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New Analysis Shows People with Cancer Who Received XARELTO® (rivaroxaban) for Blood Clots Had Fewer ER Visits and Lower Healthcare Costs than Those Given Standard Treatment

Findings align with the ongoing CALLISTO clinical research program

Economic and real-world research for XARELTO® in cancer-associated thrombosis (CAT) among other studies presented confirming the medicine's safety and efficacy profile

SAN DIEGO (Dec. 6, 2016) — A new analysis shows people with cancer treated with XARELTO® (rivaroxaban) for blood clots had significantly fewer emergency room (ER) visits and lower healthcare costs at initiation of therapy than those given standard treatment. The analysis presented this week by Janssen Pharmaceuticals, Inc. (Janssen) and its development partner, Bayer, at the 2016 American Society of Hematology (ASH) Annual Meeting examines the use of XARELTO® in cancer-associated thrombosis, an area of critical unmet need. Also presented were economic research and real-world evidence confirming the overall safety and efficacy profile of XARELTO® in this patient group.

Blood clots, or venous thromboembolisms (VTE), are the second leading cause of death in people with cancer. The risk of VTE in people with cancer is up to five times higher than in people the same age without cancer, and magnifies in those receiving certain types of chemotherapy. The current standard of care for treating cancer-associated blood clots is low-molecular-weight heparin (LMWH), an injectable anticoagulant.

"Standard therapy for cancer-associated blood clots is burdensome for patients who endure daily

painful injections. It also incurs considerable costs for healthcare systems throughout the entire treatment process," said Gerald A. Soff, MD, Chief, Hematology Service, Memorial Sloan Kettering Cancer Center, New York, NY, and CALLISTO principal investigator. "This study found the majority of people with cancer treated with rivaroxaban did not require an ER visit to initiate therapy, thus sparing costly healthcare resources."

According to the analysis, fewer people had to go to the ER to start treatment with XARELTO® than LMWH, demonstrating significant changes in practice and cost savings. In the first six months of the study, similar rates of people were sent to the ER to start anticoagulation treatment between the XARELTO® and LMWH* groups (71% vs. 63%, respectively). After those six months, there was a significant decrease in people starting treatment with XARELTO® in the ER from 71% at baseline to 42% at one year (p=0.008) and 34% at 18 months (p=0.0001), which researchers attributed to physicians becoming more familiar with XARELTO®. After one year, 18% of people who were prescribed XARELTO® were managed by a simple telephone call, typically after a recent outpatient visit. Researchers also observed significant cost savings for people taking XARELTO®, which was mainly due to the reduction in ER visits.

The start of anticoagulation treatment was classified in one of four ways: an ER visit, a second return outpatient visit on the same day, a single outpatient visit or a telephone communication. Patients whose VTE developed as an inpatient were excluded.

This economic analysis stems from an investigator-initiated study, which followed patients with active cancer who were newly diagnosed with VTE and treated with either XARELTO® or the LMWH enoxaparin. Investigators noted there was no evidence of loss of safety or efficacy in the analysis.

*LMWH data were only collected once in the six months prior to the first XARELTO® period.

Other Economic Cancer-Associated Thrombosis Research

Other economic data presented at ASH found that people newly diagnosed with cancer who experienced a VTE recurrence (17.1% of 2,428 patients) utilized significantly more healthcare resources (defined as ER visits, outpatient visits, hospitalizations and hospital days) than those who did not have a VTE recurrence. Baseline total healthcare costs were similar for both groups.

A companion study found VTE-related healthcare resource utilization was lowest in people with cancer receiving XARELTO® compared to those receiving LMWH or warfarin. Healthcare costs were also lower in the XARELTO® group compared to the LWMH group and similar between the XARELTO®

and warfarin groups. Both studies evaluated claims data from the U.S. Humana database.

“Data presented at this conference and earlier this year support an enhanced role for rivaroxaban in cancer patients, particularly given its value in reducing the burden of care on patients and resources for health systems. Ongoing large randomized trials will aim to further clarify this role and help reduce the public health impact of cancer-associated thrombosis,” said Alok Khorana, MD, FACP, Sondra and Stephen Hardis Chair in Oncology, Vice Chair for Clinical Services, Director of the GI Malignancies Program, Cleveland Clinic, Cleveland, OH. Dr. Khorana is compensated by Janssen for his role as chair of the CALLISTO advisory council and co-chair of the VTE prevention study steering committee.

Additional CAT Research at ASH

In addition to economic research, new real-world studies confirming the safety and efficacy profile of XARELTO® in people with cancer were presented at ASH:

- A subgroup analysis of XALIA, a Phase 4, prospective, non-interventional, observational study, found people with cancer who switched to treatment with XARELTO® for VTE had the lowest rates of all-cause mortality and major bleeding. Highest rates were observed in those taking standard anticoagulation (heparin/fondaparinux and a vitamin K antagonist, or a vitamin K antagonist alone) for major bleeding, and in those taking heparin/fondaparinux for recurrent VTE and all-cause mortality.
- An analysis of Janssen's ongoing post-marketing safety surveillance study (PMSS) for VTE, found the incidence of major bleeding to be relatively low and similar between people with cancer (active or a history of) and those without cancer. More than 10 million electronic medical records from the U.S. Department of Defense Military Health System were queried to evaluate the safety of XARELTO® for the treatment of VTE. This analysis included 9,638 patients with VTE: 17.9% with active cancer, 16.1% with a history of cancer, and 66% with no cancer. PMSS is a retrospective study with no comparator arm.

"These studies presented at ASH may play an important role in reducing the significant economic burden of cancer-associated blood clots,” said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Janssen. “We continue to explore the potential and benefits of XARELTO® as a treatment alternative for patients in this area of critical medical need.”

About CALLISTO and EXPLORER

The CALLISTO research program is the largest and broadest prospective clinical program evaluating a non-vitamin K antagonist oral anticoagulant (NOAC), specifically XARELTO®, for the prevention and treatment of cancer-associated blood clots. CALLISTO, which includes clinical trials and registries in more than 4,000 patients, is evaluating XARELTO® for the prevention and treatment of blood clots in people with a wide range of cancer types. It builds on prior findings from the Phase 3 EINSTEIN clinical program, which was used by regulatory authorities worldwide to approve XARELTO®.

CALLISTO is an integral part of Janssen and Bayer's broader EXPLORER clinical research program for XARELTO®. Unmatched by any oral anticoagulant in the NOAC class in its size, scope and ambition, EXPLORER continues to generate important clinical evidence on the safety and efficacy performance of XARELTO® and its potential role in addressing additional critical medical needs. By the time of its completion, more than 275,000 patients will have participated in EXPLORER, which includes ongoing and completed studies, independent registries and non-interventional studies. The EXPLORER program includes six additional indication-seeking programs underway beyond the currently approved six indications in the U.S.

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 on Twitter at @JanssenUS.

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, including the impact of ongoing clinical research programs and benefits 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 Pharmaceuticals, Inc., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description 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 January 3, 2016, including in Exhibit 99 thereto, 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 or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

#Hashtags

#JanssenCV
#JanssenRWE16
#CALLISTO
#BloodClots
#Thrombosis
#VTE
#RealWorldEvidence
#EXPLORER
#ASH16