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Janssen Initiates CREDENCE Study in Patients with Type 2 Diabetes and Diabetic Nephropathy

Trial Seeks to Examine the Effects of INVOKANA® on the Progression of Diabetic Nephropathy

Raritan, NJ (February 21, 2014) - Janssen Research & Development, LLC (Janssen) today announced the initiation of CREDENCE (**C**anagliflozin and **R**enal **E**vents in **D**iabetes with **E**stablished **N**ephropathy **C**linical **E**valuation), a global, multicenter study of INVOKANA® (canagliflozin). This Phase 3 study is a randomized, double-blind, placebo-controlled, parallel group trial designed to enroll more than 3,700 patients with type 2 diabetes and diabetic nephropathy. The objective of the study is to examine whether canagliflozin can slow the progression of diabetic nephropathy, a form of renal impairment that is the most common cause of end-stage renal disease worldwide.

"Nearly one-third of all patients with type 2 diabetes will develop evidence of nephropathy. Despite the availability of existing therapies proven to slow its progression, diabetic nephropathy is associated with a 36 percent mortality rate over a five-year period," said Norman Rosenthal, MD, FACE, FACP, canagliflozin compound development team leader, Janssen. "Clearly, patients need new, safe and effective treatment options. We look forward to determining if canagliflozin can be used to treat diabetic nephropathy, as we continue to assess additional uses for canagliflozin."

The CREDENCE trial will evaluate patients with type 2 diabetes and diabetic nephropathy receiving standard of care, which includes treatment with angiotensin converting enzyme inhibitors or angiotensin receptor blockers. The trial's composite primary endpoint includes a doubling of serum creatinine, the occurrence of end-stage renal failure and cardiovascular death. Janssen is partnering with The George Institute, a leading Academic Research Organization based in Sydney, Australia, to provide academic leadership for the study.

About INVOKANA®

INVOKANA® is the first sodium glucose co-transporter 2 (SGLT2) inhibitor available in the United States (U.S.). It is an oral medication that selectively inhibits SGLT2, a cell transporter responsible for the reabsorption of glucose by the kidney, thereby promoting the loss of glucose in the urine and lowering blood glucose levels in adults with type 2 diabetes.

In March 2013, the FDA approved INVOKANA® as a single agent as an adjunct to diet and exercise to lower blood sugar in adults with type 2 diabetes. INVOKANA® has since been widely adopted and today it is the number one branded therapy prescribed by U.S. endocrinologists when adding or switching non-insulin type 2 diabetes medications. More than a half a million prescriptions have now been written for INVOKANA® in the U.S. since its approval in March 2013. In November 2013, the European Commission approved INVOKANA® for adults aged 18 years and older with type 2 diabetes mellitus to improve glycemic control. INVOKANA® has also been approved in Australia, Chile, Mexico and Switzerland.

INVOKANA® has been studied as monotherapy and in combination with other type 2 diabetes therapies. The comprehensive global Phase 3 clinical development program for INVOKANA® enrolled 10,285 patients in nine studies and was one of the largest clinical programs in type 2 diabetes submitted to health authorities to date. In two separate trials, INVOKANA® 300mg demonstrated greater reductions in A1C versus sitagliptin 100mg at 52 weeks, as well as greater reductions in body weight and systolic blood pressure. The recommended starting dose on INVOKANA® is 100mg. A1C is the percent of red blood cell hemoglobin with glucose attached to it and an indicator of average blood glucose over the previous two to three months.

The most common adverse events with INVOKANA® are genital mycotic (fungal) infections, urinary tract infections and increased urination. These specific adverse events were generally mild to moderate in intensity and infrequently led to discontinuation in Phase 3 studies.

About Type 2 Diabetes and Diabetic Nephropathy

Type 2 diabetes is a chronic condition that affects the body's ability to metabolize sugar, or glucose, and is characterized by the inability of pancreatic beta cell function to keep up with the body's demand for insulin.[2] The International Diabetes Federation estimates that in 2013, 382 million people were living with diabetes (type 1 and 2) and the diabetes population is expected to grow to over 592 million in less than 20 years.[3] The World Health Organization estimates that 90 percent of the diabetes

population has type 2 diabetes.[4]

Patients with type 2 diabetes can develop severe complications. Diabetic nephropathy (renal impairment) is a potential complication of type 2 diabetes and is characterized by persistent albuminuria (protein in the urine) and a progressive decline in renal function. Diabetes is the primary cause of end-stage renal disease.[5]

Approximately 44 percent of patients beginning dialysis in the U.S. have diabetes, so early diagnosis and treatment is important to potentially prevent progression to renal failure.[5] Approximately 20 - 30 percent of all patients with type 2 diabetes will develop evidence of nephropathy; however, fewer type 2 diabetes patients actually progress to end stage renal disease.[5]

INDICATION STATEMENT

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.
- INVOKANA® is not for people 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

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT INVOKANA®?

INVOKANA® can cause important side effects, including:

- **Dehydration. INVOKANA® can cause some people to have dehydration (the loss of body water and salt). Dehydration 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 pill)
- are on low sodium (salt) diet
- have kidney problems
- are 65 years of age or older

• **Vaginal yeast infection.** Women who take INVOKANA® may get vaginal yeast infections. Symptoms of a vaginal yeast infection include:

- vaginal odor
- white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
- 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. Certain men who are not circumcised may have swelling of the penis that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of yeast infection of the penis include:

- redness, itching, or swelling of the penis
- rash of the penis
- foul smelling discharge from the penis
- 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. Your doctor may suggest you use an over-the-counter antifungal medicine. Talk to your doctor right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

WHO SHOULD NOT TAKE INVOKANA®?

Do not take INVOKANA® if you:

- are allergic to canagliflozin or any of the ingredients in INVOKANA®. See the end of the Medication Guide for a list of ingredients in INVOKANA®. Symptoms of allergic reaction to INVOKANA® may include:
  - rash
  - raised red patches on your skin (hives)
  - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing
- have severe kidney problems or are on dialysis

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING INVOKANA®?

Before you take INVOKANA®, tell your doctor if you:

- have kidney problems
- have liver problems
- are on a low sodium (salt) diet. Your doctor may change your diet or your dose of INVOKANA®.
- have ever had an allergic reaction to INVOKANA®
- have other medical conditions
- are pregnant or plan to become pregnant. It is not known if INVOKANA® will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if INVOKANA® passes into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking INVOKANA®.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

INVOKANA® may affect the way other medicines work, and other medicines may affect how INVOKANA® works. 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®, Lopinavir ®)* (used to treat HIV infection)
- digoxin (Lanoxin®)* (used to treat heart problems)

Ask your doctor or pharmacist for a list of these medicines if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

HOW SHOULD I TAKE INVOKANA®?

- Take INVOKANA® by mouth 1 time each day exactly as your doctor tells you to take it.
- Your doctor will tell you how much INVOKANA® to take and when to take it. Your doctor may change your dose if needed.
- It is best to take INVOKANA® before the first meal of the day.
- Your doctor may tell you to take INVOKANA® along with other diabetes medicines. Low blood sugar can happen more often when INVOKANA® is taken with certain other diabetes medicines. See **"What are the possible side effects of INVOKANA®?**
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take two doses of INVOKANA® at the same time. Talk to your doctor if you have questions about a missed dose.
- If you take too much INVOKANA®, call your doctor or go to the nearest hospital emergency room right away. When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor's instructions.
- Stay on your prescribed diet and exercise program while taking INVOKANA®.
- Check your blood sugar as your doctor tells you to.
- INVOKANA® will cause your urine to test positive for glucose.
- Your doctor may do certain blood tests before you start INVOKANA® and during treatment as needed. Your doctor may change your dose of INVOKANA® based on the results of your blood tests.

- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF INVOKANA®?

INVOKANA® may cause serious side effects, including:

See **"What is the most important information I should know about INVOKANA®?"**

- **kidney problems**
- **a high amount of potassium in your blood (hyperkalemia)**
- **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. See **"Who should not take INVOKANA®?".** Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

The most common side effects of INVOKANA® include:

- **vaginal yeast infections and yeast infections of the penis (See "What is the most important information I should know about INVOKANA®?")**
- **urinary tract infection**
- **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. These are not all the possible side effects of INVOKANA®. For more information, ask your doctor or pharmacist.

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 the full Prescribing Information and Medication Guide.

About Janssen Research & Development, LLC
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development, LLC and Janssen Scientific Affairs, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit http://www.janssenrnd.com for more information.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and

uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent 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 statements as a result of new information or future events or developments.

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[1] Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data through 9/20/13.

[2] International Diabetes Federation. About Diabetes. Available: http://www.idf.org/about-diabetes. Last accessed: Feb 2013.

[3] International Diabetes Federation. Diabetes: Facts and Figures. Available: http://www.idf.org/worlddiabetesday/toolkit/gp/facts-figures. Last accessed: January 2014.

[4] Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: Diagnosis and classification of diabetes mellitus. Geneva, World Health Organization, 1999 (WHO/NCD/NCS/99.2).

[5] Cleveland Clinic. Diabetic Neuropathy. Available: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/nephrology/diabetic-nephropathy/#prevalence. Last accessed: January 2014.

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