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Janssen Highlights Continued Commitment to Cardiovascular & Metabolic Healthcare Solutions with Late-Breaking Data at the First Fully Virtual American College of Cardiology Scientific Session

Highlights include four late-breaking XARELTO® (rivaroxaban) abstracts

Four INVOKANA® (canagliflozin) abstracts from the pivotal CREDENCE study will also be presented

RARITAN, N.J., March 20, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that it will unveil late-breaking data from its leading cardiovascular and metabolism portfolio during the virtual American College of Cardiology’s 69th Annual Scientific Session together with the World Congress of Cardiology (ACC.20/WCC) on March 28-30, 2020. Notably, four late-breaking abstracts for XARELTO® (rivaroxaban) will be presented, including data from the Phase 3 VOYAGER PAD study in patients with symptomatic peripheral artery disease (PAD) after lower-extremity revascularization.

[Click to Tweet: Janssen highlights continued commitment to #cardiovascular and metabolic healthcare solutions with late-breaking research at the first fully virtual #ACC20/#WCCardio http://bit.ly/3ddwFNr](http://bit.ly/3ddwFNr)

“The depth of our research at ACC this year is a testament to how our medicines help improve care for people living with cardiovascular diseases, type 2 diabetes and diabetic kidney disease,” said James List, M.D., Ph.D., Global Therapeutic Area Head, Cardiovascular & Metabolism, Janssen Research & Development, LLC. “We look forward to sharing the latest evidence from our portfolio that we believe will continue to help shape clinical practice.”

Janssen’s cardiovascular and metabolism franchise includes XARELTO[®], a direct oral anticoagulant (DOAC) with eight indications – the most of any DOAC in the class – and INVOKANA[®] (canagliflozin), the only type 2 diabetes (T2D) medicine proven to slow the progression of diabetic nephropathy, also known as diabetic kidney disease (DKD), and reduce the risk of hospitalization for heart failure in patients with T2D and DKD with albuminuria >300 mg/day.

Highlights from the Janssen cardiovascular and metabolism portfolio to be presented during ACC.20/WCC include:

Cardiovascular:

- **VOYAGER PAD (main results and subgroup analysis):** The first Phase 3 randomized study to evaluate a dual pathway approach with XARELTO[®] (2.5 mg twice daily) plus aspirin (100 mg once daily) for reducing the risk of major adverse limb and cardiovascular (CV) events in patients with symptomatic PAD undergoing lower-extremity revascularization (a procedure to improve blood flow in the legs). A prespecified subgroup analysis that evaluated outcomes in patients who received clopidogrel will also be presented.
- **COMPASS (diabetes analysis):** A prespecified subgroup analysis from the COMPASS study evaluated the benefit of XARELTO[®] (2.5 mg twice daily) plus aspirin (100 mg once daily) in patients with stable coronary artery disease (CAD) and/or PAD with T2D versus those without T2D. Primary results from [COMPASS](#) showed that the dual pathway approach of XARELTO[®] plus aspirin

significantly reduced the risk of major CV events in patients with chronic PAD and/or CAD compared to aspirin alone.

- **PRONOMOS:** This randomized study evaluated the use of XARELTO® in preventing venous thromboembolism (VTE), or blood clots, in patients after undergoing non-major orthopedic surgery.

Metabolism:

- **CREDESCENCE:** Four new analyses from the CREDESCENCE study in T2D and DKD examined the effect of INVOKANA® on specific patient subgroups. Primary endpoint results from [CREDESCENCE](#) showed INVOKANA® significantly reduced the composite risk of end-stage kidney disease (ESKD), doubling of serum creatinine and renal or CV death in patients with DKD and T2D, and also reduced the risk of hospitalization for heart failure.

Following is a full list of abstracts for XARELTO® and INVOKANA® to be presented during ACC.20/WCC:

Abstract No.	Title	Date/Time
XARELTO®: Late-Breaking Presentations		
402-10	Rivaroxaban for Prevention of Cardiovascular and Limb Events after Lower Extremity Revascularization: Primary Results of the VOYAGER PAD Randomized Trial	March 28 9:20 – 9:32 am CT
403-14	The Role of Combination Antiplatelet and Anticoagulation Therapy in Diabetes and Cardiovascular Disease: Insights from the COMPASS Trial	March 28 10:45 – 10:55 am CT
406-11	Rivaroxaban versus Enoxaparin in Nonmajor Orthopedic Surgery (PRONOMOS)	March 29 11:00 – 11:10 am CT
406-13	The Benefit and Risk of Rivaroxaban Plus Aspirin in Patients with Peripheral Artery Disease after Lower Extremity Revascularization (LER) with and without Concomitant Clopidogrel: A Key Subgroup Analysis from VOYAGER PAD	March 29 11:15 – 11:25 am CT
XARELTO®: Stroke Prevention		
1167-228	Rivaroxaban versus Warfarin in African American Patients with Nonvalvular Atrial Fibrillation	March 28 12:30 – 1:15 pm CT
XARELTO®: Vascular Protection		
1313-087	Temporal Changes in Secondary Prevention and Cardiovascular Outcomes after	March 29 12:30 – 1:15 pm CT

	Revascularization for Peripheral Arterial Disease in Denmark: Nationwide Cohort Study	
INVOKANA®: Poster Presentations		
1027-05	The Effects of Canagliflozin on Heart Failure and Cardiovascular Death by Baseline Participant Characteristics: Analysis of the CREDENCE Trial	March 28 4:00 – 4:10 pm CT
1054-05	Effects of Canagliflozin on Cardiovascular, Renal and Safety Outcomes by Baseline Loop Diuretic Use: Data from the CREDENCE Trial	March 29 12:45 – 12:55 pm CT
1422-145	Effects of Canagliflozin on Stroke in the CREDENCE Trial	March 30 9:45 – 10:30 am CT
1422-162	Effects of SGLT2 Inhibitors on Stroke in Type 2 Diabetes According to Baseline Kidney Function	March 30 9:45 – 10:30 am CT
1415-72	Canagliflozin (CANA) Reduces Cardiovascular (CV) and Renal Events Independent of Baseline Heart Failure (HF): A CREDENCE Secondary Analysis	March 30 9:45 – 10:30 am CT

WHAT IS XARELTO® (rivaroxaban)?

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
- help prevent blood clots in certain people hospitalized for an acute illness and after discharge, who are at risk of getting blood clots because of the loss of or decreased ability to move around (mobility) and other risks for getting blood clots, and who do not have a high risk of bleeding

XARELTO® is used with low dose aspirin to:

- reduce the risk of serious heart problems, heart attack and stroke in people with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral artery 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 be at higher risk of bleeding if you take XARELTO® and have certain other medical problems.

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 use in people with artificial heart valves.

XARELTO® is not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing.

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
- Have antiphospholipid syndrome (APS)

- 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. Talk to your doctor about the best way to feed your baby during treatment with XARELTO®.

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.
- Your doctor will decide how long you should take XARELTO®.
- XARELTO® may need to be stopped for one or more days before any surgery or medical or dental procedure. Your doctor will tell you when to stop taking XARELTO® and when to start taking XARELTO® again after your surgery or procedure.
- If you need to stop taking XARELTO® for any reason, talk to the doctor who prescribed XARELTO® to you to find out when you should stop taking it. Do not stop taking XARELTO® without first talking to the doctor who prescribes it to you.
- If you have difficulty swallowing XARELTO® tablets whole, talk to your doctor about other ways to take XARELTO®.
- Do not run out of XARELTO®. Refill your prescription of XARELTO® before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will 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.

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 **10-mg dose**, XARELTO® **may be taken with or without food.**
 - For the **15-mg and 20-mg doses**, take XARELTO® **with food 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.
- **Blood clots in people hospitalized for an acute illness:**
 - Take XARELTO® 1 time a day, with or without food, while you are in the hospital and after you are discharged as prescribed by your doctor.
 - 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 artery disease:**
 - Take XARELTO® 2.5 mg 2 times a day with or without food.
 - If you miss a dose of XARELTO®, take your next dose at your regularly scheduled time.
 - Take aspirin 75 to 100 mg once daily as instructed by your doctor.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF XARELTO®?

XARELTO® may cause serious side effects:

- See **“What is the most important information I should know about XARELTO®?”**

The most common side effect of XARELTO® was bleeding.

Call your doctor for medical advice about side effects. **You may report side effects to the 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 read full [Prescribing Information](#), including **Boxed Warnings**, and [Medication Guide](#) for XARELTO®.

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WHAT IS INVOKANA®?

INVOKANA® is a prescription medicine used:

- along with diet and exercise to lower blood sugar (glucose) in adults with type 2 diabetes
- to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes who have known cardiovascular disease
- to reduce the risk of end-stage kidney disease (ESKD), worsening of kidney function, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic kidney disease (nephropathy) with a certain amount of protein in the urine

INVOKANA® is not for people with type 1 diabetes or with diabetic ketoacidosis (increased ketones in blood or urine). It is not known if INVOKANA® is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

INVOKANA® can cause important side effects, including:

- **Amputations.** INVOKANA® may increase your risk of lower-limb amputations. Amputations mainly involve removal of the toe or part of the foot; however, amputations involving the leg, below and above the knee, have also occurred. Some people had more than one amputation, some on both sides of the body. You may be at a higher risk of lower-limb amputation if you: have a history of amputation, have heart disease or are at risk for heart disease, have had blocked or narrowed blood vessels (usually in leg), have damage to the nerves (neuropathy) in the leg, or have had diabetic foot ulcers or sores. **Call your doctor right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot.** Your doctor may decide to stop your INVOKANA® for a while if you have any of these signs or symptoms. Talk to your doctor about proper foot care
- **Dehydration.** INVOKANA® can cause some people to become dehydrated (the loss of too much body water), which may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). You may be at higher risk of dehydration if you have low blood pressure, take medicines to lower your blood pressure (including diuretics [water

pills]), are on a low sodium (salt) diet, have kidney problems, or are 65 years of age or older. Talk to your doctor about what you can do to prevent dehydration including how much fluid you should drink on a daily basis

- **Vaginal yeast infection.** Women who take INVOKANA® may get vaginal yeast infections. Symptoms include: vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), or vaginal itching
- **Yeast infection of the penis (balanitis or balanoposthitis).** Men who take INVOKANA® may get a yeast infection of the skin around the penis. Symptoms include: redness, itching, or swelling of the penis; rash of the penis; foul-smelling discharge from the penis; or pain in the skin around penis

Talk to your doctor about what to do if you get symptoms of a yeast infection of the vagina or penis.

Do not take INVOKANA® if you:

- are allergic to canagliflozin or any of the ingredients in INVOKANA®. Symptoms of allergic reaction may include: rash; raised red patches on your skin (hives); or swelling of the face, lips, mouth, tongue, and throat that may cause difficulty in breathing or swallowing
- have severe kidney problems and are taking INVOKANA® to lower your blood sugar
- are on kidney dialysis

Before you take INVOKANA®, tell your doctor if you have a history of amputation; heart disease or are at risk for heart disease; blocked or narrowed blood vessels (usually in leg); damage to the nerves (neuropathy) of your leg; diabetic foot ulcers or sores; kidney problems; liver problems; history of urinary tract infections or problems with urination; are on a low sodium (salt) diet; are going to have surgery (your doctor may stop your INVOKANA® before you have surgery; talk to your doctor if you are having surgery about when to stop taking INVOKANA® and when to start it again); are eating less, or there is a change in diet; pancreas problems; drink alcohol very often (or drink a lot of alcohol in short-term); ever had an allergic reaction to INVOKANA®; or have other medical conditions.

Tell your doctor if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed. INVOKANA® may harm your unborn baby. If you become pregnant while taking INVOKANA®, tell your doctor right away. INVOKANA® may pass into your breast milk and may harm your baby. Do not breastfeed while taking INVOKANA®.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take diuretics (water pills), rifampin (used to treat or prevent tuberculosis), phenytoin or phenobarbital (used to control seizures), ritonavir (Norvir®, Kaletra® – used to treat HIV infection), or digoxin (Lanoxin®– used to treat heart problems).

Possible Side Effects of INVOKANA®

INVOKANA® may cause serious side effects, including:

- **Ketoacidosis** (increased ketones in your blood or urine). **Ketoacidosis has happened in people who have type 1 or type 2 diabetes**, during treatment with INVOKANA®. Ketoacidosis has also happened in people with diabetes who were sick or who had surgery during treatment with INVOKANA®. Ketoacidosis is a serious condition, which may need to be treated in a hospital. Ketoacidosis may lead to death. **Ketoacidosis can happen with INVOKANA® even if your blood sugar is less than 250 mg/dL. Stop taking INVOKANA® and call your doctor right away if you get any of the following symptoms: nausea, vomiting, stomach-area pain, tiredness, or trouble breathing**
- **Kidney problems.** Sudden kidney injury has happened to people taking INVOKANA®. Talk to your doctor right away if you: 1) reduce the amount of food or liquid you drink, if you are sick, or cannot eat or 2) you start to lose liquids from your body from vomiting, diarrhea, or being in the sun too long
- **Serious Urinary Tract Infections:** may lead to hospitalization and have happened in people taking INVOKANA®. Tell your doctor if you have signs or symptoms of a urinary tract infection such as: burning feeling while urinating, need to urinate often or right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Some people may also have high fever, back pain, nausea, or vomiting
- **Low blood sugar (hypoglycemia).** If you take INVOKANA® with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take INVOKANA®. Signs and symptoms of low blood sugar may include: headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, shaking, or feeling jittery
- **A rare but serious bacterial infection that destroys the tissue under the skin (necrotizing fasciitis) in the area between and around the anus and genitals (perineum).** Necrotizing fasciitis of the perineum has happened in women and men who take INVOKANA®. Necrotizing fasciitis of the perineum may lead to hospitalization, may require multiple surgeries, and may lead to death. **Seek medical attention immediately if you have fever or you are feeling very weak, tired, or uncomfortable (malaise) and you develop any of the following symptoms in the area between and around your anus and genitals:** pain or tenderness, swelling, or redness of the skin (erythema)
- **Serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking INVOKANA® and call your doctor right away or go to the nearest hospital emergency room
- **Broken Bones (fractures):** Bone fractures have been seen in patients taking INVOKANA®. Talk to your doctor about factors that may increase your risk of bone fracture

The most common side effects of INVOKANA® include: vaginal yeast infections and yeast infections of the penis; changes in urination, including urgent need to urinate more often, in larger amounts, or at night.

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 may report side effects to FDA at 1-800-FDA-1088.** You may also report side effects to Janssen Scientific Affairs, LLC at 1-800-526-7736.

Please read the full [Prescribing Information](#), including Boxed Warning, and Medication Guide for INVOKANA®.

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About Janssen Cardiovascular & Metabolism

In Cardiovascular & Metabolism (CVM), we take on the most pervasive diseases that burden hundreds of millions of people and healthcare systems around the world. As part of this long-standing commitment and propelled by our successes in treating type 2 diabetes (T2D) and thrombosis, we advance highly differentiated therapies that prevent and treat life-threatening cardiovascular and metabolic diseases.

Uncovering new therapies that can improve the quality of life for this large segment of the population is an important endeavor – one which Janssen CVM will continue to lead in the years to come. Our mission is global, and local and personal. Together, we can reshape the future of cardiovascular and metabolic disease prevention and treatment. Please visit www.janssen.com/cardiovascular-and-metabolism.

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 Research & Development, LLC, is part 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 rivaroxaban and canagliflozin. 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 Research & Development, LLC, 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 29, 2019, 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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