



NEWS RELEASE

# New Study Shows Reduced Hospital Admissions and Costs for Deep Vein Thrombosis Patients Treated with XARELTO® Compared to Traditional Therapy, With No Difference in Subsequent Hospital Visits

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Findings Add to Existing Research Showing XARELTO® Cost-Savings Value Across Multiple Indications

**National Harbor, MD (March 30, 2015)** - New, real-world data presented today at the Hospital Medicine 2015 congress show patients diagnosed with deep vein thrombosis (DVT) and treated with XARELTO® (rivaroxaban) were admitted to the hospital less frequently than those treated with the standard treatment of low-molecular-weight heparin (LMWH) and warfarin. This reduction in hospital admissions with XARELTO® resulted in significant cost savings with no difference in subsequent hospital visits versus the standard of care.

This observational study included 134 people treated with XARELTO® and 536 patients treated with LMWH and warfarin (prior to the approval of XARELTO®) from the Truven MarketScan Hospital Drug Database. Researchers found:

- A 27 percent reduction in hospital admissions when patients were treated with XARELTO® instead of LMWH and warfarin ( $p < 0.001$ ). Of those given XARELTO®, 60 percent were admitted to the hospital, while 40 percent were discharged within 24 hours. Of the LMWH/warfarin group, 82 percent were admitted to the hospital, with 18 percent discharged within 24 hours.
- Similar rates of subsequent hospital visits were observed during the first six months between the two groups, with a trend toward fewer hospital visits in the XARELTO® group as compared to the LMWH/warfarin group

(4.4 percent vs. 7.2 percent,  $p=0.342$ ).

- Corresponding hospitalization costs were also significantly lower for people given XARELTO® (\$5,257 per person) compared to those given LMWH and warfarin (\$6,764 per person), which resulted in a cost difference of \$1,508 per person ( $p=0.002$ ).

Many of these findings, including hospital admission rates and subsequent hospital visits, were published online this month in **Hospital Practice**.

"This study indicates fewer hospital admissions and less hospital costs for DVT patients treated with rivaroxaban compared to those treated with older therapies, which often require hospitalization for blood monitoring," said Geno Merli, M.D., Professor of Medicine and Surgery, Co-Director of the Jefferson Vascular Center, Thomas Jefferson University Hospital, Philadelphia, PA, and lead author of the study. "As there were similar rates in subsequent hospital visits, it is reasonable for doctors to assess each person presenting with DVT and determine who can be treated with rivaroxaban and safely discharged, and who should be admitted. This is important news for the 700,000 people in the U.S. who experience DVT each year."

It is important to note that the sample size of the rivaroxaban cohort was relatively small, patients were largely from the southern U.S. and were matched based only on information available, which may limit the generalizability of the study findings.

This study adds to existing research demonstrating the value that XARELTO® brings to hospitals, doctors and patients across multiple indications. XARELTO® has been shown to reduce hospital length of stay (LOS), and now hospital admissions, as compared to traditional treatment. This often results in cost savings. Prior research includes:

- DVT/PE: Data from a post-hoc analysis of the EINSTEIN studies published in the **Journal of Medical Economics** show hospitalized patients with DVT or pulmonary embolism (PE) treated with XARELTO® had significantly shorter LOS ( $p=0.0004$ ) compared to those taking the LMWH enoxaparin and warfarin, resulting in a total cost savings of more than \$3,400 per patient. Of note, cost savings in the study were estimated based on average cost per day rather than actual cost reductions due to shorter LOS. In addition, both doctors and patients may demonstrate different behaviors when they are being studied, so results may not reflect real-world practice.
- NVAF: In two separate analyses from the Premier Perspective Comparative Hospital Database published in **Current Medical Research Opinion**, patients with non-valvular atrial fibrillation (NVAF) taking XARELTO® had significantly shorter hospital LOS ( $p<0.001$ ) and significantly lower hospitalization costs ( $p<0.001$ ) compared to those taking warfarin. Of note, hospital data included in the analyses may have possible inaccuracies or omissions in diagnoses due to evaluation of claims, completeness of baseline characteristics, and patients matched based only on information available during hospitalizations occurring at the same hospital.

- Multi-Indication: A cross-indication, economic study published in the **Journal of Medical Economics** found XARELTO® was associated with an overall cost savings of \$1,520 per hospitalized patient, across five of its six approved indications. Of note, the distribution of patients across indications used in the model may not be generalizable to all hospitals, where practice patterns may vary and average LOS cost may not reflect the actual reimbursements that hospitals receive.

"Beyond our clinical and economic research, we are committed to supporting patients as they undergo treatment," said Paul Burton, M.D., Ph.D., Vice President, Medical Affairs, Janssen. "One of the ways we are helping patients is by ensuring that they better understand their dosing regimen during the critical time right after an event, which is why we launched the XARELTO® Starter Pack for use during the first 30 days."

For DVT and PE patients, the XARELTO® Starter Pack is a clearly marked 30-day supply. XARELTO® is dosed twice daily at 15 mg for the first 21 days; on day 22, the dose switches to 20 mg once daily for the remainder of treatment. Launched in October 2014, XARELTO® is the only anticoagulant to offer the first 30 days of treatment in one package, with one prescription.

In the U.S., XARELTO® has the strongest access position of any novel oral anticoagulant. For patients with commercial insurance using a co-pay card, XARELTO® has no cost. It is broadly reimbursed, with 93 percent of patients on Medicare Part D and 95 percent of commercial patients covered at the lowest branded co-pay. XARELTO® has also the lowest average out-of-pocket cost of any novel oral anticoagulant available in the U.S. today.

### **About XARELTO® (rivaroxaban)**

XARELTO® works by blocking the blood clotting Factor Xa. XARELTO® does not require routine blood monitoring. XARELTO® has a broad indication profile and is approved for six indications that include:

To reduce the risk of strokes and blood clots in patients 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.

To treat patients with deep vein thrombosis (DVT).

To treat patients with pulmonary embolism (PE).

To reduce the risk of recurrence of DVT or PE following an initial six-month treatment for acute venous thromboembolism.

To reduce the risk of blood clots in the legs and lungs of patients who have just had knee replacement surgery.

To reduce the risk of blood clots in the legs and lungs of patients who have just had 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®)
- 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™, Eptol®)
- 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®?" above.

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 HealthCare together are developing rivaroxaban.

For more information about XARELTO®, visit **www.xarelto-us.com**. The XARELTO® CarePath™ Support Program is a resource designed for healthcare providers, patients and caregivers. Visit **www.xareltocarepath.com** or call 1-888-XARELTO to learn more about the XARELTO® CarePath™ resources focused on access, education and adherence.

## About Janssen

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Pharmaceuticals, Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit [JanssenPharmaceuticalsInc.com](http://JanssenPharmaceuticalsInc.com) for more information.

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