Insulet Corporation

Insulet Announces CE Mark Approval for Omnipod® 5 Automated Insulin Delivery System

ACTON, Mass.—Sep. 20, 2022 — (BUSINESS WIRE)— Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in tubeless insulin pump technology with its Omnipod® brand of products, today announced it has received CE marking under the European Medical Device Regulation for its Omnipod 5 Automated Insulin Delivery System (Omnipod 5) for individuals aged two years and older with type 1 diabetes.

“There is tremendous enthusiasm for Omnipod 5 from the global diabetes community, and we are thrilled to have achieved this latest milestone,” said Jim Hollingshead, President and CEO of Insulet. “With Omnipod 5, customers can enjoy the lifestyle benefits of a tubeless, wearable innovation and achieve positive clinical outcomes while managing their diabetes.”

Omnipod 5 is the first CE marked tubeless hybrid closed loop system (also known as automated insulin delivery) that integrates with the Dexcom G6 Continuous Glucose Monitoring (CGM) System to automatically adjust insulin and help protect against high and low glucose levels [1]. The system[2] consists of the tubeless Pod enhanced with SmartAdjust™ technology, the Omnipod 5 Controller with its integrated SmartBolus Calculator, and the Dexcom G6 CGM.

Every five minutes, SmartAdjust technology receives a CGM value and trend, and predicts where glucose will be 60 minutes into the future. The system then increases, decreases, or pauses insulin delivery based on the user’s desired and customized glucose target.

"Today’s announcement is a significant step forward for people in Europe living with diabetes,” said Kevin Sayer, Chairman, President and CEO of Dexcom. “We’re proud to partner with Insulet, combining our industry-leading Dexcom G6 CGM technology with their tubeless, wearable insulin delivery system, to improve clinical outcomes and reduce the burden of glucose management for people with diabetes.”

New clinical data demonstrating the safety and effectiveness of Omnipod 5 on recently diagnosed people with type 1 diabetes will be presented at the upcoming European Association for the Study of Diabetes (EASD) meeting in Stockholm, Sweden on Thursday 22 September. To learn more and to register for EASD, visit the conference website.

Insulet expects Omnipod 5 to be available in select countries starting mid-2023. To learn more about Omnipod 5, visit the Omnipod website.

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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 and zero fingersticks[3]. 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.

[1]Study in 240 people with T1D aged 6 - 70 years involving 2 weeks standard diabetes therapy followed by 3 months Omnipod 5 use in Automated Mode. Average time with high blood glucose in adults/adolescents and children, standard therapy vs. 3-month Omnipod 5: 32.4% vs. 24.7%; 45.3% vs. 30.2%. Median time with low blood glucose in adults/adolescents and children, standard therapy vs. 3-month Omnipod 5: 2.0% vs. 1.1%; 1.4% vs. 1.5%. Brown et al. Diabetes Care (2021). Study in 80 children with T1D aged 2 to 5.9 years involving two weeks of standard diabetes therapy followed by three months Omnipod 5 use in Automated Mode. Average overnight time (12AM-6AM) with high blood glucose in children for standard therapy vs. Omnipod 5 was 38.4% vs. 16.9%. Average day time (6AM-12AM) with high blood glucose in children for standard therapy vs. Omnipod 5 was 39.4% vs. 29.5%. Median overnight time (12AM-6AM) with low blood glucose in children for standard therapy vs. Omnipod 5 was

3.41% vs. 2.13%. Median day time (6AM-12AM) with low blood glucose in children for standard therapy vs. Omnipod 5 was 3.43% vs. 2.46%. Sherr J, et al. Diabetes Care (2022).

[2]*Integration with the Dexcom G6 CGM is required for automated insulin delivery.*

[3]*If a user's glucose alerts and readings from the G6 do not match symptoms or expectations or a user is taking over the recommended maximum dosage amount of 1,000 mg of acetaminophen every six hours, one should use a blood glucose meter to make diabetes treatment decisions.*

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