Safety Evaluation of the Omnipod® 5 Automated Insulin Delivery System Over Three Months of Use in Adults and Adolescents with Type 1 Diabetes (T1D)

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Advances in diabetes technology have transformed the treatment paradigm for type 1 diabetes (T1D), yet the burden of disease remains significant. The Omnipod 5 Automated Insulin Delivery System is a novel hybrid closed-loop (HCL) system with fully on-body operation. The system consists of a tubeless insulin pump (pod) containing a personalized Model Predictive Control algorithm which communicates directly with a Dexcom G6 continuous glucose monitor (CGM, or sensor) to automate insulin delivery. Therapy customization is enabled through glucose targets from 110-150 mg/dL, adjustable by time of day. The system adapts to changing insulin needs with each pod change. We report on the first, pivotal outpatient safety evaluation of the system in a large cohort of adults and adolescents with T1D.

Participants aged 14-70y with T1D≥6 months and A1C<10% used the HCL system for 3 months at home after a 14-day run-in phase of their standard therapy (ST). Prior therapy included both pump therapy and multiple daily injections. The primary safety and effectiveness endpoints, respectively, were occurrence of severe hypoglycemia (SH) and diabetic ketoacidosis (DKA), and change in A1C and sensor glucose percent time in target range (TIR) (70-180 mg/dL) during HCL compared with ST.

Participants (N=128) were aged (mean±SD) 37±14y with T1D duration 18±12y and baseline A1C 7.2±0.9% (range 5.2-9.8%). There was a significant increase in TIR from ST to HCL, from 64.7±16.6% to 73.9±11.0% ($p<0.0001$), corresponding to an additional 2.2 hours/day in target range. A1C at end of study was reduced by 0.4%, from 7.2±0.9% to 6.8±0.7% ($p<0.0001$). Glycemic outcomes for percent of time with CGM readings below and above target range were all reduced ($p<0.0001$): <54 mg/dL from 0.6±1.2% to 0.2±0.3% (a decrease of 6 minutes/day), <70 mg/dL from 2.9±3.1% to 1.3±1.1% (a decrease of 23 minutes/day), >180 mg/dL from 32.4±17.3% to 24.7±11.2% (a decrease of 1.8 hours/day), and ≥250 mg/dL from 10.1±10.5% to 5.8±5.5% (a decrease of 1.0 hours/day). The mean glucose also decreased from 161±28 to 154±17 mg/dL ($p=0.0002$). During the 3-month HCL phase there were 2 episodes of SH (both following user-initiated boluses) and no episodes of DKA reported. Most participants completing the pivotal study (92%) opted to continue using the system during an extension phase.

In this outpatient, multi-center pivotal study in a large cohort of adults and adolescents with T1D, the Omnipod 5 System was safe and effective when used for 3 months at home. There were significant improvements in both TIR and A1C with use of the system, while time in hypoglycemic ranges was also reduced. The current results and commitment to the extension phase highlight the safe and effective use of the HCL system, as well as the preference for the Omnipod 5 System over participants' previous therapy.