NEWS RELEASE

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U.S. FDA Approves INVOKANA™ (Canagliflozin) for the Treatment of Adults with Type 2 Diabetes

INVOKANA™ is the first in a new class of type 2 diabetes medications available in the United States

In Phase 3 studies, INVOKANA™ improved blood glucose control and was associated with reductions in body weight and systolic blood pressure

Janssen will partner with other Johnson & Johnson companies focused on diabetes to bring INVOKANA™ to healthcare professionals

RARITAN, N.J., March 29, 2013 – Janssen Pharmaceuticals, Inc. announced today the U.S. Food and Drug Administration (FDA) has approved INVOKANA™ (canagliflozin) for the treatment of adults with type 2 diabetes. INVOKANA™ is the first in a new class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors to be approved in the United States. It is also the only oral, once-daily medication available in the United States offering improved glycemic control while also showing reduced body weight and systolic blood pressure in clinical trials.

“Patients with type 2 diabetes struggle managing their blood sugar, and nearly half of adults with type 2 diabetes do not achieve recommended levels of glucose control, increasing their risks for potentially life-threatening complications,” said Richard Aguilar*, M.D., Medical Director, Diabetes Nation, LLC and Diabetes Care Foundation, a non-profit organization committed to improving diabetes care. "INVOKANA™ is thought to work differently than other currently-available medicines because it reduces blood glucose by acting on the kidneys as a ‘glucuretic,’ increasing the loss of glucose in the urine. What

has historically been viewed as a sign of diabetes – glucose in the urine – may also reflect the efficacy of a new and unique approach to treatment."

The kidneys make an important contribution to balancing blood glucose. As glucose is filtered from the blood into the kidneys, it is reabsorbed back into the bloodstream. An important carrier responsible for this reabsorption is called sodium glucose co-transporter 2 (SGLT2). INVOKANA™ selectively inhibits SGLT2, and as a result promotes the loss of glucose in the urine, lowering blood glucose levels in adults with type 2 diabetes.

"INVOKANA™ provides patients with type 2 diabetes the option of a once-daily oral therapy that offers improved glycemic control and, in Phase 3 studies, showed an incidence of hypoglycemia – low blood glucose – that was lower than with glimepiride and similar to that of sitagliptin," said Jimmy Ren, Ph.D., Therapeutic Area Lead, Metabolics, Medical Affairs, Janssen Pharmaceuticals, Inc. "In addition, this new treatment option is associated with reductions in body weight and systolic blood pressure."

INVOKANA™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. INVOKANA™ has been studied as a single agent (monotherapy), in combination with metformin, and in combination with other glucose-lowering agents, including insulin, in patients who need further glucose control. Results from the Phase 3 studies showed INVOKANA™ was generally well tolerated. 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. Overall the rate of discontinuation due to adverse events was 4.3 percent for the INVOKANA™ starting dose of 100 milligrams (mg), 3.6 percent for INVOKANA™ 300 mg and 3.1 percent versus competitors.

INVOKANA™ is an important addition to the comprehensive platform of offerings for patients with diabetes from the Johnson & Johnson Family of Companies. Janssen will partner with other Johnson & Johnson companies focused on diabetes, such as LifeScan, Inc., and Animas Corporation, to bring INVOKANA™ to healthcare professionals treating patients with diabetes.

Janssen also will offer a dedicated INVOKANA™ CarePath support program to patients and caregivers. The program provides important support and information regarding affordable access, adherence and education, thereby helping patients to start and appropriately manage their disease and therapy over time.

"We are delighted with the approval of INVOKANA™ because it provides a much-needed, new treatment option to help adults with type 2 diabetes and their physicians manage this disease," said Kirk Ways, M.D., Ph.D., Development Head, Cardiovascular & Metabolism and Compound Development Team Leader, Canagliflozin, Janssen Research & Development.

The new drug application for INVOKANA™ was based on a comprehensive global Phase 3 clinical program, which enrolled 10,285 patients in nine studies and is one of the largest clinical programs in type 2 diabetes submitted to health authorities to date.

Results from this program showed that the 100 mg and the 300 mg doses of INVOKANA™ improved glycemic control and, in prespecified secondary endpoints, were associated with significant reductions in body weight and systolic blood pressure. In two studies comparing INVOKANA™ to current standard treatments – 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. 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. In the two studies, the overall incidence of adverse events was similar with INVOKANA™ and the comparators.

In studies of INVOKANA™ as monotherapy or in combination with agents not associated with hypoglycemia (such as metformin or metformin and pioglitazone), the incidence of hypoglycemic episodes were less than 5 percent across the groups (INVOKANA™ 100 mg [3.8 percent], INVOKANA™ 300 mg [4.3 percent], and placebo [2.2 percent]). There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic medication. Additional data are being collected to further characterize the cardiovascular profile of INVOKANA™.

The Phase 3 studies for INVOKANA™ were presented at the American Diabetes Association (ADA) Annual Scientific Sessions in June 2012, at the European Association for the Study of Diabetes (EASD) Annual Meeting in October 2012, and at the World Congress on Controversies to Consensus in Diabetes, Obesity, and Hypertension (CODHy) in November 2012.

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

About Type 2 Diabetes

The U.S. Centers for Disease Control and Prevention estimates that nearly 26 million Americans have diabetes, 90 to 95 percent of which is type 2 diabetes. 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.[1] U.S. national data from 2007 to 2010 show that nearly half of adults with type 2 diabetes were not achieving recommended levels of glucose control.[2]

Approximately 60 percent of patients with type 2 diabetes in the United States are obese, while another 30 percent are overweight. In most people at risk for type 2 diabetes, obesity causes the body to resist the action of insulin, and if the pancreatic beta cell cannot produce enough insulin, hyperglycemia and type 2 diabetes ensue. If left uncontrolled, type 2 diabetes can lead to serious complications; improved glycemic control has been demonstrated to reduce the onset and progression of these complications.[1]

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.

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About Janssen Pharmaceuticals, Inc.

As a member of the Janssen Pharmaceutical Companies of Johnson & Johnson, Janssen Pharmaceuticals, Inc. is dedicated to addressing and resolving the major unmet medical needs of our time. Driven by our commitment to patients, healthcare professionals, and caregivers, we strive to develop sustainable and integrated healthcare solutions by working in partnership with all stakeholders on the basis of trust and transparency. Our daily work is guided by meeting goals of excellence in quality, innovation, safety, and efficacy in order to advance patient care.

Our company provides medicines for an array of illnesses and disorders in several therapeutic areas. Other innovative therapies that Janssen Pharmaceuticals, Inc. offers include ACIPHEX® (rabeprazole sodium), ELMIRON® (pentosan polysulfate sodium), INVEGA® SUSTENNA® (paliperidone palmitate)

extended-release injectable suspension, NUCYNTA® ER (tapentadol extended-release tablets), RISPERDAL® CONSTA® (risperidone) Long-Acting Injection and XARELTO® (rivaroxaban). The full prescribing information for INVEGA® SUSTENNA®, NUCYNTA® ER, RISPERDAL® CONSTA® and XARELTO®, including boxed warnings, are available here, here, here, and here.

For more information on Janssen Pharmaceuticals, Inc., visit us at www.janssenpharmaceuticalsinc.com or follow us on Twitter at www.twitter.com/JanssenUS and on YouTube at www.Youtube.com/JanssenUS.

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 Pharmaceuticals, Inc. 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. Neither Janssen Pharmaceuticals, Inc. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

**Dr. Aguilar was not associated with the INVOKANA™ clinical trials and was not compensated for any media work. He has been a paid consultant to Janssen Pharmaceuticals, Inc.*

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References

[1] Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011. Available at: http://www.diabetes.org/in-my-community/local-offices/miami-florida/assets/files/national-diabetes-fact-sheet.pdf. Accessed January 28, 2013.

[2] Casagrande SS, Fradkin JE, Saydah SH, Rust KF, Cowie CC. The prevalence of meeting A1C, blood pressure, and LDL goals among people with diabetes, 1988–2010. Diabetes Care. 2013 Feb 15. Epub ahead of print.

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