

## Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customisable Glycaemic Targets in Paediatric and Adult Participants With Type 1 Diabetes

- **Clinical objective:** to evaluate the safety and efficacy of the Omnipod<sup>®</sup> 5 Automated Insulin Delivery (AID) System, the first tubeless, on-body AID system with customisable glycaemic targets.
- **Primary end points** were change in HbA1c at the end of the AID phase compared with baseline and Time in Range 3.9-10.0 mmol/L during the AID phase compared with the Standard Therapy (ST) phase. Primary safety outcomes were incidence of severe hypoglycaemia and diabetic ketoacidosis (DKA).
- **Secondary end points** included percent time with glucose levels <3.9 mmol/L, >10.0 mmol/L and <3.0 mmol/L during the AID phase compared with the ST phase.
- **Significant improvements** in HbA1c and glycaemic measures, with a low rate of hypoglycaemia in a heterogeneous participant group with varied age, baseline glycaemia and prior insulin delivery regimen.

### Study Design

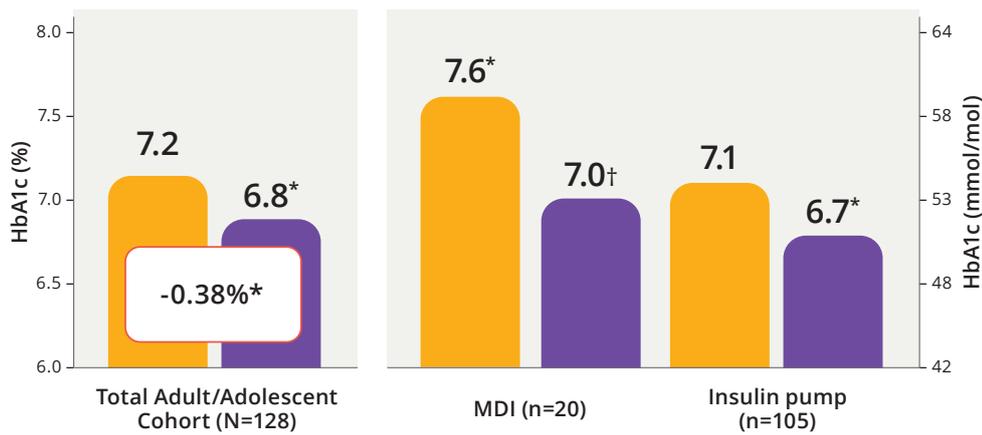
- Prospective, multicenter, single-arm outpatient study:
  - 14-day standard therapy phase
  - 3-month AID phase with Omnipod 5 system
- 240 children, adolescents and adults enrolled at 17 institutions across the US
- User-selected target glucose ranges from 6.1-8.3 mmol/L
- Unrestricted diet and exercise throughout

### Study Participants

- 112 Children: Age 6 to <14 years
- 128 Adolescents and Adults: Age 14 to 70 years
- All participants:
  - Type 1 diabetes for ≥6 months
  - HbA1c <10.0%
  - Any prior insulin therapy (MDI or CSII)

# Omnipod 5 System reduced HbA1c

## HbA1c is reduced by 0.38% in Adolescents and Adults<sup>1</sup>



Participant endorsement of the system was evident, with 95% enrolling in the extension phase.

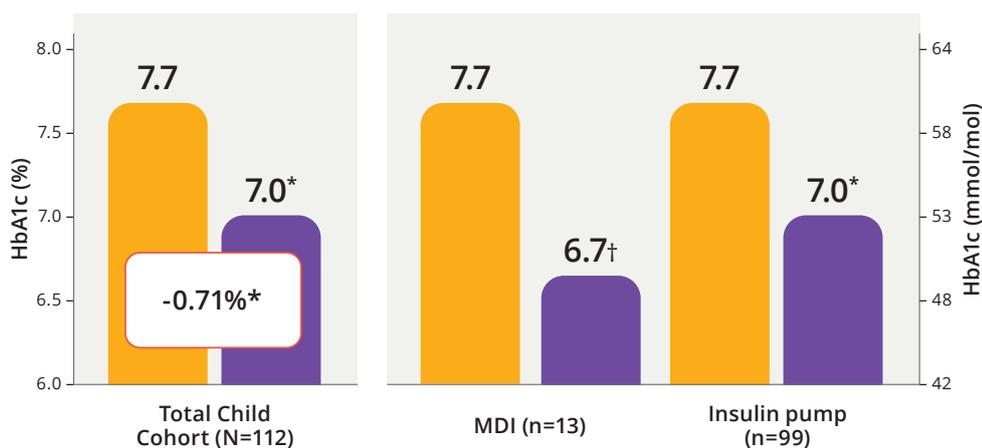
● Standard Therapy phase ● Omnipod 5 System phase

\* p<0.0001; † p=0.046. Baseline and follow-up data were used for the HbA1c primary endpoint. Data shown for Standard Therapy phase and AID phase.

Data shown as mean HbA1c.

MDI, multiple daily injections with insulin.

## HbA1c is reduced by 0.71% in Children<sup>1</sup>



Connectivity of the on-body devices was excellent, allowing use of automated insulin delivery for median 96.4% of possible time for children.

● Standard Therapy phase ● Omnipod 5 System phase

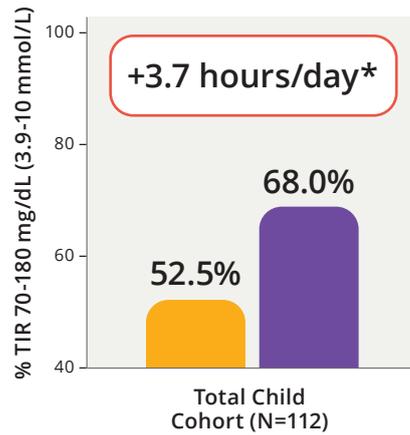
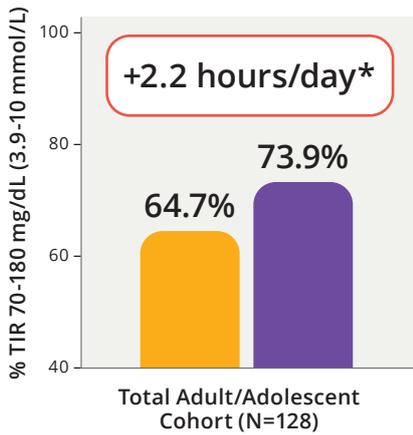
\* p<0.0001; † p<0.0005. Baseline and follow-up data were used for the HbA1c primary endpoint. Data shown for Standard Therapy phase and AID phase.

Data shown as mean HbA1c.

MDI, multiple daily injections with insulin.

# Omnipod 5 System increased Time in Range (TIR)

- TIR is improved by 2.2 hours/day (9.3%) in Adolescents and Adults<sup>1</sup>
- TIR is improved by 3.7 hours/day (15.6%) in Children<sup>1</sup>



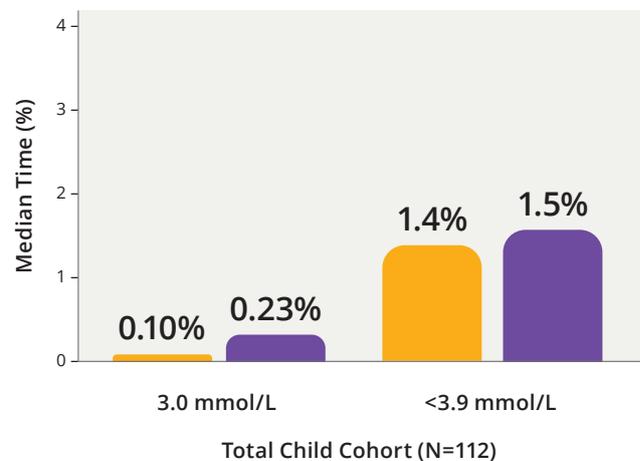
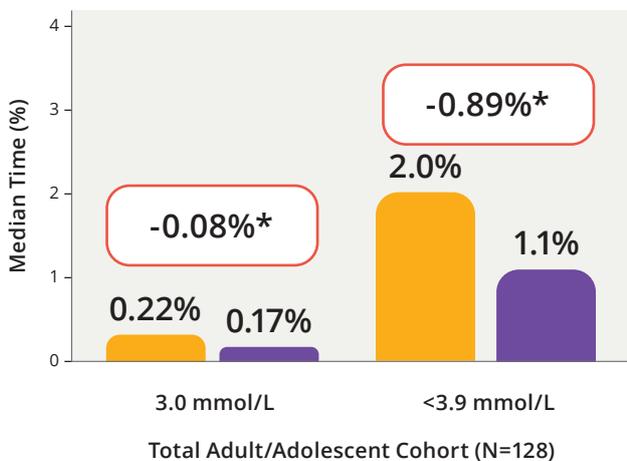
Children spent median 96.4% and adults/adolescents spent median 96.7% of total study time in automated mode.

● Standard Therapy phase ● Omnipod 5 System phase

\* p<0.0001. Data shown as mean %TIR

## Reduced time in hypoglycaemia in adolescents and adults, while time in hypoglycaemia remained low in children.

- Time in hypoglycaemia is reduced by 46% in Adolescents and Adults<sup>1</sup>
- Time in hypoglycaemia remains low in children



● Standard Therapy phase ● Omnipod 5 System phase

\* p<0.0001. Data shown as median %Time Below Ranges <3.9 mmol/L and <3.0 mmol/L.

3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis (DKA) were reported in participants aged 6-70 years durin Omnipod® 5 System use. These cases were not related to automated insulin delivery malfunction.

## Study Highlights:<sup>1</sup>

### Reduced HbA1c

- Omnipod 5 System lowered HbA1c by 0.38% in Adolescents/Adults, and by 0.71% in Children
- 66% of Adults/Adolescents and 53% of Children achieved the ADA recommended HbA1c target of <7.0%

### Increased Time in Range (TIR)

- Improved TIR by 2.2 hours/day (9.3%) in in Adolescents/Adults, and by 3.7 hours/day (15.6%) in Children
- 82% of Children and 69% of Adults/Adolescents met consensus clinical targets for TIR
- All age groups demonstrated 78% TIR overnight from 00:00–06:00 h during the study

### Low time in hypoglycaemia

- Omnipod 5 System reduced time in hypoglycaemia by 46% in Adults and Adolescents, including a 60% reduction in nocturnal hypoglycaemia<sup>2</sup> (00:00–06:00 h)
- Time in hypoglycaemia remained low throughout the study in Children

### System use

- Children spent median 96.4% and Adults/Adolescents spent median 96.7% of total study time in automated mode
- Incidence of severe hypoglycaemia and DKA were below reported rates in the US T1D Exchange Registry and were not attributable to AID malfunction



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published study



This summary has been provided as part of the Omnipod Academy, an educational service provided for Healthcare Professionals by Insulet International.

#### References:

1. Brown S A et al. Diabetes Care. 2021;44(7):1630-1640. Multicenter trial of a tubeless, on-body automated insulin delivery system with customisable glycaemic targets in paediatric and adult participants with type 1 diabetes. Study funded by Insulet.
2. Brown S A et al. Diabetes Care. 2021;44:1630-1640. Prospective pivotal trial in 240 participants with T1D, including 128 participants aged 14-70 yrs. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop (HCL) phase. Mean time in hypoglycaemic range (<3.9 mmol/L as measured by CGM; 12AM - < 6AM) as measured by CGM: ST: 2.07% vs. Omnipod 5: 0.82%, P<0.0001 Comparison is a relative change.

Always read the label and follow the directions for use.

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