Insulet Corporation

Insulet's Omnipod® 5 Automated Insulin Delivery System Pivotal Studies Demonstrate Improved Outcomes Across the Lifespan from Ages 2 to 70 years

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ACTON, Mass.--(BUSINESS WIRE)--Jun. 26, 2021-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in tubeless insulin pump technology with its Omnipod® brand of products, today announced promising results from its latest pivotal trial for the Omnipod 5 Automated Insulin Delivery System (Omnipod 5) in very young children. Omnipod 5, the world's first tubeless, wearable automated insulin delivery (AID) system that continuously adapts insulin delivery based on glucose levels and trends, significantly improved time in range and reduced HbA1c in children aged 2 through 5.9 years with type 1 diabetes. These pivotal study data from the preschool age group were presented at the American Diabetes Association (ADA) Virtual 81st Scientific Sessions.

"Managing type 1 diabetes in very young children is particularly challenging due to their unpredictable eating patterns, erratic physical activity, and an increased fear of hypoglycemia from caregivers, since these patients often cannot self-treat or verbalize their symptoms," said Dr. Trang Ly MBBS, FRACP, PhD, Insulet Senior Vice President and Medical Director. "Omnipod 5 has tremendous potential to improve outcomes and ease of use for our youngest patients, and we are delighted to share these pivotal trial results."

Omnipod 5 Preschool Pivotal Study Overview

Insulet enrolled a group of 80 preschool aged children across 10 U.S. sites for this study. The participants, who were between 2 and 5.9 years of age with an HbA1c of under 10.0%, used Omnipod 5 at home for a period of 3 months after a 14-day period using their standard therapy, which included either pump therapy or multiple daily injections (MDI). The children were unrestricted in eating and exercise throughout the study.

The study showed an overall reduction in HbA1c from an average of 7.4% to 6.9%, and a significant increase in time in range (70-180 mg/dL), from an average of 57.2% to 68.1%, or an additional 2.6 hours per day. Median time in hypoglycemia (<70 mg/dL) was reduced, from 2.2% to 1.9% overall.

In addition, parents and caregivers of study participants reported improved sleep quality as assessed by the Pittsburgh Sleep Quality Index (PSQI)[1], a questionnaire considered to be the gold standard in measuring subjective sleep quality. Parents and caregivers reporting "very good" or "fairly good" sleep increased from 65% at baseline to 90% at the end of the study.

"These results are impressive, not only for our youngest patients, but also for their families," said Dr. Jennifer Sherr, Principal Investigator and Associate Professor, Yale University School of Medicine. "Diabetes is a team sport — all members of the family are impacted, often with far-reaching consequences. Caregivers often have poor sleep quality as they strive for safety, with ensuing fatigue that affects family dynamics. These results show that Omnipod 5 can have a positive impact on the entire family."

It is also noteworthy that 100% of the preschool pivotal trial participants opted to continue using Omnipod 5 in a 12-month extension phase, which demonstrates their overall satisfaction with the system and the clinical outcomes achieved.

Additional Omnipod 5 Data Presented at ADA

Insulet also shared additional results from the Omnipod 5 pivotal study in people aged 6 through 70 years with type 1 diabetes, including clinical outcomes after transitioning from MDI, extension study results with 6 months of system use, and quality of life and user satisfaction data:

- **Transition from MDI to Omnipod 5 Improves HbA1c**
  The 33 participants in the pivotal trial transitioning from MDI to Omnipod 5 achieved significant improvement in HbA1c (children: 7.73% to 6.74%, adolescents and adults: 7.57% to 6.97%) and time in range (children: 52.2% to 68.9%; adolescents and adults: 60.4% to 72.3%) after 3 months of use. These results support the feasibility of transitioning directly from MDI to automated insulin delivery with Omnipod 5.

- **Improved Glycemic Outcomes over 6 Months with Omnipod 5**
  A total of 224 pivotal study participants continuing use of Omnipod 5 in an extension study demonstrated sustained improvements in HbA1c over a total of 6 months of system use. Pediatric results decreased from an average of 7.7% at baseline to 6.9% at 6 months, and the adolescent and adult cohort decreased from an average of 7.2% to 6.7%. The extension study also revealed sustained improvements in time in range with minimal time below range.

- **Adults, Adolescents, and Caregivers Report Improved System Usability, Satisfaction, and Quality of Life with Omnipod 5**
  Equally as important as the glycemic outcomes are the results describing Omnipod 5 usability, user satisfaction, and impact on quality of life from the pivotal trial. Users reported significantly improved scores with the System Usability Scale following 3 months of Omnipod 5 use, with a mean baseline score of 75.9, 79.4 and 77.5 out of a maximum of 100 to a final score of 83.8, 86.3 and 89.0 for adults, teens, and caregivers of children, respectively. These results demonstrate that users perceived Omnipod 5 to be a more usable product compared to their prior therapy.

  Adults and caregivers of teens and children also reported increased satisfaction with their treatment as measured by the

Insulin Delivery Satisfaction Survey and the Diabetes Treatment Satisfaction Questionnaire, suggesting that Omnipod 5 may alleviate some of the burdens associated with existing treatment options for type 1 diabetes both for adults and caregivers of younger users.

Furthermore, Omnipod 5 led to significant improvements in quality-of-life measures, including reductions in diabetes-related distress across all groups, and improved hypoglycemic confidence among adults and caregivers of children. As indicated by these outcomes, reduced diabetes distress and improved quality of life are key benefits of using the Omnipod 5 AID system that are complementary to the glycemic benefits achieved.

Omnipod System and Omnipod DASH® Improve Clinical Outcomes in Children and Adults Living with Type 1 Diabetes

Insulet also presented data related to the Company's non-AID insulin delivery system products, the Omnipod System and Omnipod DASH System, both currently available in the U.S., Canada, and in several international markets. In the largest adult cohort study of 13,389 people with type 1 diabetes initiating therapy with the Omnipod System or Omnipod DASH System in the U.S. to date, HbA1c was reduced significantly (-0.8%), which was achieved with an 18% reduction in daily insulin dosage and a reduction in self-reported hypoglycemia from 3 episodes to 1.6 episodes per week. Similar results were seen in an analysis in 6,034 children, which included data from children below the age of 2 years.

Upcoming Webinar

Next month, Insulet will host a webinar summarizing all of the Company's data presented at ADA. This webinar will be led by Dr. Ly and will feature U.S. health care providers presenting the clinical data and sharing the features and benefits of Omnipod 5. To learn more and to register for the event, scheduled for July 22, click here.

The Omnipod 5 System received breakthrough device designation from the U.S. Food and Drug Administration and is currently under review. The Company expects to launch Omnipod 5 in the U.S. in limited release during the second half of 2021.

[1] *The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research (Authors Daniel J. Buysse, Charles F. Reynolds III, Timothy H. Monk, Susan R. Berman, and David J Kupfer, © 1989 and 2010, University of Pittsburgh. All rights reserved.)*

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: www.insulet.com and www.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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