Insulet Corporation

Omnipod® 5 Automated Insulin Delivery System Significantly Improves Glycemic Outcomes Over 12 Months of Use in Children Aged 2 through 5.9 Years

June 3, 2022

Insulet Presents Pivotal Extension Data for Preschool Children and Other Omnipod® 5 System Clinical Research at American Diabetes Association 82nd Scientific Sessions

ACTON, Mass.--(BUSINESS WIRE)--Jun. 3, 2022-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in tubeless insulin pump technology with its Omnipod® brand of products, today presented new Omnipod® 5 Automated Insulin Delivery System (Omnipod 5) study results for very young children with type 1 diabetes. Omnipod 5, the first tubeless, wearable automated insulin delivery (AID) system in the U.S., significantly improved time in range and reduced HbA1c in children aged 2 through 5.9 years with type 1 diabetes over 12 months of use. This pivotal trial extension data was presented at the American Diabetes Association (ADA) 82nd Scientific Sessions in New Orleans, Louisiana.

“One of our biggest goals in the development of Omnipod 5 was to ease the burden that type 1 diabetes places on families and caregivers of this vulnerable age group,” said Dr. Trang Ly MBBS, FRACP, PhD, Insulet Senior Vice President and Medical Director. “With these preschool extension trial results, we have demonstrated improved glycemic results over the long term for very young children managing diabetes. I’m incredibly proud of this remarkable achievement and know that Omnipod 5 will have a big impact on these families.”

In the original three-month pivotal trial, Omnipod 5 was shown to be safe and effective, significantly improving time in range and reducing HbA1c in 80 very young children (ages 2 to 5.9 years) with type 1 diabetes. Insulet previously presented these results at the ADA Virtual 81st Scientific Sessions in 2021.

The pivotal trial participants were invited to continue using the Omnipod 5 System in an ongoing 12+ month extension phase, with 100% electing to participate. Results were analyzed after all participants had completed a total of 12 months of Omnipod 5 use (three months in the pivotal trial and nine months in the extension phase). The extension phase results demonstrated that participants continued to experience significantly improved outcomes compared with baseline throughout 12 months of system use, including lower HbA1c and greater time in range, and there were no episodes of DKA or severe hypoglycemia.

After 12 months of Omnipod 5 use, average HbA1c was 6.9%, compared with 7.4% at baseline and 6.9% at the end of the three-month pivotal trial. Similarly, percent time in range during months 10 – 12 of use was 67.6%, compared with 57.2% during standard therapy and 68.1% during the three-month pivotal trial. Percent time in hypoglycemia (<70 mg/dL) was reduced compared with standard therapy: the median was 1.9% during months 10 – 12 of use compared with 2.2% during standard therapy and 1.9% during the three-month pivotal trial.

“I’m delighted to report that the safety and improved glycemic outcomes from the initial three-month pivotal study in pre-school aged children continued for an additional nine months, indicating the potential long-term benefit of the Omnipod 5 System in very young people with type 1 diabetes,” said Dr. Daniel DeSalvo, MD of Baylor College of Medicine. “It is particularly challenging for caregivers to manage diabetes in children under six, given their unpredictable eating habits and activity levels. These results, along with the system’s tubeless form factor and ease of use, make Omnipod 5 an excellent choice for automated insulin delivery in this age group, not only for optimizing glycemic outcomes but for alleviating the burden of diabetes for the entire family.”

Additional clinical data will be presented, demonstrating improved outcomes for adults and children with type 1 diabetes, as well as adults with type 2 diabetes, using the Omnipod 5 System. In particular, Insulet anticipates great interest in the results from the extension phase of the Omnipod 5 feasibility trial in people with type 2 diabetes. There are a total of five oral and poster presentations at ADA.

The following is the schedule of Omnipod clinical presentations:

Oral Presentation:

Friday, June 3, 4:15 – 4:30 p.m. CT (Hall E-2, Level 1)

33-OR **Glycemic Outcomes over 12 Months in Very Young Children with the Omnipod 5 Automated Insulin Delivery (AID) System**, ADA Presidents’ Select Abstract with Dr. Daniel DeSalvo

Poster Presentations:

Saturday, June 4, 12:30 – 1:30 p.m. CT (ePoster, Theater A)

759-P **Glycemic Outcomes over 15 Months with the Omnipod 5 Automated Insulin Delivery System** with Dr. Amy Criego *(will also be presented in Sunday’s General Poster Session 12:00-1:00 p.m. CT)*

Sunday, June 5, 12:00 – 1:00 p.m. CT (Poster Hall, Halls D-E)

769-P **Glycemic Outcomes in Adults with Type 2 Diabetes over 34 Weeks with the Omnipod 5 Automated Insulin Delivery System** with Dr. Georgia Davis

766-P **Glycemic Outcomes with the Omnipod 5 Automated Insulin Delivery System Stratified by Baseline Hypoglycemia Risk among People with Type 1 Diabetes Ages 2 to 70 Years** with Dr. Gregory Forlenza

765-P **Glycemic Outcomes across Total Daily Insulin Doses with the Omnipod 5 Automated Insulin Delivery System among People with**

Type 1 Diabetes Ages 2 to 70 Years with Dr. Melissa Schoelwer

Promotional Activities:

Insulet will host a Product Theater, "*Omnipod® 5 Automated Insulin Delivery System – Simplified Glucose Management & Improved Clinical Results for Type 1 Diabetes,"* on Monday, June 6 from 10:15 – 11:00 a.m. CT. During this program, Insulet will share key insights gained from clinical investigators, best practices for optimizing glycemic management, and several case studies highlighting the simplicity and improved clinical results for those transitioning from MDI and other therapies. Dr. Trang Ly will moderate, with Dr. Grazia Aleppo from the Feinberg School of Medicine at Northwestern University and Dr. Viral Shah from the Barbara Davis Center for Diabetes at the University of Colorado participating as panelists.

Insulet will debut a new podcast geared toward healthcare providers caring for people with diabetes, recording the first episode in front of a live audience at the Omnipod booth. Dr. Grazia Aleppo and Dr. Amy Criego will be interviewed on the Omnipod 5 extension data and other topics from ADA. Dr. Diana Isaacs and Dr. Gregory Forlenza will also be interviewed about the importance of the entire diabetes care team, particularly how the collaboration between this team can strive to meet the needs of people living with diabetes.

In addition, the Omnipod booth will include a pharmacy area to demonstrate the value of accessing Omnipod DASH® and Omnipod 5 at retail pharmacies and educate healthcare providers on prescribing Omnipod products.

Sponsored Programs:

Insulet will also sponsor the Diabetes Mine d-data Exchange, an annual program focusing on diabetes technology and innovation, and the TCOYD diaTribe Diabetes Forum, an impactful and sophisticated discussion on the cutting-edge developments in diabetes from key opinion leaders.

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's latest innovation, the Omnipod 5 Automated Insulin Delivery System, is a tubeless automated insulin delivery system, integrated with a continuous glucose monitor to manage blood sugar with no multiple daily injections, zero fingersticks, and is fully controlled by a compatible personal smartphone. 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, 2022 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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