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Real-World Evidence Shows Oral INVOKANA® (canagliflozin) Results in Greater Weight Loss and Treatment Adherence Than Injectable GLP-1 Receptor Agonists in Type 2 Diabetes Patients

INVOKANA® nearly doubled the likelihood of clinically significant weight loss compared to GLP-1s

INVOKANA® also associated with a 31 percent lower annual initial medication cost

TITUSVILLE, NJ, and ORLANDO, FL, June 23, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new findings from two real-world studies comparing sodium glucose co-transporter-2 inhibitor (SGLT2i) INVOKANA® (canagliflozin) and glucagon-like peptide-1 receptor agonists (GLP-1s) in treating adults with type 2 diabetes. One study showed INVOKANA® treatment resulted in similar blood glucose control while achieving greater treatment adherence, less therapy discontinuation and lower treatment cost, while a second study showed INVOKANA® resulted in greater and longer-lasting weight loss. These findings were revealed in two poster presentations at the American Diabetes Association's (ADA) 78th Scientific Sessions in Orlando, FL.

One of the two real-world studies, which was based on data from the HealthCore Integrated Research Database, showed that INVOKANA® treatment resulted in similar

levels of glucose control based on A1C levels at three-month intervals, compared to treatment with GLP-1s, while demonstrating better outcomes on multiple endpoints:

- Over 12 months, about ten percent more patients maintained treatment adherence with INVOKANA®: 47.5 percent vs 37.5 percent ($p<0.001$). Adherence was defined as a patient taking the medication for 80 percent or more of the days during the 12-month period.
- Over 12 months, patients were 22 percent less likely to discontinue treatment with INVOKANA® – 49.6 percent vs 57.4 percent (HR 0.78, 95 percent CI 0.70, 0.88; $p<0.001$) – or to initiate insulin (4.1% vs. 7.8%, $p=0.001$).
- Approximately 31 percent lower initial anti-hyperglycemic agent annual medication cost: $1,421 less with INVOKANA® than with GLP-1 therapy.

The second study, which was based on the U.S. Optum database, also assessed patient data at three-month intervals, and showed that, over nine months, treatment with INVOKANA® nearly doubled the likelihood of achieving clinically significant weight loss (defined as five percent or more of body weight) compared to GLP-1s (HR: 1.93, CI: 1.40, 2.66; $p<0.0001$).

"The real-world outcomes that we're seeing in these studies show that INVOKANA® performs better on these measures than GLP-1s," said Paul Burton, MD, PhD, FACC, Vice President, Medical Affairs, Janssen Scientific Affairs, LLC. "The findings of similar blood glucose control, greater adherence and lower treatment costs with INVOKANA® are especially relevant for physicians and payers to consider for the treatment of type 2 diabetes."

Studies and Findings

Abstract No. 1287-P

Based on medical claims data from the HealthCore Integrated Research Database (HIRD), this real-world study evaluated adults with type 2 diabetes who initiated therapy with INVOKANA® (750 patients) or a GLP-1 (2,417 patients). Patient data were collected at three-month intervals, beginning 12 months before initiating INVOKANA® or a GLP-1, and ending 12 months afterwards. In the 12 months following therapy initiation, the propensity-adjusted analysis showed that treatment with INVOKANA® also resulted in similar reductions in A1C at each three-month measurement after treatment initiation, and at 12 months.

Abstract No. 1291-P

A second real-world study was based on health records data from the U.S. Optum database. It evaluated adults with type 2 diabetes who had one or more prescription claim for INVOKANA® (213 patients) or a GLP-1 (235 patients), and at least two body weight measurements, including one at baseline and at least one at 31 days or more after starting treatment. The analysis showed that in the nine months following therapy

initiation, the results of INVOKANA® treatment and GLP-1 treatment were as follows:

- With INVOKANA® treatment, significantly lower body weight levels over six months (104.4 kg vs. 108.4 kg) and 9 months (101.1 kg vs. 110.2); $p<0.05$ for both six-month and nine-month comparisons.

- With INVOKANA® treatment, a significantly longer duration of clinically significant weight loss: 133 vs. 103 days, $p=0.01$.

Real-World Study Limitations

Real-world data have the potential to supplement randomized controlled trial data by providing additional information about how a medicine performs in routine medical practice. However, they have limitations and cannot be used as stand-alone evidence to validate the efficacy and/or safety of a treatment.

In retrospective analyses, diagnosis coding errors are possible based on administrative claims data. For these two ADA analyses, the results apply to the patients in the databases and may not be generalizable to the overall U.S. managed care population. Further, a prescription claim does not ensure that the medication was taken as prescribed nor does it reflect the use of medication samples, which is what likely resulted in an underestimate of adherence to INVOKANA® versus GLP-1s in the HIRD study.

Although the recommended starting dose of INVOKANA® is 100 mg, the HIRD study examined results for patients initiated on the 300 mg dose, which is associated with broad utilization in the real world. Additionally, not all risk factors, including length of diabetes history and body mass index, could be determined and balanced. In the U.S. Optum database analysis, there were standardized differences in baseline variables in the balanced cohorts. However, the remaining differences in the subset of patients with weight data were driven by low event numbers, small sample sizes, or were already identified in the results.

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®.

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 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 Janssen Scientific Affairs, 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 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.

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