

Johnson & Johnson to Showcase its Broad Scientific Leadership and Latest Innovations to Combat Cardiovascular Disease at ACC.24

Clinical and real-world evidence presentations highlight how the Company is transforming care for patients who are fighting some of the most common and devastating cardiovascular diseases

NEW BRUNSWICK, NJ (April 4, 2024) – Johnson & Johnson announced today that clinical and real-world evidence from its cardiovascular portfolio will be featured at the American College of Cardiology 73rd Annual Scientific Session & Expo (ACC.24) taking place April 6-8, 2024, in Atlanta, Georgia. Eleven abstracts, including five oral presentations, will showcase data from Company-sponsored studies demonstrating therapeutic benefit of breakthrough medicines, such as XARELTO® (rivaroxaban), and interventional technologies, such as those from Abiomed® and Biosense Webster®, to help treat cardiovascular diseases, including atrial fibrillation (AF) and peripheral artery disease (PAD).

“Cardiovascular disease remains the leading cause of death for adults worldwide and millions more may be at risk of stroke and other life-threatening cardiovascular conditions as the population ages.¹ As a global leader in healthcare, we are determined to improve these statistics and empower those living with cardiovascular disease to lead fuller, healthier lives,” said Katie Devine, President, US General Medicines, Canada and Puerto Rico, Johnson & Johnson Innovative Medicine. “At ACC.24, we look forward to sharing the latest research and innovation from our broad portfolio, including XARELTO®, to equip clinicians and researchers with knowledge and insights that can help transform cardiovascular care for all.”

Improving the outlook for people with cardiovascular disease

Johnson & Johnson is committed to elevating the standard of care in cardiovascular diseases and unlocking the potential of medicines and solutions of tomorrow. Several data presentations at ACC.24 demonstrate how the Company is improving outcomes for people living with cardiovascular disease, including older adults and other patient populations often considered hard to treat. These include:

- Data from the PIONEER AF-PCI Phase 3 clinical trial evaluating the safety and efficacy of rivaroxaban for reducing the rate of bleeding among elderly and non-elderly patients with nonvalvular AF undergoing percutaneous coronary intervention (Abstract #906-04).
- Data from the Real-World Experience of Catheter Ablation for the Treatment of Symptomatic Paroxysmal and Persistent Atrial Fibrillation Using Novel Contact Force Technologies (REAL AF) Registry study evaluating the impact of scar burden on ablation strategy (Abstract #916-10).
- Data about Impella® heart pumps will be featured in more than 50 presentations, abstracts and posters, including the Danish-German Cardiogenic Shock Trial (DanGer), which is a Late Breaking Clinical Trial (Abstract #406-14).

“Our advancements have changed how cardiovascular diseases are diagnosed and treated and have had a meaningful impact on the lives of millions of patients and families. The data we’re presenting at ACC.24 demonstrate how we’re continuing to deliver on our commitment,” said Tim Schmid, Executive Vice President and Worldwide Chairman, Johnson & Johnson MedTech. “We are intent on elevating the standard of care in cardiovascular diseases and, with our partners, are leading research in areas like nonvalvular AF, stroke, and acute coronary syndrome. The real-world and clinical evidence presented at ACC.24 will provide cardiology teams with critical information to help deliver improved care for their patients.”

The list of Company-sponsored abstracts follows:

XARELTO® (rivaroxaban)

Oral sessions

Abstract #903-04	Efficacy and Safety of Dual Antiplatelet Therapy After Peripheral Artery Revascularization: Insights from VOYAGER PAD
Abstract #903-10	Risk of Adverse Events in Peripheral Artery Disease Patients with Below-Knee Disease: An Analysis from the VOYAGER-PAD Catheter-Based Angiographic Core Lab
Abstract #903-12	Risk Stratification for Amputation in Patients with Symptomatic PAD After Lower Extremity Revascularization: Insights from VOYAGER PAD
Abstract #906-04	Effect of Rivaroxaban on Bleeding or Ischemic Event and Rehospitalization Among Elderly or Non-Elderly Patients with Atrial Fibrillation Undergoing Percutaneous Coronary Intervention: Insights from the PIONEER AF-PCI Trial

Poster session

Abstract #1403-154	Efficacy of Rivaroxaban in Reducing Coronary or Peripheral Hospitalizations According to Smoking Status: A Post Hoc Analysis of the VOYAGER PAD Trial
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Biosense Webster

Oral session

Abstract #916-10	Scar Burden and Outcomes in Paroxysmal Atrial Fibrillation in the REAL-AF Registry
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Poster sessions

Abstract #1293-202	Left Atrial Volume Index and Scar Burden are Not Associated with Recurrence After Persistent Atrial Fibrillation Ablation
Abstract #1293-203	Patients with Severe Left Atrial Scar Burden May Benefit from More Extensive Ablation
Abstract #1511-205	Utilization of ICE vs TEE and Recurrence of Arrhythmias at 12 Months Post-Ablation in Paroxysmal (PAF) and Persistent Atrial Fibrillation (PSAF) in the REAL-AF Registry

Abiomed

Late Breaking Clinical Trial

Abstract #406-14	Percutaneous Transvalvular Micro-axial Flow Pump in Infarct Related Cardiogenic Shock. Results of The Danger-shock Trial.
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Population Health

Poster session

Abstract #1044-05	Neighborhood Health Predicts Peripheral Artery Disease Outcomes After Controlling for Quality of Medical Care: A Cohort Analysis Applying the Area Deprivation Index
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About XARELTO® (rivaroxaban)

XARELTO® is a prescription medicine used to:

- reduce the risk of stroke and blood clots in adults 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 from happening again in adults 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 adults who have just had hip or knee replacement surgery
- help prevent blood clots in certain adults 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 adults with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked)
- reduce the risk of a sudden decrease in blood flow to the legs, major amputation, serious heart problems or stroke in adults with peripheral artery disease (a condition where the blood flow to the legs is reduced) and includes adults who have recently had a procedure to improve blood flow to the legs

XARELTO® is used in children to:

- treat blood clots or reduce the risk of blood clots from happening again in children from birth to less than 18 years, after receiving at least 5 days of treatment with injectable or intravenous medicines used to treat blood clots
- help prevent blood clots in children 2 years and older with congenital heart disease after the Fontan procedure

XARELTO® was not studied and is not recommended in children less than 6 months of age who:

- were less than 37 weeks of growth (gestation) at birth
- had less than 10 days of oral feeding, **or**
- had a body weight of less than 5.7 pounds (2.6 kg)

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 or your child 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.

Do not take XARELTO® if you or your child:

- 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 or your child:

- 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.
 - Females who are able to become pregnant: Talk with your doctor about pregnancy planning during treatment with XARELTO®. Talk with your doctor about your risk for severe uterine bleeding if you are treated with blood thinner medicines, including XARELTO®.
 - 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 or your child 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 or your child 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:**
 - 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.
- **Reducing the risk of a sudden decrease in blood flow to the legs, major amputation, serious heart problems or stroke in people with peripheral artery disease, including those who have recently had a procedure to improve blood flow to the legs:**
 - 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.

For children who take XARELTO®:

- The dose of XARELTO® depends on your child's body weight and will be calculated by your child's doctor. Your child's doctor will tell you if XARELTO® can be given to your child with or without food.
- The adult caregiver should give the dose.
- If your child is taking the tablet, the tablet should be taken whole and should not be split in an attempt to provide a lower dose of XARELTO®.
- If your child is taking the oral suspension, use the syringes provided in the original carton. The suspension will be prepared by the pharmacy. See the **Instructions for Use** included in the carton on how to properly give a dose of XARELTO® oral suspension to your child.
- Do not switch between the XARELTO® oral suspension or tablet without first talking to your doctor.
- If your child vomits or spits up:
 - right after or within 30 minutes of taking the oral suspension, give a new full dose.
 - more than 30 minutes after taking the oral suspension, do not give the dose again. Give the next dose at the regularly scheduled time.

- if vomiting or spitting up persists, contact your child's doctor right away.
- If your child misses a dose:
 - If your child is taking XARELTO® 1 time a day, give the dose as soon as you remember on the same day. If this is not possible, skip this dose and give the next dose at the regularly scheduled time.
 - If your child is taking XARELTO® 2 times a day, give the missed morning dose as soon as you remember. You may give the missed morning dose together with the evening dose. However, a missed evening dose can only be taken in the same evening.
 - If your child is taking XARELTO® 3 times a day, skip the missed dose and give the next dose at the regularly scheduled time.

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® in adults was bleeding.

The most common side effects of XARELTO® in children include:

- bleeding
- vomiting
- cough
- inflamed stomach and gut

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 read full [Prescribing Information](#), including [Boxed Warnings](#), and [Medication Guide](#) for XARELTO®.

Trademarks are those of their respective owners. Janssen and Bayer together are developing rivaroxaban.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

Learn more at <https://www.jnj.com/> or at www.janssen.com/johnson-johnson-innovative-medicine. Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen Pharmaceuticals, Inc. are Johnson & Johnson companies.

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 and the potential benefits and treatment impact of 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 Research & Development, LLC, Janssen Biotech, Inc., Janssen Pharmaceuticals, Inc. 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 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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 Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Pharmaceuticals, Inc. nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

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¹ World Health Organization. Cardiovascular diseases (CVDs). 2021. Accessed February 15, 2024. Available at: [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)).