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XARELTO® (rivaroxaban) Significantly Reduced the Risk of Overall Strokes and the Most Severe Strokes and Was Associated with Fewer Stroke-Related Deaths in the Real World Versus Warfarin in Patients with Nonvalvular Atrial Fibrillation

New study uses artificial intelligence to predict stroke severity in patients who suffered from stroke

Study builds on Janssen's commitment to innovation in early detection of atrial fibrillation and stroke prevention

NEW ORLEANS, March 18, 2019 — The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results of a new real-world study, which found newly diagnosed patients with nonvalvular atrial fibrillation (NVAF) taking XARELTO® (rivaroxaban) experienced significantly fewer strokes, significantly fewer severe strokes and fewer stroke-related deaths compared to those taking warfarin. These results were presented today at this year's American College of Cardiology's 68th Annual Scientific Session (ACC.19).

Click to Tweet: New real-world data provides insights on significant advantages in stroke severity and mortality with Janssen's blood thinner in #AFib patients #ACC19 https://ctt.ec/JzHfP+

The study found XARELTO® significantly reduced overall strokes (across all severities) by 18 percent compared to warfarin (p=0.0005) and reduced the risk of experiencing the most severe strokes (NIHSS Score 16-42) by 47 percent (p=0.0059), moderate stroke by five percent (p=0.5178) and minor stroke by 18 percent (p=0.0240). Also, across the entire study population, XARELTO® significantly reduced the risk of post-stroke mortality at 30 days by 59 percent (p<0.0001) and at any time by 22 percent (p=0.0248).

"Stroke caused by atrial fibrillation tends to be more severe, and can result in more irreversible harm, and even death, than stroke from other causes," said Mark Alberts, MD, FAHA, Chief, Neurology, Hartford Hospital, Physician-in-Chief, Ayer Neuroscience Institute, Hartford, CT[1]. "These results show the importance of offering a medicine like rivaroxaban over warfarin to better protect patients with NVAF from strokes across all severities."

In additional to clinical benefit, recent real-world data has demonstrated the economic impact of XARELTO®. Findings recently presented at the 2019 International Stroke Conference (ISC) showed a favorable long-term cost benefit with XARELTO® over warfarin in patients with NVAF. While total cost of care for stroke prevention was similar for both groups, post-stroke cost was 21 percent lower for those taking XARELTO®. Of those who experienced a less severe stroke, total health care costs were 40 percent lower for those taking XARELTO®.

Click to Tweet: New study shows long-term cost savings with Janssen's blood thinner in patients with #AFib https://ctt.ec/2M63R+

"While randomized clinical trials help to establish the efficacy and safety profile of XARELTO®, real-world research complements and confirms how XARELTO® is performing in everyday clinical practice," said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Internal Medicine, Janssen Scientific Affairs, LLC. "We're confident that physicians will consider these findings, along with XARELTO®'s proven once-daily dosing regimen, when treating their patients."

[1] Dr. Mark Alberts received compensation from Janssen for his work on this study.

More than 200,000 people have been evaluated in published real-world research since the approval of XARELTO®, making it the most-studied oral Factor Xa inhibitor in the world today. This study builds on that wide body of research and is another example of Janssen's continued innovation in stroke prevention.

Study background

The study was based on patients from the Optum Clinformatics® Database who initiated treatment within 30 days of their first diagnosis of NVAF between 2011 and 2017 and were tracked from treatment initiation to the end of study, death or stroke diagnosis. For those who experienced a stroke, researchers evaluated the severity of the stroke and 30-day mortality rates post-stroke. The predictive model was based on 127 clinical features and developed using a new artificial intelligence technology to impute National Institutes of Health Stroke Scores (NIHSS) from the administrative database.

After balancing the cohorts, a total of 20,596 patients taking XARELTO® and 20,431 patients taking warfarin were included. Patients must have had a CHA_2DS_2-VASc score of equal or greater than two (indicating moderate to high risk of stroke), no prior stroke and no anticoagulation for at least six months prior to the NVAF diagnosis. Baseline characteristics, including comorbidity index and CHA_2DS_2-VASc scores, were similar between the two groups. Mean follow up was 23 and 29 months for the XARELTO® and warfarin groups, respectively.

Stroke was identified in the hospital inpatient setting using ICD-9/-10 codes[i], and mortality was assessed within 30 days and any time post-stroke. Stroke severity was defined by the National Institutes of Health Stroke Scale (NIHSS), which provides a quantitative measure of stroke-related neurologic deficit. Minor strokes are classified as NIHSS 1-<5, moderate as NIHSS 5-<16 and severe as 16-42.

More on AFib and Stroke

Approximately six million Americans have AFib, which puts them at an increased risk of stroke.[ii] In fact, one in three of these people will have a stroke at some point during their life.[iii] Stroke is a leading cause of serious long-term disability and its economic impact adds $40 billion in U.S. health care costs each year.[iv] Treatment guidelines currently recommend oral anticoagulant therapy in people with NVAF for stroke prevention, which include Factor Xa inhibitors like XARELTO®.

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

XARELTO® is also used with low dose aspirin to:

- reduce the reduce the risk of serious heart problems, heart attack and stroke in patients with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral arterial 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 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 people with artificial heart valves.**

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
- 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. 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 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.
- 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 **15-mg and 20-mg doses,** XARELTO® **should be taken with food.**
    - For the **10-mg dose**, XARELTO® **may be taken with or without food.**
    - Take your XARELTO® doses 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.
  - **Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease or peripheral arterial disease:**
    - Take XARELTO® 2 times a day with or without food.
    - If you miss a dose of XARELTO®, take your next dose at your regularly scheduled time.
- If you have difficulty swallowing the XARELTO® tablet whole, talk to your doctor about other ways to take XARELTO®.
- Your doctor will decide how long you should take XARELTO®**.**
- XARELTO® may need to be stopped, if possible for one or more days before any surgery or medical/dental procedure. If you need to stop taking XARELTO® for any reason, talk to your doctor to find out when you should stop taking it. **Do not stop taking XARELTO® without first talking to the doctor who prescribed it to you.** 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®?

- The most common side effect of XARELTO® was bleeding.
- **See "What is the most important information I should know about XARELTO®?"**

Call your doctor for medical advice about side effects. **You may report side effects to 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.

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 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. Follow us at www.twitter.com/JanssenGlobal. Janssen Pharmaceuticals, Inc., and Janssen Scientific Affairs, LLC, are two 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® (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., 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 30, 2018, 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, 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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[i] Created by World Health Organization (WHO), International Classification of Diseases (ICD) codes are diagnostic codes that represent all aspects of a medical diagnosis and are an essential piece of the medical billing/code process.

[ii] Atrial fibrillation fact sheet. 2011. at https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm. Accessed March 8, 2019.

[iii] StopAfib.org. Stroke Risks from AFib. http://www.stopafib.org/stroke.cfm. Accessed February 20, 2019.

[iv] Benjamin EJ et al on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2018 update: a report from the American Heart Association. *Circulation*. 2018;137:e67–e492.