New Late-Breaking Data on the Use of Type 2 Diabetes Treatment INVOKANA® (canagliflozin) in the Real World Will Be Presented at the American Diabetes Association’s 78th Annual Scientific Sessions

Featured Data Includes Findings From OBSERVE-4D – the Largest Real-World Study to Evaluate the Risk of Lower Extremity Amputation and Hospitalization for Heart Failure

Several Comparative Studies Between INVOKANA® and Other Diabetes Medications, Including Glucagon-Like Peptide-1 Receptor Agonists (GLP-1s), Will Also Be Presented

TITUSVILLE, NJ, June 8, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that a new late-breaking analysis (OBSERVE-4D) examining how INVOKANA® (canagliflozin) and other type 2 diabetes (T2D) therapies are being used by U.S. patients is among the 15 company abstracts accepted for oral and poster presentations at the American Diabetes Association’s (ADA) 78th Annual Scientific Sessions from June 22-26, 2018, in Orlando, FL.

OBSERVE-4D is the largest, most comprehensive, retrospective real-world observational study to evaluate the risk of lower extremity amputation and hospitalization for heart failure (HHF) with INVOKANA® and other T2D medications. This study compared the effects of INVOKANA® with other sodium glucose cotransporter 2 inhibitor (SGLT2i) therapies, and non-SGLT2is across a broad U.S. T2D population of more than 700,000
patients. Until this year’s ADA meeting, no real-world study has shown direct head-to-head comparative evidence among individual SGLT2i medicines.

**Click to Tweet:** First read-out of new real-world type 2 diabetes data to be unveiled at #ADA2018, including late-breaking analysis of more than 700K U.S. patients [https://ctt.ac/YpUo2+](https://ctt.ac/YpUo2+)

“The breadth of this year’s accepted data demonstrates our deep commitment to help address the needs of a broad range of type 2 diabetes patients, including those physicians routinely see in clinical practice,” said Paul Burton, M.D., Ph.D., Vice President, Janssen Scientific Affairs, LLC. “We look forward to sharing our extensive clinical and real-world INVOKANA® data at the upcoming ADA Scientific Sessions.”

In addition to several comparative studies between INVOKANA® and other diabetes medications, including GLP-1s and sitagliptin, Janssen will also share six new analyses of data from the landmark CANVAS Program (CANagliflozin cardioVascular Assessment Study) in people with type 2 diabetes evaluating:

- Overall long-term safety
- Cardiovascular and renal-related outcomes in patient groups based on body mass index (obese vs. non-obese), level of blood glucose control (A1C levels), and global geographic regions
- CV outcomes in patient groups based on kidney function levels

**Notable INVOKANA® data accepted at ADA include:**

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<tr>
<th>Abstract No.</th>
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<td><strong>Late-Breaking Findings</strong>&lt;br&gt;This study is embargoed until <strong>Sunday, June 24, 2018 at 10:15 am ET.</strong></td>
<td>4-LB Canagliflozin vs. Other Antihyperglycemic Agents on the Risk of Below-Knee Amputation for Patients with T2DM--A Real-World Analysis of &gt;700,000 U.S. Patients (OBSERVE-4D)</td>
<td>Moderated session: Jun 24, 2018 12:00-1:00 pm ET</td>
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<td><strong>Oral Presentations</strong>&lt;br&gt;These data are embargoed until <strong>Monday, June 25, 2018 at 8:00 am ET.</strong></td>
<td>258-OR Canagliflozin and Cardiovascular (CV) Outcomes in Patients with Chronic Kidney Disease</td>
<td>June 25, 2018 9:00 am ET</td>
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<td>259-OR Overall Safety of Canagliflozin (CANA) in the CANagliflozin cardioVascular Assessment Study (CANVAS) Program</td>
<td>June 25, 2018 9:15 am ET</td>
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<td><strong>This study is embargoed until Saturday, June 23, 2018 at 8:00 am ET.</strong></td>
<td>109-OR Effect of Combination Therapy With Liraglutide Plus Canagliflozin on HGP and HbA1c versus Each Therapy Alone in T2DM</td>
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<td><strong>Poster Presentations</strong>&lt;br&gt;These data are embargoed until <strong>Saturday, June 23, 2018 at 10:00 am ET.</strong></td>
<td>1191-P Relatively Consistent Effects of Canagliflozin</td>
<td>June 24, 2018</td>
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<td>1193-P</td>
<td>Consistent Outcomes With Canagliflozin (CANA) in Patients With Type 2 Diabetes Across Geographic Regions: Results from the CANagliflozin cardioVascular Assessment Study (CANVAS) Program</td>
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<td>1206-P</td>
<td>Improved Cardiovascular and Renal Outcomes in the CANagliflozin cardioVascular Assessment Study (CANVAS) Program Irrespective of Baseline (BL) Body Mass Index (BMI)</td>
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<td>1210-P</td>
<td>Improvements in Blood Pressure (BP) and Markers of Arterial Stiffness With Canagliflozin (CANA) in the CANagliflozin cardioVascular Assessment Study (CANVAS) Program</td>
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<td>1126-P</td>
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<td>1272-P</td>
<td>Assessing the Value of Canagliflozin (CANA) versus Sitagliptin (SITA) as 2nd Line Therapy in the US: The Importance of Considering Evidence from the CANVAS Program</td>
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<td>1291-P</td>
<td>Body Weight (BW) Outcomes With Canagliflozin 300 mg (CANA) vs Glucagon-like Peptide-1 Receptor Agonists (GLP-1s) in a Real-world (RW) Setting</td>
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<td>1287-P</td>
<td>Real-World Comparative Effectiveness, Treatment Patterns, and Costs in Type 2 Diabetes Mellitus (T2DM) Patients Initiated on Canagliflozin 300 mg (CANA) or a Glucagon-like Peptide-1 Receptor Agonist (GLP-1)</td>
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<td>Real-world Impact of HbA1c Reduction on Treatment Intensification and HbA1c Goal Attainment in T2DM Patients Initiated on SGLT2i</td>
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<td>1184-P</td>
<td>CANadian CANagliflozin REgistry (CanCARE) – A Prospective, Observational, Assessment of Canagliflozin (CANA) Treatment in Type 2 Diabetes Mellitus (T2DM); 12 Month Results</td>
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<td>821-P</td>
<td>Relationship Between Weight Change</td>
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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. The recommended starting dose is 100 mg once daily, taken before the first meal of the day. The dose can be increased to 300 mg once daily in patients tolerating INVOKANA® 100 mg once daily who have an eGFR of 60 mL/min/1.73 m² or greater and require additional glycemic control.

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®.

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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. Janssen Pharmaceuticals, Inc. and Janssen Scientific Affairs, LLC are 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 the potential benefits and further development of 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 Pharmaceuticals, Inc., 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 31, 2017, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in the company’s subsequent Quarterly Reports on Form 10-Q, and other 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.