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Janssen Announces 25 Presentations at Upcoming ESC Congress 2016, Including New Clinical and Real-World Research on XARELTO® and Latest Findings from REVISIT-US

- *New research from EXPLORER program provides further insights into safety, efficacy and cost-savings profile of XARELTO® (rivaroxaban) across a broad spectrum of patients*
- *Latest results from REVISIT-US identify the real-world incidence of ischemic stroke and intracranial hemorrhage in people with non-valvular atrial fibrillation, comparing XARELTO®, apixaban and dabigatran each with warfarin*
- *GALILEO trial seeks to address unmet medical need of patients following transcatheter aortic valve replacement (TAVR)*

RARITAN, NJ (August 22, 2016) – Janssen Pharmaceuticals, Inc., today announced that 25 abstracts have been accepted for presentation by Janssen and its development partner, Bayer, at the ESC Congress 2016, taking place August 27-31 in Rome, Italy. New real-world evidence from the EXPLORER research program, including latest findings from the REVISIT-US study, will address how XARELTO® (rivaroxaban), a non-vitamin K antagonist oral anticoagulant (NOAC), is performing in routine clinical practice. Also, the companies will unveil the design of the GALILEO trial, which seeks to address blood clot prevention for patients following successful transcatheter aortic valve replacement (TAVR).

"As more real-world research on the NOAC class of medicines becomes available, we continue to see that the benefit-risk profile of XARELTO® remains favorable and consistent with clinical trials," said Paul Burton, MD, PhD, Vice President, Medical Affairs, Janssen. "Our significant

presence and the robustness of data at this year's ESC Congress 2016 underscore our commitment to providing physicians with the latest evidence on how XARELTO® is performing in the real world."

A listing of the data presentations is below:

Abstract Type/Title	**Presentation Information**
New Real-World Insights In Non-Valvular Atrial Fibrillation	
Poster Presentation: Real-world evidence of stroke prevention in patients with non-valvular atrial fibrillation in the United States: the REVISIT-US study	Poster Session 3: Anticoagulation in Atrial Fibrillation II Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Poster Presentation: Oral anticoagulant prescribing patterns for stroke prevention in atrial fibrillation among general practitioners and cardiologists in three European countries	Poster Session 3: Anticoagulation in Atrial Fibrillation III Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Poster Presentation: Real-world evidence of stroke prevention in patients with non-valvular atrial fibrillation	Poster Session 3: Anticoagulation in Atrial Fibrillation II Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Poster Presentation: Predictors of major bleeding in patients with atrial fibrillation treated with rivaroxaban in XANTUS: findings from a real-world prospective study	Poster Session 3: Anticoagulation in Atrial Fibrillation III Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Poster Presentation: Economic evaluation of rivaroxaban versus acenocoumarol in the prevention of stroke in patients with non-valvular atrial fibrillation in Spain	Poster Session 3: Stroke and More Sunday, August 28 2:00pm – 6:00 pm CEST Poster Area
Oral Presentation: Major bleeding among patients with atrial fibrillation treated with rivaroxaban or warfarin in Sweden: interim results from an on-going post-authorization study	Are You Still Afraid about Bleeding Risk of Antithrombotic Therapy in Atrial Fibrillation? Sunday, August 28 2:54 pm CEST Minsk – Village 4
Oral Presentation: XAPASS: evidence of safety and effectiveness in Japanese patients treated with rivaroxaban for stroke prevention in atrial fibrillation under real-world clinical practice	Registries Atrial Fibrillation Monday, August 29 9:15 am CEST Raphael – The Hub
Rapid Fire Abstract - Oral Presentation: The CHA_2DS_2-VASc score strongly correlates with glomerular filtration rate and predicts decline in renal function over time in patients with atrial fibrillation and chronic kidney disease	Clinical Features and Management of Atrial Fibrillation Monday, August 29 9:33 am CEST Agora 1 – Poster Area

New Unmet Medical Need Research	
Oral Presentation: GALILEO: rivaroxaban in TAVR patients	The Future is in the Pipeline Tuesday, August 30 10:30 am CEST Agora 1 - Poster Area
Registry Data	
Oral Presentation: Identifying patients with atrial fibrillation and "truly low" thromboembolic risk who are poorly characterized by CHA2DS2-VASc: superior performance of a novel machine learning tool in GARFIELD-AF	Registries Atrial Fibrillation Monday, August 29 8:30 am CEST Raphael – The Hub
Poster Presentation: Pharmacotherapy for atrial fibrillation in patients with chronic kidney disease: insights from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF)	Poster Session 4: Miscellaneous in Arrhythmia Monday, August 29 8:30 am – 12:30 pm CEST Poster Area
Poster Presentation: Patterns of amiodarone use and outcomes in clinical practice for atrial fibrillation: insights from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF)	Poster Session 4: Miscellaneous in Arrhythmia Monday, August 29 8:30 am – 12:30 pm CEST Poster Area
Oral Presentation: Association of inappropriate dosing of non-vitamin K oral anticoagulants and risk of adverse events: results from the ORBIT-AF II registry	Registries Atrial Fibrillation Monday, August 29 9:30 am CEST Raphael – The Hub
Moderated Poster Presentation: Do baseline characteristics account for geographical variations in event rates in patients with newly diagnosed atrial fibrillation? The GARFIELD-AF registry	Antithrombotic Therapy in Atrial Fibrillation 1 Monday, August 29 3:56 pm CEST Moderated Poster Station – Poster Area
Moderated Poster Presentation: Vitamin K antagonist control for patients with non-valvular atrial fibrillation in Eastern and Southeastern Asia: an analysis of event rates from GARFIELD-AF	Antithrombotic Therapy in Atrial Fibrillation 2 Tuesday, August 30 10:35 am CEST Moderated Poster Station – Poster Area
Additional Non-Valvular Atrial Fibrillation Research	
Poster Presentation: Systemic embolization in patients with atrial fibrillation: results from ROCKET AF	Poster Session 3: Anticoagulation in Atrial Fibrillation III Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Poster Presentation: Left atrial thrombus resolution in atrial fibrillation or flutter: results of a prospective study with rivaroxaban (X-TRA) and a retrospective observational registry providing baseline data (CLOT-AF)	Poster Session 3: Anticoagulation in Atrial Fibrillation II Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Poster Presentation: Left atrial thrombus resolution in non-valvular atrial fibrillation or flutter: results of a prospective study with rivaroxaban (X-TRA) – biomarker substudy	Poster Session 3: Anticoagulation in Atrial Fibrillation II Sunday, August 28 2:00 – 6:00 pm CEST Poster Area

Poster Presentation: Net clinical benefit of rivaroxaban compared with warfarin in patients with atrial fibrillation	Poster Session 3: Anticoagulation in Atrial Fibrillation II Sunday, August 28 2:00 – 6:00 pm CEST Poster Area
Pulmonary Embolism and Deep Vein Thrombosis Research	
Oral Presentation: Is rivaroxaban associated with shorter hospital stays and reduced costs vs. parenteral bridging to warfarin among pulmonary embolism patients?	Optimizing the Treatment of Pulmonary Embolism Sunday, August 28 5:24 pm CEST Vienne – Village 9
Poster Presentation: Outcomes associated with observation versus inpatient stays for pulmonary embolism	Poster Session 4: Acute Pulmonary Embolism Monday, August 29 8:30 am – 12:30 pm CEST Poster Area
Poster Presentation: External validation of a multivariable claims-based prediction rule for in-hospital pulmonary embolism mortality	Poster Session 4: Acute Pulmonary Embolism Monday, August 29 8:30 am – 12:30 pm CEST Poster Area
Poster Presentation: Hospitalizations and other healthcare resource utilization among patients with deep vein thrombosis treated with rivaroxaban versus low-molecular-weight heparin and warfarin in the outpatient setting	Poster Session 4: Thrombosis and Coagulation Monday, August 29 8:30 am – 12:30 pm CEST Poster Area
Moderated Poster Presentation: Subgroup analysis of patients with concomitant pulmonary embolism in XALIA, a non-interventional study of rivaroxaban in routine treatment of deep vein thrombosis	Advances in Pulmonary Embolism Monday, August 29 3:35 pm CEST Moderated Poster Station – Poster Area
Rapid Fire Abstract - Oral Presentation: Risk of venous thromboembolism recurrences in patients who continued versus discontinued rivaroxaban therapy after an initial six-month therapy	Antithrombotics in Daily Clinical Practice Tuesday, August 30 4:39 pm CEST Galileo – The Hub

About EXPLORER

Unmatched by any oral anticoagulant in the NOAC class in its size, scope and ambition, our EXPLORER research program continues to generate important clinical evidence on the safety and efficacy performance of XARELTO® and its potential role in addressing additional critical medical needs. 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. The EXPLORER program includes six additional indication-seeking programs underway beyond the currently approved six indications in the U.S. It is a collaborative research effort with Bayer that includes:

- COMMANDER HF: Reduction of the risk of major adverse cardiac events (MACE) in patients with chronic heart failure and significant coronary artery disease;

- COMPASS: Prevention of major cardiovascular events (heart attack, stroke, cardiovascular death) in patients with coronary or peripheral artery disease;
- MARINER: Prevention of symptomatic venous thromboembolism (VTE) and VTE-related death in high-risk, medically ill patients;
- NAVIGATE ESUS: Secondary prevention of stroke in patients who have experienced an embolic stroke of undetermined source (ESUS);
- VOYAGER PAD: Reduction of the risk of MACE in patients with coronary or peripheral artery disease; and,
- GEMINI ACS 1 (phase 2): Long-term secondary prevention of additional cardiovascular events in patients with acute coronary syndrome (ACS).

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.
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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 on Twitter 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 product development, including expectations for research programs and clinical trials. 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., any of the other Janssen Pharmaceutical Companies 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 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.