST Moderated Poster Station - Poster Area
P3237	One-year clinical outcomes and management of patients with ischaemic vs non-ischaemic cardiomyopathy and newly diagnosed atrial fibrillation: results from GARFIELD-AF	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Best Poster Screen - Poster Area

P3609	Which definition of hypertension best defines thromboembolic risk in patients with atrial fibrillation? Data from the GARFIELD-AF registry	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
P3581	Real-world effectiveness of stroke prevention in patients with non-valvular atrial fibrillation treated with rivaroxaban vs. phenprocoumon in Germany – insights from the RELOAD study	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
P3600	Characteristics of 15 mg once-daily rivaroxaban patients from the RELOAD study	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
P3569	Impact of body mass index in newly diagnosed atrial fibrillation in the GARFIELD-AF registry	Poster Presentation Monday, August 28 8:30 a.m.-12:30 p.m. CEST Poster Area
3058 - 3059	An international multicenter clustered randomized trial to IMProve treatment with oral AntiCoagulanTs in Atrial Fibrillation	Hot Line: Late-Breaking Clinical Trials 2 Monday, August 28 11:36-11:51 a.m. CEST Barcelona - Main Auditorium
P4603	The burden of atrial fibrillation in the more populated European countries: perspectives from the GARFIELD-AF registry	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
P4594	Global healthcare resource use in 39,670 patients with AF: perspectives from GARFIELD-AF	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
P4602	Similar clinical outcomes of asymptomatic and symptomatic patients with newly diagnosed atrial fibrillation: results from GARFIELD-AF	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
P4601	Differences in two-year outcomes according to type of atrial fibrillation: results from the GARFIELD-AF registry	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
P4608	Benefits of active involvement of community pharmacists in know your pulse awareness campaign	Poster Presentation Monday, August 28 2:00-6:00 p.m. CEST Poster Area
P4893	A scheme based on ICD-10 diagnoses and drug prescriptions to stage chronic kidney disease severity in healthcare administrative records	Poster Presentation Tuesday, August 29 10:05-10:55 a.m. CEST Moderated Poster Station - Poster Area

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®)
- Selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- 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®?"

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.
Trademarks are those of their respective owners.

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 Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding ongoing development of XARELTO® (rivaroxaban). 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., Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in 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 1, 2017, including under "Item 1A. Risk Factors", its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements" 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.

1. *Circulation*. 2017; CIR.0000000000000485;ii AHA Statistical Update, Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association, Originally published January 25, 2017, page 360, downloaded from http://circ.ahajournals.org/content/early/2017/01/25/CIR.0000000000000485
2. *Circulation*. 2017;CIR.0000000000000485; AHA Statistical Update, Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association, Originally published January 25, 2017, page 408, downloaded from http://circ.ahajournals.org/content/early/2017/01/25/CIR.0000000000000485
3. Hankey GJ, Norman PE, Eikelboom JW. Medical Treatment of Peripheral Arterial Disease. *JAMA* 2006;295(5):547-553.
4. Bhatt DL, Eagle KA, Ohman EM, et al. Comparative determinants of 4-year cardiovascular event rates in stable outpatients at risk of or with atherothrombosis. *JAMA* 2010;304:1350-7.