Insulet's Omnipod® 5 Pivotal Study Extension Data Shows Significant Improvements in Glycemic Control With One Year of Use

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ACTON, Mass.--(BUSINESS WIRE)--Sep. 30, 2021-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in tubeless insulin pump technology with its Omnipod® brand of products, has presented positive pivotal trial extension phase results for the Omnipod® 5 Automated Insulin Delivery System (Omnipod 5). Omnipod 5, the world's first tubeless, wearable system that continuously adapts insulin delivery based on glucose levels and trends, significantly improved time in range and reduced HbA1c in children, adolescents, and adults, aged 6-70 years, with type 1 diabetes over a period of 12 months. The data was presented at EASD 2021, the annual meeting of the European Association for the Study of Diabetes.

"Reducing burden and making diabetes management easier through innovative technology is our number one goal at Insulet," said Dr. Trang Ly MBBS, FRACP, PhD, Insulet Senior Vice President and Medical Director. "We are very pleased that the positive safety and efficacy outcomes resulting from our pivotal study continued for those patients who used Omnipod 5 for a total of 12 months. This product is having an enduring positive impact on trial participants' health, and we couldn't be more proud."

Insulet also presented new clinical outcomes data for people with type 1 diabetes using the Omnipod DASH® System (Omnipod DASH) for 90 days, as well as overall positive self-management behaviors among individuals using Omnipod DASH, Continuous Glucose Monitoring (CGM) and a cloud-based diabetes data management system.

Omnipod 5 System Extension Data Overview

Following completion of the 3-month pivotal trial, the results of which were previously shared, 95% of study participants chose to continue use of Omnipod 5 in an ongoing extension study. Insulet presented its data in two groups of extension study participants with type 1 diabetes: 114 adults and adolescents between 14 and 70 years old, and 110 children aged 6 to 13.9 years. The participants used Omnipod 5 at home for a period of 12 months after a 14-day period using their standard therapy, which included both pump therapy and multiple daily injections. The results were presented in 3-month intervals: months 1-3 (the pivotal study), months 4-6, months 7-9, and months 10-12.

After 3 months of system use, adults and adolescents had a decrease in HbA1c from 7.2% to 6.8%. This decrease was maintained after a total of 12 months of use, with mean HbA1c remaining at 6.8%. Time in range (TIR) increased from 63.6% to 73.8% in the first 3 months of use, and persisted at 72.7% in months 10-12 of use, corresponding to an additional 2.3 hours in target range. Median time <70 mg/dL (<3.9 mmol/L) decreased from 2.1% to 1.1% after 3 months of use and remained at 1.1% in months 10-12 of use.

Children had a decrease in HbA1c from 7.7% to 7.0% after 3 months of system use. This decrease was maintained after a total of 12 months of system use, with mean HbA1c remaining at 7.0%. TIR increased from 52.4% to 67.9% in the first 3 months of use, and persisted at 66.8% in months 10-12 of use, corresponding to an additional 3.5 hours per day in target range. Median time <70 mg/dL (<3.9 mmol/L) remained low at 1.5% in the first 3 months of use and 1.4% in months 10-12 of use.

"The pivotal study results were certainly impressive, but what's even more exciting is that these outcomes were maintained over an entire year of use," said Dr. Anders Carlson, Medical Director of the International Diabetes Center. "Insulet has shown that these positive clinical outcomes can be maintained in real-world conditions, with a frequency of visits very similar to the usual standard of care."

The Omnipod 5 System received breakthrough device designation from the U.S. Food and Drug Administration and is currently under premarket review. The Company expects to launch Omnipod 5 in limited release in the U.S. late in the fourth quarter 2021. The device is currently not CE marked or available in Europe.

Omnipod DASH Study Results

Insulet also presented two studies of people living with type 1 diabetes using Omnipod DASH. The first study evaluated glycemic improvement after 90 days of use in 4,738 individuals ranging in age from under 2 to over 65 years. The study was divided into two groups: children and adolescents under 18 years of age and adults 18 years or older.

Overall, there was a significant decrease in HbA1c of -0.9% and a reduction in self-reported hypoglycemic events (<70 mg/dL [<3.9 mmol/L]) from 2.9 episodes to 1.3 episodes per week in adults and from 2.8 to 1.5 in children and adolescents. These patient-reported outcomes provide positive evidence that the use of Omnipod DASH was associated with significant reductions in HbA1c and hypoglycemic events after the initial 90 days of use for children, adolescents, and adults living with type 1 diabetes.

The second presentation covered the first real-world study of 2,586 people living with type 1 diabetes on Omnipod DASH with CGM and cloud-based data management. Participants included Omnipod DASH users with at least 90 days of insulin pump data in a cloud-based data management system between July 2018 and August 2021, as well as a minimum of 14 days of CGM readings over a 3-month period. The study resulted in positive glycemic outcomes, with mean estimated HbA1c ranging from 7.2 to 7.7%, and a low percentage of time in hypoglycemia across all age groups. Overall, the mean TIR (70-180 mg/dl [3.9 – 10.0 mmol/L]) was 59.6%, with median 1.3% of time below 70mg/dL (<3.9 mmol/L) and 0.2% of time below 54 mg/dL (<3.0 mmol/L).

These real-world data demonstrate positive self-management behaviors among a large cohort of Omnipod DASH users, ranging from young children to older adults.

About Insulet Corporation:

Insulet Corporation (NASDAQ: PODD), headquartered in Massachusetts, is an innovative medical device company dedicated to simplifying life for people with diabetes and other conditions through its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet also leverages the unique design of its Pod by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across other therapeutic areas. For more information, please visit: insulet.com and omnipod.com

Forward-Looking Statement:

This press release may contain forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs, or strategies regarding the future. These forward-looking statements are based on its current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 24, 2021 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

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