NEWS RELEASE

New Clinical Research Program Initiated for the Prevention and Treatment of Life-Threatening Blood Clots in Patients with Cancer

5/28/2015

New Clinical Research Program Initiated for the Prevention and Treatment of Life-Threatening Blood Clots in Patients with Cancer

Raritan, NJ (May 28, 2015) - Janssen Pharmaceuticals, Inc. (Janssen) and its development partner, Bayer HealthCare, today announced the initiation of CALLISTO, a new comprehensive clinical research program for their novel oral anticoagulant, rivaroxaban, in patients with active cancer. The studies are evaluating the medicine for the prevention and treatment of life-threatening blood clots in patients with a wide range of cancer types.

In patients with cancer, the risk of venous thromboembolism (VTE), which is a blood clot in the deep veins or the lungs, is up to five times higher compared to people the same age without cancer, and the risk magnifies in those receiving chemotherapy. The occurrence of VTE may also cause delays in patients receiving critical treatment for their cancer, including surgery or chemotherapy. Blood clots are the second leading cause of death in patients with cancer and preventing their occurrence represents a significant unmet need for patients and their providers.

"Not only are blood clots more severe and widespread in the body of patients with cancer, but their development is also linked to the management of cancer," said Gerald A. Soff, MD, Chief, Hematology Service, Memorial Sloan Kettering Cancer Center, New York, NY, and a principal investigator in CALLISTO. "Though blood clots are largely preventable, current therapy is only approved for the treatment of these clots after they've formed, or to prevent clots in patients who are hospitalized. This means a large number of the one million patients who are treating their cancer outside the hospital each year are at risk of developing blood clots, and reducing their incidence is a high priority in cancer care." Dr. Soff is compensated by Janssen Pharmaceuticals, Inc., for his role as a principal investigator in the clinical research program.

Known as CALLISTO, the new oncology research program is part of Janssen and Bayer HealthCare's broader EXPLORER clinical development program, evaluating patient populations being treated for blood clots or at high risk for developing them. The CALLISTO program will encompass the field of cancer-associated thrombosis (blood clots) through nine studies, including seven clinical trials and two registries across various cancer types, in more than 4,000 patients globally.

The advisory council for the program will be chaired by Alok A. Khorana, MD, FACP, Sondra and Stephen Hardis Chair in Oncology, Vice Chair for Clinical Services, Director of the GI Malignancies Program, Taussig Cancer Institute Cleveland Clinic, Cleveland, OH.

"Cancer-associated thrombosis is a highly prevalent complication of cancer treatments, including chemotherapy, targeted therapy and small molecules. Occurrence of clots can disrupt patient quality of life, affect delivery of cancer treatments and increase the number of hospitalizations and use of healthcare resources," said Dr. Khorana. "Although it may be largely preventable, focused studies in the cancer population using newer, more patient-friendly agents have not yet been conducted. This planned program that will engage cancer researchers nationwide seeks to address this unmet need of cancer patients, and the prevention and treatment of cancer-associated thrombosis." Dr. Khorana is compensated by Janssen Pharmaceuticals, Inc., for his role as chair of the CALLISTO advisory council and
co-chair of the VTE prevention study steering committee.

The research will evaluate rivaroxaban in the following studies:

- Prevention of VTE. A prospective, randomized, double-blind, placebo-controlled trial for the primary prevention of blood clots in adult patients with active cancer who are scheduled to receive therapy to control, slow or eradicate the cancer, such as chemotherapy, in the outpatient setting. Endpoints include incidence of VTE and major bleeding events. The trial will enroll patients at high risk of developing blood clots based on their modified Khorana risk score (a recognized scoring system for predicting blood clots in patients with cancer), and will study patients with solid cancers, including but not limited to the pancreas, lung, stomach, colon, rectum, bladder, breast, kidney and ovary, and those with lymphoma. As one-third of all VTE events are "silent," or asymptomatic, the study will follow patients over a six-month period and use periodic medical imaging to evaluate the occurrence of "silent" clot formation, which will help identify when these events are happening.
- Treatment of VTE.
    - Three studies comparing rivaroxaban to the low-molecular-weight heparin (LMWH) dalteparin, the current standard of care, for the treatment of blood clots in patients with active cancer. Endpoints include incidence of recurrent events and major bleeding. The studies will enroll patients with various

cancer types, and will include two randomized studies and one quality of care improvement analysis.
    - Two observational registries, one in the U.S. and one outside the U.S., will follow various outcomes of cancer patients with blood clots who are treated with an anticoagulant to better understand the treatment of VTE and the prevention of recurrent events in this patient population. A sub-study will assess the treatment of blood clots specifically in patients with cancer who must undergo surgical procedures.
- Relevant Clinical Aspects. Three additional studies will focus on important clinical aspects, such as concomitant use of rivaroxaban with standard cancer therapies, like chemotherapy, and assessment of a bridging strategy for patients taking rivaroxaban or LMWH in instances where chemotherapy-induced vomiting makes oral therapies challenging.

"CALLISTO is unlike any other initiative for cancer-associated blood clots in its scope, size and ambition," said Paul Burton, MD, PhD, Vice President, Medical Affairs, Janssen. "The program will harness our deep experience in oncology and thrombosis so that we can better assess how to reduce the burden of blood clots in patients with cancer, while also improving our understanding of how rivaroxaban may be used in the context of complex cancer treatment strategies.

"Through CALLISTO, part of our broader EXPLORER program which includes six additional indication-seeking studies underway in collaboration with Bayer HealthCare, we are striving to uncover the full potential of our medicine in making a difference for patients with critical medical needs," he continued.

The EXPLORER program is evaluating patients with chronic heart failure, coronary artery disease, peripheral artery disease, acute coronary syndrome, embolic stroke of undetermined source and now, active cancer. By the time of its completion, more than 275,000 patients will have participated in the clinical development program, other completed and ongoing clinical trials, investigative registries, and non-interventional studies.

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment. Please visit oncology.janssenrnd.com for additional information.

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™, 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®?" 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** for more information.

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. 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. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product 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 December 28, 2014, 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.

Media Contacts:

Kristina Chang
Tel: (908) 927-2416
Mobile: (201) 213-4115
kchang12@its.jnj.com

Christina Chan
Tel: (908) 927-5769
Mobile: (908) 635-2406
cchan20@its.jnj.com

Investor Relations Contacts:

Johnson & Johnson
Louise Mehrotra
Tel: (732) 524-6491

Johnson & Johnson
Lesley Fishman
Tel: (732) 524-3922