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**New XARELTO® (rivaroxaban) Peripheral Artery Disease (PAD) Data from EXPLORER Clinical Research Program to be Unveiled at American Heart Association (AHA) Scientific Sessions 2020**

*Data includes several analyses from the landmark VOYAGER PAD trial, including findings in high-risk patients with critical limb ischemia (CLI) after lower-extremity revascularization (LER)*

*XARELTO® has the potential to be the first anticoagulant in 20 years to show a benefit in patients with PAD after LER<sup>i</sup>*

*The comprehensive PAD program within EXPLORER continues to generate new findings that may shift the way symptomatic and chronic patients are managed*

**RARITAN, N.J., November 9, 2020** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that 10 data presentations will be shared at the virtual American Heart Association (AHA) Scientific Sessions 2020 from November 13-17. Most notably, four new sub-analyses of XARELTO® (rivaroxaban) from the landmark VOYAGER PAD trial, part of the EXPLORER global cardiovascular research program, will be presented, including two live, featured science oral presentations.

“We're pleased VOYAGER PAD was selected to be front and center once again at a major medical congress, as there's an urgent need for data in the symptomatic PAD population,” said James List, M.D., Ph.D., Global Therapeutic Area Head, Cardiovascular & Metabolism, Janssen Research & Development, LLC. “We have presented a total of 12 VOYAGER PAD datasets this year and continue to evaluate subgroups of PAD patients within the pivotal trials for rivaroxaban. We look forward to sharing these new analyses with the medical community at AHA.”

**[CLICK TO TWEET:](https://ctt.ec/xe305+) Click to learn more about PAD, including risk factors and causes; signs and symptoms; screening and prevention; health disparities and more at the @JanssenUS Cardiovascular & Metabolism online newsroom. <https://ctt.ec/xe305+>**

On October 26, 2020, [Janssen announced that it submitted a supplemental New Drug Application \(sNDA\) to the FDA to expand the use of XARELTO®](#) in patients with PAD to include reducing the risk of major thrombotic vascular events, such as heart attack and amputation, in symptomatic patients after recent lower-extremity revascularization (LER). XARELTO® is currently approved to reduce the risk of major cardiovascular (CV) events in people with chronic coronary artery disease (CAD) or PAD.

Highlights of the presentations at AHA 2020 include four VOYAGER PAD sub-analyses examining XARELTO® plus aspirin across a diverse range of patient subgroups, including those with critical limb ischemia (CLI). This analysis is of particular importance as patients with CLI are at increased risk of major limb and CV events and many require unplanned revascularization.<sup>ii</sup>

The following is a list of highlighted abstracts to be presented at AHA 2020:

<b><u>Abstract No.</u></b>	<b><u>Title</u></b>	<b><u>Date/Time/Location</u></b>
<b>Late-Breaking/Featured Science Presentations</b>		

FS.03	Efficacy and Safety of Rivaroxaban in Patients With PAD Undergoing Lower Extremity Revascularization for Critical Limb Ischemia: Insights from VOYAGER PAD	November 14, 2020 3:42-3:54 p.m. CT*
FS.03	Rivaroxaban Plus Aspirin Versus Aspirin Alone After Endovascular Revascularization for Symptomatic PAD: Insights From VOYAGER PAD	November 14, 2020 3:54-4:06 p.m. CT*
FS.03	Efficacy and Safety of Rivaroxaban Monotherapy in Patients With Atrial Fibrillation After Coronary Stenting: Insights From the Afire Trial	November 14, 2020 4:18-4:30 p.m. CT*
LBS.03	Rivaroxaban Versus Warfarin in Patients With Bioprosthetic Mitral Valves and Atrial Fibrillation or Flutter: Primary Results From the RIVER Randomized Trial – RIVER Trial	November 14, 2020 12:40-12:50 p.m. CT
LBS.06	3-year Clinical Outcomes in a Nationwide, Randomized, Pragmatic Clinical Trial of Atrial Fibrillation Screening - Mhealth Screening To Prevent Strokes (mSToPS)	November 16, 2020 9:21-9:29 a.m. CT
<b>Vascular Protection</b>		
291	Reduction in Venous Thromboembolism With Rivaroxaban Versus Placebo in Peripheral Artery Disease After Lower Extremity Revascularization: Insights from VOYAGER PAD	November 13, 2020 9:00-10:00 a.m. CT*
293	Rivaroxaban Reduces Major Cardiovascular and Limb Events in Patients With the High-Risk Triad of Chronic Kidney Disease, Peripheral Artery Disease and Recent Lower Extremity Revascularization: Insights From VOYAGER PAD	November 13, 2020 9:00-10:00 a.m. CT*
P1714	Incidence and Costs of Major Atherothrombotic Vascular Events Among Patients with Peripheral Artery Disease After Revascularization	November 13, 2020 9:00-10:00 a.m. CT*
<b>Stroke Prevention</b>		
P1089	Advanced Age and Preferential Use of Vitamin K Antagonists in Severe Renal Impairment: First Results of the XARENO Registry in Patients with Non-Valvular Atrial Fibrillation and Non-Dialysis Dependent Advanced Chronic Kidney Disease	November 13, 2020 9:00-10:00 a.m. CT*
P1971	Oral Anticoagulation Use in High-Risk Atrial Fibrillation Patients is Much Higher than Previously Reported	November 13, 2020 9:00-10:00 a.m. CT*

*\*Available on demand for the duration of the Congress*

## **About Peripheral Artery Disease (PAD)**

Peripheral artery disease is a narrowing of the peripheral arteries serving the legs, arms and head. The most common symptoms of PAD involving the lower extremities are cramping, pain or tiredness in the leg or hip muscles while walking or climbing stairs.<sup>iii</sup> It is a serious underlying health condition that impacts an estimated 20 million Americans with only 8.5 million diagnosed.<sup>iv,v</sup> Often starting as asymptomatic, PAD typically progresses to a more symptomatic, chronic form, with revascularization needed when symptoms become severe or limb-threatening.

## **WHAT IS XARELTO®?**

XARELTO® is a prescription medicine used to:

- reduce the risk of stroke and blood clots in people who have a medical condition called atrial fibrillation that is not caused by a heart valve problem. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to the formation of blood clots, which can travel to the brain, causing a stroke, or to other parts of the body
- treat blood clots in the veins of your legs (deep vein thrombosis or DVT) or lungs (pulmonary embolism or PE)
- reduce the risk of blood clots happening again in people who continue to be at risk for DVT or PE after receiving treatment for blood clots for at least 6 months
- help prevent a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery
- help prevent blood clots in certain people hospitalized for an acute illness and after discharge, who are at risk of getting blood clots because of the loss of or decreased ability to move around (mobility) and other risks for getting blood clots, and who do not have a high risk of bleeding

XARELTO® is used with low dose aspirin to:

- reduce the risk of serious heart problems, heart attack and stroke in people with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral artery disease (a condition where the blood flow to the legs is reduced)

It is not known if XARELTO® is safe and effective in children.

## **IMPORTANT SAFETY INFORMATION**

### **WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT XARELTO®?**

**XARELTO® may cause serious side effects, including:**

- **Increased risk of blood clots if you stop taking XARELTO®.** People with atrial fibrillation (an irregular heart beat) that is not caused by a heart valve problem (nonvalvular) 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.

- **Increased risk of bleeding.** XARELTO® can cause bleeding which can be serious, and may lead to death. This is because XARELTO® is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with XARELTO® you are likely to bruise more easily, and it may take longer for bleeding to stop. You may be at higher risk of bleeding if you take XARELTO® and have certain other medical problems.

**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
- Long-term (chronic) use of 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 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 use in people with artificial heart valves.

XARELTO® is not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing, who have a history of blood clots.

**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®.

**Before taking XARELTO®, tell your doctor about all your medical conditions, including if you:**

- Have ever had bleeding problems
- Have liver or kidney problems
- Have antiphospholipid syndrome (APS)
- 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 during treatment with XARELTO®. Taking XARELTO® while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
  - If you take XARELTO® during pregnancy, tell your doctor right away if you have any signs or symptoms of bleeding or blood loss. **See “What is the most important information I should know about XARELTO®?” for signs and symptoms of bleeding.**

- Are breastfeeding or plan to breastfeed. XARELTO® may pass into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with XARELTO®.

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 over-the-counter medicines, vitamins, and herbal supplements.

Some of your other medicines may affect the way XARELTO® works, causing side effects. Certain medicines may increase your risk of bleeding. **See "What is the most important information I should know about XARELTO®?"**

### **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 may change your dose if needed.
- Your doctor will decide how long you should take XARELTO®.
- XARELTO® may need to be stopped for one or more days before any surgery or medical or dental procedure. Your doctor will tell you when to stop taking XARELTO® and when to start taking XARELTO® again after your surgery or procedure.
- If you need to stop taking XARELTO® for any reason, talk to the doctor who prescribed XARELTO® to you to find out when you should stop taking it. Do not stop taking XARELTO® without first talking to the doctor who prescribes it to you.
- If you have difficulty swallowing XARELTO® tablets whole, talk to your doctor about other ways to take XARELTO®.
- Do not run out of XARELTO®. Refill your prescription of XARELTO® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will 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.

#### **If you take XARELTO® for:**

- **Atrial Fibrillation that is not caused by a heart valve problem:**
  - 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® **1 or 2 times a day** as prescribed by your doctor.
  - For the **10-mg dose**, XARELTO® **may be taken with or without food.**
  - For the **15-mg and 20-mg doses**, take XARELTO® **with food at the same time each day.**
  - If you miss a dose:

- **If you take the 15-mg dose of XARELTO® 2 times a day (a total of 30 mg of XARELTO® in 1 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.
- **If you 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.
- **Blood clots in people hospitalized for an acute illness:**
  - Take XARELTO® 1 time a day, with or without food, while you are in the hospital and after you are discharged as prescribed by your doctor.
  - 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.
- **Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease or peripheral artery disease:**
  - Take XARELTO® 2.5 mg 2 times a day with or without food.
  - If you miss a dose of XARELTO®, take your next dose at your regularly scheduled time.
  - Take aspirin 75 to 100 mg once daily as instructed by your doctor.

## **WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?**

### **XARELTO® may cause serious side effects:**

- See **"What is the most important information I should know about XARELTO®?"**

**The most common side effect of XARELTO® was bleeding.**

Call your doctor for medical advice about side effects. **You may report side effects to the FDA at 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<sup>®</sup>, visit [www.xarelto.com](http://www.xarelto.com).

### **About Janssen Cardiovascular & Metabolism**

In Cardiovascular & Metabolism (CVM), we take on the most pervasive diseases that burden hundreds of millions of people and healthcare systems around the world. As part of this long-standing commitment and propelled by our successes in treating type 2 diabetes and thrombosis, we advance highly differentiated therapies that prevent and treat life-threatening cardiovascular, metabolic and retinal diseases. Uncovering new therapies that can improve the quality of life for this large segment of the population is an important endeavor – one which Janssen CVM will continue to lead in the years to come. Our mission is global, local and personal. Together, we can reshape the future of cardiovascular, metabolic and retinal disease prevention and treatment. Please visit [www.janssen.com/cardiovascular-and-metabolism](http://www.janssen.com/cardiovascular-and-metabolism).

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenUS](https://www.twitter.com/JanssenUS) and [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal). Janssen Research & Development, LLC, is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

### **Cautions Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding XARELTO<sup>®</sup>. 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 Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions 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 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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<sup>i</sup> Tangelder MJD, Algra A, Lawson JA, Eikelboom BC, et al. Efficacy of oral anticoagulants compared with aspirin after infrainguinal bypass surgery (The Dutch Bypass Oral anticoagulants or Aspirin study): a randomised trial. *Lancet*. 2000;355(9201):346-351.

<sup>ii</sup> Dua A, Lee CJ. Epidemiology of peripheral arterial disease and critical limb ischemia. *Tech Vasc Interv Radiol*. 2016;19(2):91-95.

<sup>iii</sup> American Heart Association. About Peripheral Artery Disease (PAD). Retrieved November 2, 2020 from <https://www.heart.org/en/health-topics/peripheral-artery-disease/about-peripheral-artery-disease-pad>.

<sup>iv</sup> Racial Disparities in Vascular Care. (n.d.). Retrieved October 2, 2020 from <https://cardiovascularcoalition.com/our-patients/racial-disparities-in-vascular-care/>

<sup>v</sup> Centers for Disease Control and Prevention. Peripheral Arterial Disease Fact Sheet/Data & Statistics. Retrieved March 20, 2020 from <https://www.cdc.gov/heartdisease/pad.htm>.