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## **FIRST-IN-CLASS TYPE 2 DIABETES MEDICATION APPROVED IN CANADA**

*INVOKANA™ offers a new approach to treatment*

Toronto, ON (May 26, 2014) — Janssen Inc. announced today that Health Canada has approved INVOKANA™ (canagliflozin), an oral, once-daily prescription treatment used to lower blood glucose (sugar) levels in adults with type 2 diabetes.<sup>1</sup> INVOKANA™ belongs to a new class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors that offers a novel approach to treating diabetes by increasing the loss of glucose in the urine.

Of the three million Canadians living with diabetes, 90 per cent have been diagnosed with type 2 diabetes.<sup>2</sup> Despite the numerous treatment options available, approximately 50 per cent of patients don't reach the level of glucose control recommended by their doctor.<sup>3</sup>

“Living with diabetes can be extremely frustrating and discouraging,” said Mississauga resident, Jatinder Bawa, who has lived with type 2 diabetes for 10 years. “While I have made some lifestyle changes to control my condition, there were times when I wasn't well-managed and it was hard to always stay motivated without seeing some signs of improvement.”

### **INVOKANA™: A New Way of Treating Diabetes**

As glucose is filtered from the blood in the kidneys it is reabsorbed into the bloodstream. SGLT2 is an important transporter responsible for this reabsorption. INVOKANA™ selectively inhibits SGLT2 and as a result, promotes the loss of glucose in the urine, lowering blood sugar levels in adults with type 2 diabetes.

“In clinical trials, INVOKANA™ had a great impact on patients by improving glycemic control, while reducing body weight and systolic blood pressure,” said Dr. Ronald Goldenberg, endocrinologist, LMC Diabetes & Endocrinology. “INVOKANA™ was also associated with a low incidence of hypoglycemia, which is something that is often associated with diabetes medications. This new treatment provides an exciting option for physicians and patients.”\*

## **Clinical Trial Program**

The Health Canada approval of INVOKANA™ is based on a comprehensive global Phase 3 clinical program, including 713 Canadians in six studies, which was one of the largest global clinical programs in type 2 diabetes ever conducted. 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.<sup>4</sup>

Results from this program showed that the 100 mg and the 300 mg doses of INVOKANA™ significantly improved glycemic control, body weight and systolic blood pressure.<sup>5</sup>

In two studies comparing INVOKANA™ as an add-on therapy with metformin to current standard treatments, INVOKANA™ dosed at 300 mg provided superior reductions compared to sitagliptin and to glimepiride in both A1C levels (measure that reflects the average blood sugar levels over the past three months) and body weight.<sup>6,7</sup>

Results from the Phase 3 clinical program 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.<sup>8</sup> Due to its mechanism of action INVOKANA™ may cause volume depletion (dehydration). Uncommon adverse events related to reduced intravascular volume including orthostatic hypotension, postural dizziness (both defined as fainting, feeling dizzy or lightheaded due to a drop in blood pressure when you stand up) and hypotension (low blood pressure). This happens more often in older people (aged 75 and over), people with kidney problems and people taking water tablets (diuretics). For additional information on adverse events please visit the Canadian Product Monograph at [www.janssen.ca](http://www.janssen.ca).<sup>9</sup>

## **About INVOKANA™<sup>10</sup>**

INVOKANA™ is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus. INVOKANA™ is currently approved for use in 39 countries.

## **About Type 2 Diabetes**

Type 2 diabetes is a disease in which the pancreas does not produce enough insulin and/or the body does not properly use the insulin it makes. As a result, glucose builds up in the blood instead of being used for energy.<sup>11</sup> If left untreated or improperly managed, diabetes can result in a variety of complications, including heart disease, kidney disease, eye disease and nerve damage.<sup>12</sup> The financial burden of diabetes is also significant. By 2020 it is estimated that the number of Canadians with diabetes will grow to over four million<sup>13</sup> and diabetes will cost the Canadian healthcare system \$16.9 billion per year.<sup>14</sup>

## About Janssen Inc.

Janssen Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. Please visit [www.janssen.ca](http://www.janssen.ca) for more information.

-30-

\*Dr. Ronald Goldenberg was not compensated for any media work. He has been a paid consultant to Janssen Inc.

## References

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- <sup>3</sup> Bailey CJ. Renal glucose reabsorption inhibitors to treat diabetes. *Trends Pharmacol Sci*. 2011;32 (2):63-71.
- <sup>4</sup> INVOKANA™ Product Monograph. Page 35. May 2014.
- <sup>5</sup> INVOKANA™ Product Monograph. Page 37. May 2014.
- <sup>6</sup> INVOKANA™ Product Monograph. Page 40. May 2014
- <sup>7</sup> INVOKANA™ Product Monograph. Page 44. May 2014.
- <sup>8</sup> INVOKANA™ Product Monograph. Page 8. May 2014.
- <sup>9</sup> INVOKANA™ Product Monograph. Page 8. May 2014.
- <sup>10</sup> INVOKANA™ Product Monograph. Page 3. May 2014.
- <sup>11</sup> Canadian Diabetes Association. Type 2 Diabetes: The Basics. Available at: [http://www.diabetes.ca/documents/for-professionals/112020\\_08-399\\_type-2-diabetes-the-basics\\_0413\\_lc\\_final.pdf](http://www.diabetes.ca/documents/for-professionals/112020_08-399_type-2-diabetes-the-basics_0413_lc_final.pdf). Accessed April 2, 2014.
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