NEWS RELEASE

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Newly Published Real-World Evidence Shows Adults with Type 2 Diabetes Significantly Improve Blood Glucose Control and Achieve Treatment Goals When Using INVOKANA® (canagliflozin)

Analyses Show Approximately 20 Percent of Patients Discontinued Other Blood-Glucose-Lowering Medications After Starting on INVOKANA®

RARITAN, N.J., May 16, 2016 – Results from three separate data analyses representing diverse patient populations from real-world clinical practice show that use of the once-daily oral medication INVOKANA® (canagliflozin) is associated with significant improvements in blood glucose control (A1C) in adults with type 2 diabetes, even though most patients were already being managed with other blood-glucose-lowering medications, including insulin.[1,2,3]

Analyses over a six-month period showed that, among the 4,017 patients who initially used INVOKANA®, 80 percent of those patients were receiving treatment with other A1C-lowering medications. Of this subset, approximately 20 percent discontinued one or more of those treatments after starting treatment with INVOKANA®.[2,3]

One of these analyses showed Hispanic and Latino Americans – a group at high risk for developing type 2 diabetes and related complications – had higher baseline A1C levels compared to non-Hispanic and non-Latino Americans, and had average A1C reductions greater than 1 percent with INVOKANA®.[3] Findings from a third analysis showed a large proportion of patients achieved A1C and blood pressure goals and a reduction in body weight three months after initiating treatment with INVOKANA® and the proportions generally remained stable until the end of the analysis period at 12 months.[1]

The new findings were published in recent issues of *Current Medical Research & Opinion*[1,3] and *BMC Endocrine Disorders.*[2]

“The A1C improvements and goal achievements shown in these analyses with INVOKANA® across diverse patients with type 2 diabetes – including those with uncontrolled A1C and from different ethnic

groups – are important metrics for providers, payers and reimbursement," said Wing Chow, PharmD, MPH, Director, Real World Data Analytics & External Partnerships, Johnson & Johnson. "These analyses are consistent with findings from other real-world experience with INVOKANA®, which now includes more than 8 million prescriptions to date, and also provide a valuable addition to the large body of evidence from our clinical trial program." [4]

The retrospective analyses, based on medical and lab data from large administrative claims databases, showed that after initiation of INVOKANA® patients with type 2 diabetes who had an average baseline A1C of 8.5 to 8.9 percent achieved an average reduction in A1C of approximately 0.8 percent to 1.1 percent over a 6-month period. One of the analyses showed that patients who had poor glucose control at baseline (A1C greater than 9.0 percent) reduced their A1C level by an average of 1.8 percent after 6 months, with 38 percent of the poorly controlled patients achieving an A1C goal of less than 8 percent.[2]

A1C, or hemoglobin A1C, is used as a measure of average blood glucose over the past two to three months. The American Diabetes Association recommends most adults with type 2 diabetes maintain A1C levels of 7 percent or less. Medicare and many health plans use an A1C level of less than 8 percent as a treatment goal.[5] However, nearly half of all adults with type 2 diabetes do not achieve recommended levels of blood glucose control.

"As a leader in the SGLT2 inhibitor space, we recognize the role we play in helping those with diabetes live healthier lives," said Paul Burton, MD, PhD, Vice President, Medical Affairs, Janssen. "We are committed to continuously building on our foundation of INVOKANA® real world evidence and ensuring this high-quality data is easily accessible so payers can make informed coverage decisions and physicians can make the best treatment choices for their patients"

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 that work with the kidneys to lower A1C. INVOKANA® is not indicated for weight loss or as antihypertensive treatment.

Treatment with INVOKANA® was generally well tolerated in clinical trials. The most common side effects of INVOKANA® include genital yeast infections, urinary tract infection and increase in urination frequency; these side effects led to few discontinuations in clinical trials.

The Publications

Real-World Glycemic, Blood Pressure, and Weight Control in Patients with Type 2 Diabetes Mellitus Treated with Canagliflozin - an Electronic Health-Record-Based Analysis. In: *Current Medical Research & Opinion*.[1]
This retrospective observational analysis in 16,163 adults with type 2 diabetes prescribed INVOKANA® describes outcomes associated with use of INVOKANA® (100 mg or 300 mg daily). Prior to starting INVOKANA®, the patients had been taking an average of 2.7 anti-hyperglycemic agents (AHAs) to control their blood glucose.

Key Results

- Among patients with baseline A1C of 7 percent or more, a significant reduction in A1C, from 8.8 percent at the time of the first INVOKANA® prescription (baseline) to 8.0 percent at three months, and was maintained at six, nine and 12 months (P<0.001 vs. baseline at each time point).
    - Also, 59.5 percent achieved A1C of less than 8 percent at three months, including 21.2 percent who attained A1C of less than 7 percent. The proportion of patients achieving these A1C goals remained stable at six, nine and 12 months.
- Among patients with systolic/ diastolic blood pressure (SBP/ DBP) of 140/90 mmHg or greater at baseline, 60.0 percent and 75.6 percent achieved blood pressure reduction goals of SBP less than 140 mmHg and DBP less than 90 mmHg, respectively, after three months. The proportions of patients attaining BP control were similar at six, nine and 12 months.
- Weight loss of 5 percent or more was observed in 13.3 percent of patients at three months and 25.8 percent of patients at 12 months.

The analysis utilized a large US electronic health records database, in which 60 percent of contributors are primary care providers.

Characteristics and Outcomes of Patients with Type 2 Diabetes Mellitus Treated with Canagliflozin: A Real-World Analysis. In: *BMC Endocrine Disorders*.[2]
This retrospective cohort analysis evaluated outcomes with the use of INVOKANA® (100 mg or 300 mg daily) in 4,017 people with type 2 diabetes over a six-month period in a real-world setting.

Key Results

- Of the 4,017 patients included in the analysis, nearly 80 percent were already on an AHA at the time of INVOKANA® initiation. Of those already on an AHA, 20 percent discontinued one or more of these AHAs during the follow-up period after initiating INVOKANA®.
- Among 826 patients with available A1C measurements at baseline (average 8.59 percent) and follow-up, average A1C reduction was 0.81 percent (P< 0.001).
- The proportion of patients with A1C less than 8 percent increased from 39 percent at baseline to 66 percent at follow-up; the proportion with A1C less than 7 percent increased from 13 percent to 28 percent.
- A1C reduction was greatest in patients with higher baseline A1C levels. For example:
    - Among 501 patients with a baseline A1C of 8.0 percent or greater, A1C decreased from an average of 9.54 percent at baseline to 8.24 percent in the follow-up period, an average reduction of 1.3 percent.
    - For 270 patients with a baseline A1C of 9.0 percent or greater, average A1C decreased from 10.51 percent at baseline to 8.7 percent, an average reduction of 1.81 percent.
- The reduction in A1C was similar among patients receiving INVOKANA® as an add-on to 0, 1, 2, or 3 or more AHAs (average A1C change: 0.86%, 0.72%, 0.85%, and 0.85%, respectively; P = 0.675).

This retrospective claims-based study utilized data from the Optum Research Database (ORD). The database includes medical, pharmacy and enrollment data from a large US health care organization.

Canagliflozin Treatment of Hispanic and Non-Hispanic Patients with Type 2 Diabetes in a US Managed Care Setting. In: *Current Medical Research & Opinion*.[3]
This retrospective cohort analysis was based on 438 Hispanic/Latino (H/L) and 3,408 non-H/L adults (age 18 years or greater) with type 2 diabetes included in the Optum Research Database and followed for six months after filling their initial prescription for INVOKANA®.

At baseline, before starting on INVOKANA®, the H/L patients were younger (53 vs. 56 years, p<0.001) and had a higher average A1C (8.9 percent vs. 8.5 percent, p=0.028) compared to non-H/L patients.

Additionally, more H/L patients than non-H/L patients were taking three or more blood-glucose-lowering medications (25 percent vs. 21 percent, p=0.044).

Key Results

- Of the 3,846 H/L and non H/L patients included in the analysis, nearly 80 percent (78 percent of H/L patients and 81 percent of non-H/L patients) were already on an AHA at the time of INVOKANA® initiation. Of those already on an AHA, 20 percent (21 percent and 20 percent, respectively) discontinued one or more of these AHAs during the follow-up period after initiating INVOKANA®.
- Among 787 patients (107 [24 percent] H/L and 680 [20 percent] non-H/L) with available A1C measurements at baseline and follow-up, INVOKANA® use was associated with A1C levels decreased to an average of 7.8 percent in both groups. Since H/L patients had a higher average baseline A1C level than non-H/L patients (average 8.9 percent and 8.5 percent, respectively), the average reduction was greater (1.1 percent vs. 0.8 percent, p=0.043).

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** (the loss of body water and salt), 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; pancreas problems; are on a low sodium (salt) diet; are going to have surgery; are eating less due to illness, surgery, or a very low calorie diet; ever had an allergic reaction to INVOKANA®; drink alcohol very often (or drink a lot of alcohol in short-term); or have other medical conditions.

Tell your doctor if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed. It is not known if INVOKANA® will harm your unborn baby. It is also not known if INVOKANA® passes into your breast milk.

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) 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, a high amount of potassium in your blood (hyperkalemia), or 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®
- **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

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; urinary tract infection; or 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.

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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.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and use. 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 product research, development and commercialization, including the uncertainty of clinical success and of 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 January 3, 2016, 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.

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[1] Lefebvre P, Pilon D, Robitaille MN, Lafeuille MH, Chow W, Pfeifer M, Duh MS. Real-world glycemic, blood pressure, and weight control in patients with type 2 diabetes mellitus treated with canagliflozin-an electronic health-record-based study. *Curr Med Res Opin*. 2016 May 11:1-9. [Epub ahead of print].

[2] Buysman EK, Chow W, Henk HJ, Rupnow MFT. Characteristics and outcomes of patients with type 2 diabetes mellitus treated with canagliflozin: a real-world analysis. *BMC Endocrine Disorders*. 2015 Nov2; 15(1):67.

[3] Chow W, Buysman E, Rupnow M, Aguilar R, Henk H. Canagliflozin treatment of Hispanic and non-Hispanic patients with type 2 diabetes in a US managed care setting. *Curr Med Res Opin.* 2016 Jan; 32(1):13-22.

[4] Data on file. Janssen Pharmaceuticals, Inc. Based on IMS Health, NPA Weekly, Total Prescriptions, April 2013- April 8th 2016.[5] National Committee for Quality Assurance. http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx. Accessed 2015 May 7.