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New Late-Breaking XARELTO® (rivaroxaban) and INVOKANA® (canagliflozin) Data to be Presented at the American College of Cardiology's Annual Scientific Session

- *New analysis from COMPASS examines the use of XARELTO® plus aspirin in reducing major adverse limb events in patients with peripheral artery disease*
- *New CANVAS Program data assess the impact of INVOKANA® on heart failure in patients with T2D with an elevated risk of cardiovascular disease*
- *Janssen leads in cardiovascular innovation using real-world data from wearable electrocardiogram sensors to detect asymptomatic atrial fibrillation*

TITUSVILLE, NJ (February 26, 2018) – New studies and late-breaking analyses from the Janssen Pharmaceutical Companies of Johnson & Johnson are among the 11 company abstracts accepted for presentation at the American College of Cardiology's 67th Annual Scientific Session (ACC.18) taking place March 10-12, 2018, in Orlando, FL. Late-breaking data include results from the CANVAS program for INVOKANA® (canagliflozin) in type 2 diabetes (T2D), an analysis from COMPASS

for XARELTO® (rivaroxaban) in peripheral artery disease (PAD), and one-year results from the mHealth Screening To Prevent Strokes (mSToPS) study, examining the use of wearable electrocardiogram (ECG) sensor technology in detecting atrial fibrillation (AFib).

[Click to Tweet: Impressive #ACC18 lineup includes groundbreaking research in #Diabetes, #PAD and #AFib https://ctt.ec/cPv98+](https://ctt.ec/cPv98+)

"We look forward to presenting a strong line-up of potentially practice-changing, clinical and real-world data," said JoAnne Foody, MD, FACC, FAHA, Cardiovascular Therapeutic Area Head, Janssen Pharmaceuticals, Inc. "Our research at this year's ACC underscores our commitment to making a difference in the lives of millions of people impacted by cardiovascular and metabolic conditions."

[Click to Tweet: New late-breaking COMPASS, mSToPS and CANVAS data to be unveiled at #ACC18 #PAD #Diabetes #AFib https://ctt.ec/Z84Vx+](https://ctt.ec/Z84Vx+)

New analyses from the landmark CANVAS Program, assessing the effect of INVOKANA® on the risk of cardiovascular death or hospitalized heart failure in patients with T2D with and without a history of heart failure, will be featured at ACC.18 as part of the Interventional Clinical Research II late-breaking program. The data from the integrated analysis of the CANVAS and CANVAS-R trials were presented last year in a special symposium at the [2017 American Diabetes Association Scientific Sessions](#), and simultaneously published in [The New England Journal of Medicine](#). Diabetes is a major risk factor for cardiovascular disease; according to the American Heart Association, adults with diabetes are two to four times more likely to die from heart disease than adults without diabetes.ⁱ

A sub-analysis of the landmark COMPASS analysis, published in [The New England Journal of Medicine](#) and presented at the [2017 ESC Congress](#), will provide late-breaking data on the use of XARELTO® in the reduction of major adverse limb events in patients with PAD. PAD affects one in every 20 Americans over the age of

50 and occurs when fatty deposits build up in arteries in the legs and feet, restricting circulation and increasing the risk for heart attack, stroke and amputation.

Also being presented at ACC.18 are results from mSToPS, an innovative home-based clinical study evaluating the use of wearable continuous ECG sensor technology in identifying people with undiagnosed AFib. It is a novel collaboration between the Scripps Translational Science Institute (STSI), Aetna and Janssen. AFib is the most common sustained arrhythmia in the adult U.S. population and is associated with an increased risk for stroke. In fact, one in three people with AFib will experience a stroke during their lifetime and one in four experience heart failure. When AFib is diagnosed, appropriate anticoagulant treatments can be initiated to reduce the risk of stroke; however, because many people are asymptomatic or have atypical symptoms, up to 30 percent of all AFib cases go undiagnosed.

Following is a full list of company-sponsored abstracts to be presented at ACC.18:

Abstract No.	Title	Date/Time/Location
INVOKANA® (canagliflozin)		
Late-Breaking Clinical Trial		
407-10	Canagliflozin for Prevention of Heart Failure in Type 2 Diabetes: Results from the CANVAS Program	March 11, 2018 5:00 - 5:10 p.m. ET Room 202 C
XARELTO® (rivaroxaban)		
Late-Breaking Clinical Trials		
402-19	A Digital End-to-End, Nationwide, Pragmatic Trial of Screening for Undiagnosed Atrial Fibrillation Within a Health Insurance System Using a Self-Applied ECG Patch: Primary Results of the mHealth Screening to Prevent Strokes (mSToPS) Trial	March 10, 2018 1:30 - 1:40 p.m. ET Room 311 E
407-16	High Mortality after Major Adverse Limb Events in Peripheral Artery Disease: Results from the COMPASS trial	March 11, 2018 5:45 - 5:55 p.m. ET Room 202 C

Moderated Poster/Poster Contributions		
1133M-07	Provider- and Hospital-Level Variation in Oral Anticoagulant Use For Stroke Prevention in Atrial Fibrillation	March 10, 2018 10:30 - 10:40 a.m. ET Arrhythmias and Clinical EP Moderated Poster Theater, Poster Hall A/B
1172-480	Incidence and Cost of Major Cardiovascular Events among Patients with Chronic Coronary Artery Disease or Peripheral Artery Disease Identified in a Large United States Healthcare Database	March 10, 2018 3:45 - 4:30 p.m. ET Poster Hall A/B
1216M-05	Effectiveness and Safety of Apixaban, Dabigatran and Rivaroxaban versus Warfarin in Frail Patients with Nonvalvular Atrial Fibrillation	March 11, 2018 10:00 - 10:10 a.m. ET Arrhythmias and Clinical EP Moderated Poster Theater, Poster Hall A/B
1245-262	Outcomes of Cardiac Cath/PCI in Patients With AF: Insights from the ORBIT II Registry	March 11, 2018 3:45 - 4:30 p.m. ET Poster Hall A/B
1275-011	Readmissions for Major Bleeding or Falls Are Uncommon in an Unselected Population of Patients Hospitalized with Atrial Fibrillation	March 12, 2018 9:45 - 10:30 a.m. ET Poster Hall A/B
1276-025	Association between Elevated B-Type Natriuretic Peptide, Disease Progression, and Clinical Outcomes among Patients with Atrial Fibrillation	March 12, 2018 9:45 - 10:30 a.m. ET Poster Hall A/B
1293-324	Prospective Randomized Trial of Rivaroxaban versus Warfarin in the Evaluation of Progression of Coronary Artery Calcification	March 12, 2018 9:45 - 10:30 a.m. ET Poster Hall A/B
1303-415	Initial Stroke Severity Is a Crucial Predictor for Hemorrhagic Stroke- and Ischemic Stroke-Related Mortality	March 12, 2018 9:45 - 10:30 a.m. ET Poster Hall A/B

WHAT IS INVOKANA®?

INVOKANA® (canagliflozin) is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. 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® (canagliflozin) 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
- **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, tongue, and throat that may cause difficulty in breathing or swallowing
- have severe kidney problems or are on 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; are eating less due to illness, surgery, or 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 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
- **A high amount of potassium in your blood (hyperkalemia)**
- **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.

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 see full [Product Information](#), including Boxed Warning, and [Medication Guide](#) for INVOKANA®.

WHAT IS XARELTO®?

XARELTO® (rivaroxaban) 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 (DVT) and pulmonary embolism (PE), and to 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.

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® (rivaroxaban)?

- **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 (anticoagulant) 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 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 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. 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:**
 - 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® dose(s) 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.
- 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®.
- 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®?

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

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.

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

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](https://twitter.com/JanssenUS). Janssen Pharmaceuticals, Inc. 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 product development and the presentation of new clinical data and analyses regarding XARELTO® (rivaroxaban) and INVOKANA® (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 any of the 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 31, 2017, including in the sections captioned "Item 1A. Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements," 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. Neither 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 American Heart Association. Cardiovascular Disease & Diabetes.
http://www.heart.org/HEARTORG/Conditions/More/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes_UCM_313865_Article.jsp/#.WocpNKjwbIU. Accessed February 2018.