

## People with Type 2 Diabetes Achieve Superior Outcomes with Insulin Pumps vs. Multiple Daily Injections

*Comparative Efficacy Results from the OpT2mise Trial Published in The Lancet Could Redefine Management of Insulin-Requiring Type 2 Diabetes*

MINNEAPOLIS - July 2, 2014 - As an example of its commitment to improving clinical outcomes for all people with diabetes, Medtronic, Inc. (NYSE:MDT) today announced the results of the OpT2mise trial, which showed that MiniMed insulin pumps safely achieve better glucose control for people with insulin-requiring type 2 diabetes than multiple daily injections. While the benefits of insulin pump therapy for people with type 1 diabetes are well proven, this is the largest global study to evaluate the comparative efficacy of insulin pump therapy versus multiple daily insulin injections in people with type 2 diabetes with poor glycemic control. Study results were published online in *The Lancet* today.

In the OpT2mise trial, those using insulin pumps achieved a mean A1C (average blood glucose) reduction of 1.1 percent compared to only a 0.4 percent reduction by those using multiple daily injections. This improvement in glucose control was achieved without any episodes of severe hypoglycemia. In addition, those in the insulin pump group lowered the total daily dose of insulin by more than 20 percent. There was no difference in weight gain between the two groups.

Reducing A1C is critical for people with diabetes because even small percent drops aid significantly in preventing complications such as eye disease, kidney disease, nerve damage and heart attacks[1],[2]

"Many patients with type 2 diabetes are failing to reach glycemic control despite using intense pharmaceutical regimens including insulin via multiple daily injections. This patient population is sizeable and difficult to manage, which frequently results in costly complications. For these patients, insulin pumps are an essential new treatment option and have now scientifically been proven to show significant benefits," said Prof. Yves Reznik from the University Hospital of Caen, France. "These trial results are important in showing that insulin pump therapy can safely reduce A1C without causing hypoglycemic episodes and could redefine the standard of care for the growing population of insulin-requiring type 2 diabetes patients."

Approximately 20 million people around the world with type 2 diabetes require insulin replacement therapy and adherence to insulin therapy can be a challenge, with 57 percent of patients on multiple daily injection (MDI) therapy admitting to omitting insulin injections[3].

The global, randomized, controlled study was sponsored by Medtronic and conducted with participation from 331 patients, ranging in age from 30 to 75 years. Specific results include:

- Those using insulin pumps demonstrated a mean reduction of A1C levels by 1.1 percent versus only 0.4 percent for participants using multiple daily injections ( $P < 0.001$ ).
- Those in the insulin pump therapy arm experienced the A1C reduction without any episodes of severe hypoglycemia (low blood sugar, which can cause confusion, disorientation, loss of consciousness and, in the worst cases, coma and even death) or ketoacidosis (a potentially life-threatening condition caused by hyperglycemia or high blood sugar).
- The total daily insulin dose was 20.4 percent lower with pump therapy than with injection therapy ( $P < 0.001$ ) with no significant difference in body weight change between the two groups.
- The percentage of participants in the insulin pump therapy group achieving an A1C  $< 8$  percent was twice that of the multiple daily injections group (55 percent versus 28 percent).

"As Medtronic continues to expand into providing more solutions for people living with type 2 as well as type 1 diabetes, collaborating with the world's experts to build a clinical body of evidence to help guide therapy for all people with diabetes is very important," said Francine R. Kaufman, M.D., chief medical officer and vice president of global, clinical and medical affairs for Medtronic Diabetes. "OpT2mise is the latest example of this clinical leadership and a trial that has the potential to help improve access to insulin pump therapy for the many people with type 2 diabetes who could benefit."

For an infographic of the OpT2mise trial results, [please click here](#).

#### About the Diabetes Business at Medtronic

The Diabetes business at Medtronic ([www.medtronicdiabetes.com](http://www.medtronicdiabetes.com)) is the world leader in advanced diabetes management solutions, including integrated diabetes management systems, insulin pump therapy, continuous glucose monitoring systems and therapy management software, as well as world-class, 24/7 expert consumer and professional service and support.

#### About Medtronic

Medtronic, Inc. ([www.medtronic.com](http://www.medtronic.com)), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complication in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998; 352:837-853

[2]The post trial monitoring results: 10 years follow up: Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HAW. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med* 2008; 359:1577-1589

[3]Peyrot et al, *Diabetes Care* 33:240-245. 2010

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