HEALTH CANADA APPROVES INVOKAMET™ FOR THE TREATMENT OF
ADULTS WITH TYPE 2 DIABETES

TORONTO, ON, July 20, 2016 – Janssen Inc. announced today that INVOKAMET™, a twice
daily fixed-dose therapy combining INVOKANA® (canagliflozin) and metformin hydrochloride
into a single tablet, for the treatment of adults with type 2 diabetes is now available in Canada.¹

INVOKANA® is the first sodium glucose co-transporter 2 (SGLT2) inhibitor approved in
Canada that works with the kidney to promote the loss of glucose in the urine. Metformin, which
is commonly prescribed early in the treatment of type 2 diabetes, decreases the production of
-glucose in the liver and improves the body’s response to insulin.²

“By combining two proven therapies, INVOKAMET™ reduces the number of tablets people
living with type 2 diabetes take each day,” said Dr. Ronald Goldenberg, endocrinologist, LMC
Diabetes & Endocrinology.* “Clinical trials show INVOKAMET™ helps lower blood sugar and
is associated with a low risk of hypoglycemia. It can also provide a reduction in body weight and
systolic blood pressure, which are important treatment goals for this patient population.”

INVOKAMET™ is indicated as an adjunct to diet and exercise to improve glycemic control in
adults with type 2 diabetes mellitus.³ It should not be used in patients with type 1 diabetes or for
the treatment of diabetic ketoacidosis (DKA).⁴ INVOKAMET™ was approved by Health Canada
on June 1, 2016.

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.⁵ If left untreated or improperly managed, diabetes can result in
a variety of complications, including heart disease, kidney disease, eye disease and nerve
damage.⁶

Of the three million Canadians living with diabetes, 90 per cent have been diagnosed with type 2
diabetes.⁷ By 2025, it is estimated that the number of Canadians with diabetes will grow to more
than four million.⁸

CLINICAL TRIAL PROGRAM

Study results demonstrated administration of INVOKAMET™ was equivalent to co-
administration of corresponding doses of INVOKANA® and metformin as individual tablets.⁹
The co-administration of INVOKANA® and metformin has been studied in six Phase 3 clinical
studies that enrolled 5,031 patients with type 2 diabetes.¹⁰ The Phase 3 studies evaluated
INVOKANA® in combination with metformin, compared to metformin alone or to metformin
plus another diabetes therapy. The studies were part of the comprehensive global Phase 3
program for INVOKANA® that enrolled 10,285 patients, one of the largest clinical programs in type 2 diabetes submitted to health authorities to date. The Phase 3 studies showed the combination of INVOKANA® and metformin lowered blood sugar and in pre-specified secondary endpoints, was associated with significant reductions in body weight and systolic blood pressure.

In two studies comparing INVOKANA® plus metformin to current standard treatments plus metformin — 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 per cent of red blood cell hemoglobin with glucose attached to it and an indicator of average blood glucose concentration over the previous two to three months. In the two studies, the overall incidence of adverse events was similar with INVOKANA® and the comparators.

Common side effects reported for INVOKANA® include vaginal yeast infection, rash or redness of the penis or foreskin, urinary tract infection, increased urination, constipation, nausea and feeling thirsty. Common side effects reported for metformin are diarrhea, excess gas, abdominal discomfort, nausea/vomiting and indigestion.

Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with INVOKAMET™. This is more common in people whose kidneys are not working properly. As well, clinical trial cases of diabetic ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been reported in patients with type 1 and type 2 diabetes mellitus treated with SGLT2 inhibitors, including INVOKANA®. Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use. INVOKANA® can increase the risk of hypoglycemia when combined with insulin or a medication that increases insulin levels (e.g., a sulfonylurea). Therefore, a lower dose of insulin or insulin-raising medication may be required to minimize the risk of hypoglycemia when used in combination with INVOKAMET™.

ABOUT INVOKANA®

INVOKANA® was approved by Health Canada on May 23, 2014. The treatment 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 as a single agent in 70 countries.

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/canada. Follow us at @JanssenCanada.

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

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