NEWS RELEASE

Insulet Initiates EVOLVE Pivotal Study to Advance Fully Closed-Loop Automated Insulin Delivery System for Type 2 Diabetes

2026-05-04

- First participant enrolled in randomized control trial designed to demonstrate safety and efficacy of Insulet's fully closed-loop automated insulin delivery system versus standard therapy
- Unique algorithm automatically adjusts insulin delivery, eliminating mealtime interaction and redefining the healthcare provider experience

ACTON, Mass.--(BUSINESS WIRE)-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in **tubeless insulin pump technology** with its Omnipod® brand of products, has enrolled the first participant in a pivotal study for its fully closed-loop (FCL)[A] automated insulin delivery (AID) system for type 2 diabetes (T2D). FCL for T2D is a breakthrough innovation intended to further improve glycemic outcomes with less burden for users across diverse care settings. That includes eliminating user interactions for bolusing and mealtime announcements for people with T2D as well as settings to start and onboard.

"Our innovation strategy is grounded in empathy and steadfast in our mission to transform the lives of people with diabetes," said Dr. Trang Ly, Senior Vice President and Chief Medical Officer at Insulet. "Enrolling the first EVOLVE study participant marks an important step toward a fully closed-loop AID system. Powered by a novel algorithm trained on extensive real and simulated patient data to safely titrate dosing and automatically adjust insulin delivery, our fully closed-loop AID system is uniquely designed to further reduce the burden for people with type 2 diabetes and their care teams."

Advancing AID Through a Fully Closed Loop System

The EVOLVE clinical study is a multi-center randomized control trial actively enrolling up to 350 adults across a maximum of 40 U.S. sites. The participants are between 18 – 75 years of age, living with T2D and using insulin (basal-bolus or basal-only). The Company received Investigational Device Exemption (IDE) approval in March 2026 from the U.S. Food and Drug Administration (FDA).

The Company aims to remove barriers and expand access to AID, particularly in primary care, where approximately 70% of people with T2D are managed. By streamlining onboarding and training and eliminating start-up settings, Insulet's FCL for T2D is designed to reduce workload and support healthcare professionals across specialties and care settings.

The EVOLVE [D] Pivotal Study follows a three-part series of feasibility studies to support the development of Insulet's FCL AID system. The Company presented **promising feasibility results** at the 19th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD) in Barcelona, Spain, including a 24% time in range (TIR) improvement, for an average of 68%, over standard injection therapy.

Delivering Meaningful Impact Today While Innovating for Tomorrow

In 2024, Insulet shared results from its landmark **SECURE-T2D** pivotal trial, demonstrating improved glycemic outcomes with Omnipod 5 compared with prior insulin injection or pump therapy in adults with T2D. Participants experienced a reduction in HbA1c from 8.2% to 7.4% and a 20% increase in TIR– from 45% to 66% or 4.8 hours daily.

With these results, Insulet was the first company to receive 510(k) clearance for an AID system, Omnipod 5, for adults with T2D. Since then, the Company has seen impressive adoption rates and real-world evidence of glycemic improvements including more than 80% TIR with optimized settings for people with T2D using Omnipod 5 [E].

While Insulet's type 2 prescriber base in the U.S. grew by more than 60% in 2025 to more than 6,500 clinicians, AID adoption remains well below 5% for the estimated 5.5 million people with T2D who require insulin. Insulet is committed to continuing to expand adoption of AID for this population, as recommended by the American Diabetes Association's 2026 Standards of Care.

The Company plans to submit a 510(k) filing to the FDA in 2027 and launch its FCL AID system for T2D in 2028.

[A] The FCL AID System is an investigational device. Limited by Federal (or United States) law to investigational use. This product has not been reviewed by the FDA or any other regulatory agency.

[B] Venkatraman S, et al. Trends and Disparities in Glycemic Control and Severe Hyperglycemia Among U.S. Adults

with Diabetes Using Insulin, 1988-22020. JAMA Netw Open. 2022 Dec 1;5(12). The EVOLVE study will evaluate a new fully closed-looped AID system for Type 2 diabetes.

[C] Pilla, S.J., Segal, J.B. & Maruthur, N.M. Primary Care Provides the Majority of Outpatient Care for Patients with Diabetes in the US: NAMCS 2009–2015. J GEN INTERN MED 34, 1089–1091 (2019). **https://doi.org/10.1007/s11606-019-04843-9**

[D] **https://clinicaltrials.gov/study/NCT07521475**

[E] Retrospective RWE data on file. 2025. Results shown for T2D users with optimized settings including sufficient CGM data (≥75% of days with ≥220 readings), ≥90% time in Automated Mode, ≥3 bolus/day and an average Target Glucose of 110-115 mg/dL (6.1-6.4 mmol/L). Optimized settings: ISF x TDI ≤1500, I:C Ratio x TDI ≤350. RF-062025-00014.

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 tubeless disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet's flagship innovation, the Omnipod 5 Automated Insulin Delivery System, integrates with a continuous glucose monitor to manage blood sugar with no multiple daily injections, zero fingersticks, and can be controlled by a compatible personal smartphone in the U.S. or by the Omnipod 5 Controller. 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 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 21, 2025 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 materially from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

Investor Relations:

Clare Trachtman

Vice President, Investor Relations

ir@insulet.com

Media:

Cristal Downing

Chief Corporate Affairs Officer

pr@insulet.com

Source: Insulet Corporation