

HypoDE Study<sup>1</sup>

# 1<sup>st</sup> Study to Show Significant Reduction in Hypo Events in High-Risk T1D MDI patients\*

Continuous glucose monitoring (CGM) clinical trials to date have largely excluded individuals with severe hypoglycemia (SH) or impaired hypoglycemic awareness (IHA). This study examines the impact of the Dexcom G5® Mobile CGM System use in patients on multiple daily injections (MDI) insulin therapy with a history of SH or IHA.

CGM use demonstrated:



Reduction of Hypoglycemic Events by 72%



Over 50% Reduction of Hypoglycemic Events at Night

## Study Objective & Methods

### Objective:

Evaluate the effectiveness of CGM in reducing hypoglycemic events<sup>†</sup> among high-risk individuals with type 1 diabetes treated with MDI.

### Research Design/Methods:

- Randomised, controlled trial conducted in 12 diabetes practices throughout Germany
- 30-week study that included a 4-week baseline data collection period, a 22-week intervention phase, and a 4-week evaluation period (weeks 22-26) to collect CGM data
- Adults with type 1 diabetes treated on MDI (n=149); randomised to CGM use (n=75) with the Dexcom G5® Mobile CGM System, or a control group using self-monitoring of blood glucose (SMBG) (n=74)
- History of IHA (Clarke score<sup>†</sup>≥4) or recent severe hypoglycemic event
- Average baseline HbA1c of 7.5%

## Results



### Primary Outcome:

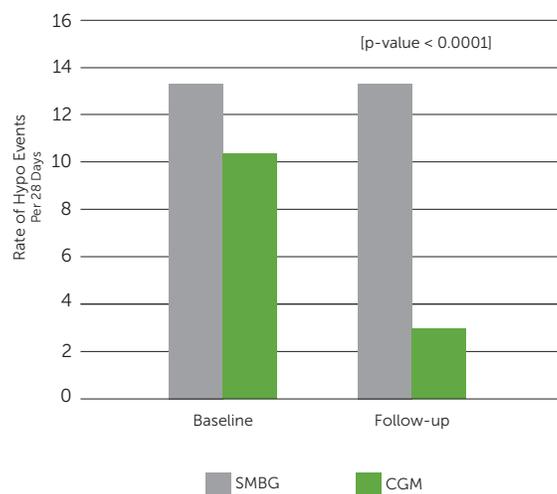
#### Dexcom CGM Use Reduced Hypoglycemic Events

Comparison of frequency of average number of hypoglycemic events per 28 days ( $\leq 3.0$  mmol/L for at least 20 minutes) in the CGM group to the control group.

- **Dexcom CGM group reduced the average number of hypo events by 72%<sup>‡</sup> from baseline (from 10.8 to 3.5).**
- SMBG group showed minimal reduction of hypo events (13.5 events at baseline; 13.2 events at follow-up).

<sup>‡</sup> Adjusted for baseline differences.

CGM use reduced frequency of hypoglycemic events compared to SMBG in individuals with MDI-treated type 1 diabetes.



# HypoDE Study<sup>1</sup>

## Dexcom CGM Significantly Reduces Hypoglycemia in High-Risk T1D MDI Patients



### Secondary Hypoglycemia Outcomes:

#### Reduced Hypo Events at Night

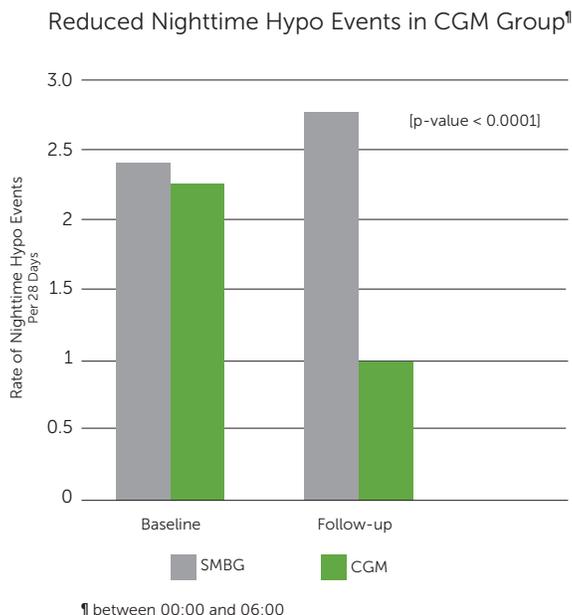
**The average rate of hypo events at night dropped by more than half in the CGM group from a rate of 2.3 events (per 28 days) at baseline to 1 event at follow-up.**

The SMBG group saw an increase from an average of 2.4 nighttime hypo events per 28 days at baseline to an average of 2.7 events at follow-up.

#### Significant Reduction of Hypoglycemia

8-fold reduction of median daily duration of glucose <3.0 mmol/L  
- from 24.1 minutes at baseline to 3.8 minutes.

SMBG group showed a modest decrease of 9%  
(from 36.3 minutes to 32.9 minutes)



## Why does reducing Hypoglycemic Events Matter?

The Hypoglycemia Study Group considers a blood glucose <3.0 mmol/L detected for at least 20 min, as sufficiently low to indicate serious, clinically significant hypoglycemia that should be included in reports of clinical trials. It needs to be avoided because of its immediate and long-term danger to the individual<sup>§</sup>.

## Dexcom CGM First™

Recognized as a standard of care in diabetes management by ADA, AACE and the Endocrine Society,<sup>4,6</sup> CGM use has been proven to both reduce HbA1c and decrease risk of hypoglycemia regardless of insulin delivery method.<sup>7</sup>

\* Baseline glucose data for all participants and the glucose data in the follow-up period for the SMBG group were collected using the Dexcom G4® PLATINUM CGM System, which uses the same software algorithm as the Dexcom G5® Mobile CGM System. Subjects in the CGM group used the Dexcom G5 Mobile in the treatment phase and the follow-up period. All CGM data collected in the baseline period and in the control group in the intervention period was blinded.

† Hypoglycemic event defined as glucose values < 3.0 mmol/L sustained for at least 20 minutes, preceded by a minimum of 30 minutes with glucose values > 3.0 mmol/L. Number of hypoglycemic events in baseline and follow-up phases were recorded for each patient and standardized to an incidence of hypo events per 28 days.

‡ The Clarke score measures hypo awareness, based on a response to 8 questions characterising an individual's exposure to moderate and severe hypo events. Scores 4 indicate IHA.

§ International Hypoglycaemia Study Group. Glucose concentrations of less than 3.0 mmol/L (54 mg/dL) should be reported in clinical trials: a joint position statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care 2017; 40:155-157

Optimize your patients' diabetes treatment plans and recommend a Dexcom CGM System today.

#### References

1 Heinemann L, Freckmann G, Faber-Heinemann G, Stefania Guerra S, Ehrmann D, Waldenmaier D, Hermanns N. Benefits of continuous glucose monitoring use in adults with type 1 diabetes and impaired hypoglycaemia awareness and/or severe hypoglycaemia treated with multiple daily insulin injections: Results of the multi-centre, randomised controlled HypoDE study. Lancet. In press. 2 Danne T, Nimri R, Battelino T, et al. International Consensus on Use of Continuous Glucose Monitoring. Diabetes Care. 2017;40(12):1631-1640. 3 Abaira C, Henderson WG, Colwell JA, et al. Response to Intensive Therapy Steps and to Glipizide Dose in Combination With Insulin in Type 2 Diabetes: VA feasibility study on glycemic control and complications (VA CSDM). Diabetes Care. 1998;21(4):574-579, as cited in Heinemann L, et al., 2018. 4 American Diabetes Association. Glycemic Targets: Standards of Medical Care in Diabetes-2018. Diabetes Care. 2018;41(Suppl 1):S55-S64. 5 Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. Endocr Pract. 2016;22(2):231-261. 6 Peters A, Ahmann A, Battelino T et al. Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2016;96(12):2534-2544. 7 Šoupal J, Petruželková L, Fleka M et al. Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study. Diabetes Technology & Therapeutics. 2016;18(9):532-538.