Insulet's Omnipod® 5 Automated Insulin Delivery System Improves Clinical Outcomes in Type 1 Diabetes

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ACTON, Mass.--(BUSINESS WIRE)--Mar. 20, 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 positive results from the first pivotal trial for the Omnipod® 5 Automated Insulin Delivery System. 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. The data was presented at ENDO 2021, the Endocrine Society's annual meeting and a leading forum for endocrinology research and clinical care worldwide.

"Our team has been committed to developing a hybrid closed-loop insulin delivery system to advance the treatment of insulin-dependent diabetes," said Trang Ly MBBS, FRACP, PhD, Insulet Senior Vice President and Medical Director. "Our pivotal study has achieved remarkable improvement in glucose control, evidenced by impressive reduction in HbA1c and improved time in range, together with the lowest rates of hypoglycemia. We are incredibly proud of these results, which demonstrate the system is safe and effective across a wide range of age groups. This is another step forward in our mission to simplify life for people with diabetes."

Omnipod 5 System Pivotal Study Overview

Insulet presented its data in two groups of type 1 diabetes patients: 128 adults and adolescents between 14 and 70 years old, and 112 children age 6 to 13.9 years. The participants used the Omnipod 5 System at home for a period of 3 months after a 14-day period using their standard therapy, which included both pump therapy and multiple daily injections.

The Omnipod 5 System showed a significant increase in time in range (70-180 mg/dL) in the adults and adolescents, from 65% to 74%, or an additional 2.2 hours per day, and an overall reduction of HbA1c from 7.16% to 6.78%. Participants also saw a decrease in mean glucose from 161 to 154 mg/dL. Median time below 70 mg/dL improved from 2.0 to 1.1%. At a target glucose of 110 mg/dL, subjects achieved 76% time in range.

In children, time in range improved from 53% to 68%, corresponding to an additional 3.7 hours per day in target range. Additionally, HbA1c improved from 7.67% to 6.99% and the mean glucose level decreased from 183 to 160 mg/dL. Median time below 70 mg/dL stayed remarkably low at 1.5%.

"The daily management of type 1 diabetes is relentless," said Jose S., father of a pediatric pivotal trial participant. "Caregivers make multiple decisions each day that profoundly affect their loved one's wellness and safety. Insulet's Omnipod 5 System reduces this burden by automating much of the decision making. It also provided me peace of mind by mitigating the threat of hypoglycemia."

Assistant Professor Gregory Forlenza at Barbara Davis Center, University of Colorado and Principal Investigator agreed that Omnipod 5 makes diabetes management simpler, while improving overall clinical results for users.

"The Omnipod 5 System is phenomenal, improving diabetes outcomes for children and adults while greatly reducing the burden of diabetes management," said Dr. Forlenza. "With the algorithm built into the Pod itself, it is easier than ever for people with diabetes to rely on automated insulin delivery to manage their blood glucose levels and keep them in range. Insulet has created a very impressive device that will surely change lives."

Nearly all participants completed the pivotal study (98% of all participants) and virtually all of those opted to continue using the Omnipod 5 System during an extension phase of the study. The study results and participants' desire to continue with the extension phase demonstrates their overall satisfaction with the Omnipod 5 System.

"It was remarkable how quickly every family learned to trust the automation, allowing people to sleep through the night for the first time in years," said Professor Irl Hirsch, University of Washington. "The significant improvement in glycemic outcomes they achieved with the use of Omnipod 5, including the remarkably low rates of hypoglycemia, led to a tremendous reduction in the burden of care for so many."

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 limited release during the first half of 2021.

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 in February 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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Investor Relations:
Deborah R. Gordon
Vice President, Investor Relations
(978) 600-7717
dgordon@insulet.com

Jason McGorman
Principal Investor Relations Analyst
(978) 600-7627
jmcgorman@insulet.com

Media:
Angela Geryak Wiczek
Senior Director, Corporate Communications
(978) 932-0611
awiczek@insulet.com

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