Janssen Expands Body of Evidence for INVOKANA® (canagliflozin) with 18 New Data Presentations at American Diabetes Association’s 76th Scientific Sessions®

Comparative Analyses with DPP-4 Inhibitors, Including Sitagliptin, and Findings on Use in Weight Management and Type 1 Diabetes Underscore Janssen Commitment to Improving Diabetes Management


RARITAN, N.J., June 6, 2016 – Janssen Research & Development, LLC (Janssen), today announced that 18 presentations on INVOKANA® (canagliflozin) will be featured at the American Diabetes Association’s (ADA) 76th Scientific Sessions®, June 10-14 in New Orleans. Presentation topics include:

- Clinical trial and real-world findings on efficacy and persistence with INVOKANA® 100 mg and 300 mg compared to DPP-4 inhibitors
- Real-world data, including a post hoc analysis of blood pressure effects of INVOKANA® in patients with type 2 diabetes; patient-reported outcomes; and cost-effectiveness evaluations
- Glycemic control with INVOKANA® in patients with type 1 diabetes
- Late-breaking findings, including the effects of INVOKANA® in combination with phentermine on weight management in overweight and obese adults without type 2 diabetes

"We look forward to sharing these robust scientific findings with healthcare providers and researchers at the American Diabetes Association’s Scientific Sessions," said Paul Burton, M.D., Ph.D., Vice President, Medical Affairs, Janssen. “These studies and analyses build on the efficacy and safety findings from the pivotal trials that informed the approval of INVOKANA® for the treatment of type 2 diabetes and further
our efforts to assess its potential benefits in patient populations who may benefit from this important medicine."

INVOKANA® is used along with diet and exercise to lower blood glucose in adults with type 2 diabetes. INVOKANA® is the number-one prescribed treatment in the newest class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors, which work with the kidneys to lower A1C. INVOKANA® is not indicated for weight loss or as antihypertensive treatment.

The abstracts for INVOKANA® data accepted for presentation at the American Diabetes Association’s 76th Scientific Sessions are as follows:

**Saturday, June 11, 2016**

**Clinical Data**

*Oral Abstract Session: 8:00-10:00 a.m.*

- Canagliflozin (CANA) Slows Progression of Renal Function Decline Independent of Glycemic Effects (Presentation 70-OR)

*Moderated Poster Discussion: 12:30-1:30 p.m.*

- Canagliflozin (CANA) Improves Risk Factors of Metabolic Syndrome (MetS) Versus Sitagliptin (SITA) in Patients With Type 2 Diabetes Mellitus (T2DM) and MetS on Background Metformin (MET) + Sulfonylurea (SU) (Poster No. 1096-P) *[Also being presented at Sunday General Poster Session]*

**Real-World Evidence**

*Moderated Poster Discussion: 12:30-1:30 p.m.*

- Real-world 12-month Outcomes of Patients with Type 2 Diabetes Mellitus (T2DM) Treated with Canagliflozin in a US Managed Care Setting (Poster No. 1223-P) *[Also being presented at Sunday General Poster Session]*

- HbA1c Outcomes in Patients Treated with Canagliflozin vs. Sitagliptin in a US Health Plan (Poster No. 1224-P) *[Also being presented at Sunday General Poster Session]*

**Sunday, June 12, 2016**

**Clinical Data**

*General Poster Session: 12:00-2:00 p.m.*

- Target Achievement and Quality Measure (QM) Attainment With Titrated Canagliflozin (CANA) in Patients With Type 2 Diabetes Mellitus (T2DM) as Add-on to Metformin (MET) + Sitagliptin (SITA) (Poster No. 1174-P)
- Blood Pressure (BP) Effects of Canagliflozin (CANA) in Patients With Type 2 Diabetes Mellitus (T2DM) (Poster No. 1156-P)
- **Late Breaker:** Coadministration of Canagliflozin (CANA) and Phentermine (PHEN) for Weight Management in Overweight and Obese Adults (Poster No. 319-LB)
- **Late Breaker:** Effects of Canagliflozin (CANA) on Serum Magnesium (Mg) in Patients With Type 2 Diabetes Mellitus (T2DM) (Poster No. 129-LB)

**Patient-Reported Outcomes**

*General Poster Session: 12:00-2:00 p.m.*

- Improved Treatment Satisfaction in People with Type 1 Diabetes Mellitus (T1DM) Treated with Canagliflozin (CANA) (Poster No. 1184-P)
Real-World Evidence

General Poster Session: 12:00-2:00 p.m.

- Efficacy of Canagliflozin (CANA) Versus Dipeptidyl Peptidase-4 Inhibitors (DPP-4i) in Patients With Type 2 Diabetes Mellitus (T2DM): Results From Randomized Controlled Trials (RCTs) and a Real-World (RW) Study (Poster No. 1194-P)
- Canagliflozin Prescribing Patterns in a Specialty Diabetes Clinic (Poster No. 1165-P)
- Real-World Impact of Canagliflozin on Glycemic Control, Body Weight and Blood Pressure in Whites and African Americans with Type 2 Diabetes Mellitus (T2DM) (Poster No. 1167-P)
- Evaluation of the Progression of Chronic Kidney Disease (CKD) and Associated Costs in US Patients with Type 2 Diabetes Mellitus (T2DM) (Poster No. 1249-P)
- Real World (RW) Glycemic Control and Medication Adherence among Patients with Type 2 Diabetes Mellitus (T2DM) Initiated on Canagliflozin (Poster No. 1161-P)
- Comparative Persistence with Antihyperglycemic Agents (AHA) Used to Treat Type 2 Diabetes Mellitus (T2DM) in the Real World (Poster No. 1155-P)

Other Health Economics & Outcomes Research

General Poster Session: 12:00 - 2:00 p.m.

- Time Until Insulin Initiation for Canagliflozin (CANA) Versus Sitagliptin (SITA) in Dual Therapy and Triple Therapy for Type 2 Diabetes Mellitus (T2DM) in the UK (Poster No. 1248-P)
- The Role of Estimated Glomerular Filtration Rate (eGFR) in Cost-Effectiveness (CE) Analyses using Canagliflozin (CANA) vs Sulfonylurea (SU) to Treat Type 2 Diabetes Mellitus (T2DM) (Poster No. 1255-P)

Monday, June 13, 2016

Clinical Data

Oral Abstract Session: 8:00-10:00 a.m.

- Canagliflozin (CANA) Improves Glycemic Control and Reduces Glycemic Variability in Patients With Type 1 Diabetes Mellitus (T1DM) Inadequately Controlled With Insulin (Presentation 291-OR)

Abstracts of all accepted presentations can be accessed on the American Diabetes Association’s Scientific Sessions website.

About INVOKANA®

In March 2013, the FDA approved canagliflozin – INVOKANA® – as a single agent. In two studies comparing INVOKANA® plus metformin to current standard treatments plus metformin – one studying sitagliptin and the other studying glimepiride – INVOKANA® dosed at 300 mg provided greater reductions in A1C levels and body weight than either comparator. In the two studies, the overall incidence of adverse events was similar with INVOKANA® and the comparators. INVOKANA® is currently the number-one branded non-insulin type 2 diabetes medication prescribed by U.S. endocrinologists. It is also the second most common branded therapy prescribed by primary care physicians when adding or switching therapies in patients. Since its launch, more than 8 million prescriptions have been written for INVOKANA®.

Janssen Pharmaceuticals, Inc., and its affiliates have rights to canagliflozin through a license agreement with Mitsubishi Tanabe Pharma Corporation. Janssen Pharmaceuticals, Inc. and its affiliates have
marketing rights in Africa, parts of Asia, Australia, Europe, the Middle East, New Zealand, North America and South America.

INVOKANA® is approved as a single agent in Aruba, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Curacao, Dominican Republic, El Salvador, the European Union (28 countries), Guatemala, Hong Kong, Iceland, India, Israel, Jamaica, Kazakhstan, Kuwait, Lebanon, Liechtenstein, Mexico, New Zealand, Nicaragua, Norway, Panama, Paraguay, Peru, Philippines, Qatar, Russia, Serbia, Singapore, South Korea, Switzerland, Thailand, United Arab Emirates and the United States.

About Type 2 Diabetes
Of the approximately 29 million people who have diabetes in the United States, 90 to 95 percent of them have type 2 diabetes, which is chronic and affects the body's ability to metabolize sugar (glucose), and is characterized by the inability of pancreatic beta cell function to keep up with the body's demand for insulin.

WHAT IS INVOKANA®?

INVOKANA® 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® can cause important side effects, including:
• 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 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 can be life-threatening and may need to be treated in a hospital. **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 and Medication Guide.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

Trademarks are those of their respective owners.

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 at @JanssenUS.


3 Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data, showing INVOKANA® has been the leading branded non-insulin type 2 diabetes medication newly prescribed by U.S. endocrinologists for thirty one weeks, through January 2, 2015, the most recent data available at time of approval of INVOKAMET®.

4 Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data through January 2, 2015.