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Late-Breaking Results from XARELTO® (rivaroxaban) EINSTEIN CHOICE and GEMINI-ACS-1 Studies Among Research Accepted for Presentation at the American College of Cardiology 66th Annual Scientific Session

- *Phase 3 EINSTEIN CHOICE evaluated the efficacy and safety of continued use of XARELTO® (rivaroxaban) compared to aspirin for the secondary prevention of venous thromboembolism*
- *Phase 2 GEMINI-ACS-1 investigated the safety of XARELTO® compared to aspirin when used in combination with a P2Y12 inhibitor for the secondary prevention of cardiovascular events in people with acute coronary syndrome*

TITUSVILLE, NJ (March 6, 2017) – Janssen Pharmaceuticals, Inc. (Janssen) today announced that the company and its development partner Bayer will present important new research for XARELTO® (rivaroxaban), at the American College of Cardiology 66th Annual Scientific Session (ACC.17) in Washington, DC, March 17-19, 2017. Most notably, results of the Phase 3 EINSTEIN CHOICE study in venous thromboembolism (VTE) and Phase 2 GEMINI-ACS-1 study in acute coronary syndrome (ACS), both of which are part of the industry-leading EXPLORER clinical research program for XARELTO®, will be presented as Late-Breaking Clinical Trials.

EINSTEIN CHOICE is the first Phase 3 randomized study to evaluate the efficacy and safety of XARELTO®, a non-vitamin K antagonist oral anticoagulant (NOAC), compared to aspirin for extended secondary prevention of VTE in people who have experienced an initial VTE and have previously received up to 12 months of treatment. VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE) and affects more than 900,000 Americans each year, with one-third of these occurrences being fatal.[1] Once a person experiences a VTE, they are at increased risk of a blood clot occurring again.

GEMINI-ACS-1 is a Phase 2 trial that evaluated the safety of XARELTO® compared to aspirin when added to a P2Y12 inhibitor (clopidogrel or ticagrelor) for the secondary prevention of cardiovascular events in people with ACS. ACS is a term used to describe a range of conditions in which blood flow to the heart is suddenly reduced, like heart attack and unstable angina. In the United States, an ACS occurs every 25 seconds, with a death from ACS occurring every minute.[2] Approximately 1.14 million Americans are discharged from the hospital each year with either a primary or secondary diagnosis of ACS.[3]

"With cardiovascular diseases on the rise and nearly 44 percent of Americans predicted to have some form by 2030,[3] Janssen remains deeply committed to reducing the burden of these conditions and helping to improve the lives of these patients," said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Janssen. "We are thrilled to have such a prominent presence at ACC.17 and look forward to sharing the latest clinical research from our EXPLORER program, which examines potential new ways XARELTO® can address areas of critical unmet medical need."

Following is a full list of company-sponsored abstracts to be presented at ACC.17:

Abstract No.	**Title**	**Date/Time/Location**
XARELTO®: Venous Protection		
404-08	Rivaroxaban or Aspirin for Extended Treatment of Venous Thromboembolism (EINSTEIN CHOICE)	Late-Breaking Clinical Trial Saturday, March 18 8:00 - 8:10 a.m. ET Hall D (Main Tent)
904-04	A Benefit-Risk Analysis of Recurrent Venous Thromboembolism in Patients Who Continued Versus Discontinued Rivaroxaban Therapy After an Initial Six-Month Therapy	Oral Presentation Saturday, March 18 8:12 - 8:22 a.m. ET Room 147 B
XARELTO®: Vascular Protection		
404-10	A Randomized Trial Evaluating Clinically Significant Bleeding With Low-Dose Rivaroxaban Versus Aspirin, in Addition to P2Y12 Inhibition, for Patients After Acute Coronary Syndromes (GEMINI-ACS-1)	Late-Breaking Clinical Trial Saturday, March 18 8:15 - 8:25 a.m. ET Hall D (Main Tent)
1123-283 / 283	Incremental Risk of Ischemic Stroke Over Time in Newly Diagnosed Heart Failure Patients Without Atrial Fibrillation	Poster Presentation Friday, March 17 10:00 - 10:45 a.m. ET Poster Hall, Hall C
1287-194 / 194	Impact of Comorbid Coronary Artery Disease and Severe Peripheral Artery Disease on Major Adverse Cardiovascular Events	Poster Presentation Sunday, March 19 9:45 - 10:30 a.m. ET Poster Hall, Hall C
XARELTO®: Stroke Prevention		
1110-097 / 097	Rates of Oral Anticoagulant Use, While Improving Over Time, Remain Low Among Hospitalized Patients With Atrial Fibrillation	Poster Presentation Friday, March 17 10:00 - 10:45 a.m. ET Poster Hall, Hall C
1189-084 / 084	Real-World Versus Randomized Trial Outcomes in Similar Populations of Rivaroxaban-Treated Patients With Non-Valvular Atrial Fibrillation in ROCKET AF and XANTUS	Poster Presentation Saturday, March 18 9:45 - 10:30 a.m. ET Poster Hall, Hall C

1190-106 / 106	Effectiveness and Safety of Apixaban and Rivaroxaban Versus Warfarin for the Secondary Prevention of Stroke or Systemic Embolism Among Non-Valvular Atrial Fibrillation Patients	Poster Presentation Saturday, March 18 9:45 - 10:30 a.m. ET Poster Hall, Hall C
1189-093 / 093	Thrombolytic Therapy in Anticoagulated Patients: Case Series From Rivaroxaban Versus Warfarin in Non-Valvular Atrial Fibrillation (ROCKET AF)	Poster Presentation Saturday, March 18 9:45 - 10:30 a.m. ET Poster Hall, Hall C
XARELTO®: Discontinuation		
1252-306 / 306	Rivaroxaban Users Have Significantly Less Treatment Discontinuation Compared With Users of Other Oral Anticoagulants in Non-Valvular Atrial Fibrillation	Poster Presentation Saturday, March 18 3:45 - 4:30 p.m. ET Poster Hall, Hall C
Independent Studies/Registries		
1110-098 / 098	Treatment and Outcomes of Patients With Non-Valvular Atrial Fibrillation According to Guideline-Defined Anticoagulation Thresholds: Results From the GARFIELD-AF Registry	Poster Presentation Friday, March 17 10:00 - 10:45 a.m. ET Poster Hall, Hall C
1130-447 / 447	Designing Tailored Health Messaging to Enhance Patient-Centered Care in Non-Valvular Atrial Fibrillation	Poster Presentation Friday, March 17 10:00 - 10:45 a.m. ET Poster Hall, Hall C
1134M-11	Early Mortality in Patients With New Onset Atrial Fibrillation: Results From the GARFIELD-AF Registry	Moderated Poster Presentation Friday, March 17 11:00 - 11:10 a.m. ET Arrhythmias and Clinical EP Moderated Poster Theater, Poster Hall, Hall C
1223M-05	The Prescribing of Antiplatelet Therapy Only in Patients With Non-Valvular Atrial Fibrillation: Results From the GARFIELD-AF Registry	Moderated Poster Presentation Saturday, March 18 12:45 - 12:55 p.m. ET Arrhythmias and Clinical EP Moderated Poster Theater, Poster Hall, Hall C
1280-097 / 097	Nuisance Bleeding in Anticoagulated Patients With Atrial Fibrillation: Insights From the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF)	Poster Presentation Sunday, March 19 9:45 - 10:30 a.m. ET Poster Hall, Hall C
1190-096 / 096	Does Frailty Alter the Benefits of Oral Anticoagulation in Patients With Atrial Fibrillation?	Poster Presentation Saturday, March 18 9:45 - 10:30 a.m. ET Poster Hall, Hall C

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.

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.

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[1] Heit JA, Cohen AT, Anderson FA, Jr. Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US. *Blood* 2005 November 16;106(11):267A (Abstract #910).
[2] Wachira JK, Stys TP. Cardiovascular disease and bridging the diagnostic gap. *S D Med*. 2013;66:366-369.
[3] Benjamin EJ et al on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics—2017 Update: A Report From the American Heart Association. *Circulation 2017; CIR.0000000000000485;* Originally published January 25, 2017