

Insulet

NEWS RELEASE

Insulet Reveals New Data Supporting Breakthrough Omnipod® 6 and Fully Closed-Loop AID Systems Designed to Improve Outcomes, Reduce Effort, and Unlock Barriers to Care

2026-06-06

- STRIVE pivotal trial shows Omnipod 6 achieved strong glycemic outcomes with fewer boluses, across age groups and diabetes types
- EVOLUTION 3 feasibility study demonstrates improved time in range using a fully closed-loop system for type 2 diabetes that automatically adjusts insulin with no user settings

ACTON, Mass.--(BUSINESS WIRE)-- Insulet Corporation (NASDAQ: PODO) (Insulet or the Company), the global leader in **tubeless insulin pump** technology with its Omnipod® brand of products, today announced new clinical results highlighting the next breakthroughs in tubeless Automated Insulin Delivery (AID) systems. The data and growing body of evidence not only confirm the impact of Insulet's technology today—it also fuels continued investment in breakthrough innovation designed to improve outcomes, reduce daily effort, and expand access to diabetes technology.

Results from the STRIVE pivotal trial and the EVOLUTION 3 feasibility study, presented at the American Diabetes Association (ADA) 86th Scientific Sessions in New Orleans, demonstrate meaningful improvements in glucose control for people with diabetes using Insulet's future AID system — Omnipod 6 — and unique fully closed-loop (FCL) system for type 2 diabetes.*

"Omnipod 6 represents one of our biggest steps forward yet, with greater personalization and responsiveness to hyperglycemia, by delivering up to 50% more automated insulin, as shown in the STRIVE results," said Dr. Trang Ly,

MBBS, FRACP, PhD, Senior Vice President and Chief Medical Officer at Insulet. “Our fully closed-loop system for type 2 diabetes is intentionally designed to unlock barriers to AID by managing mealtime insulin and simplifying workflows to expand clinic adoption. Strong results from EVOLUTION 3 bring us one big step closer to making fully closed-loop for type 2 diabetes a reality.”

Together, results from STRIVE and EVOLUTION 3 underscore Insulet’s continued commitment to building a future where managing diabetes is dramatically simpler. This progress aligns with the Company’s innovation philosophy: build technology that doesn’t just do more but demands less.

STRIVE Study Overview

The STRIVE pivotal trial was designed to evaluate the safety and efficacy of the next-generation Omnipod 6 algorithm.

The randomized, crossover study included 132 participants across the U.S., including 98 with type 1 diabetes and 34 with type 2 diabetes. The type 1 cohort spanned a broad age range, including 29 participants aged 2 to <6 years, 36 aged 6 to <14 years, and 33 aged 14–70 years. Baseline glycemia was near recommended targets, with mean HbA1c values of 6.9% and 7.3% for type 1 and type 2 diabetes, respectively.

Participants were randomized to use either the Omnipod 6 algorithm at the 100 mg/dL Target Glucose or the Omnipod 5 System at the 110 mg/dL Target Glucose for four weeks, followed by crossover to the alternate system for an additional four weeks. After the Crossover Phase, all participants entered a four-week or six-week Bolus Optional Phase to evaluate whether glycemic outcomes could be maintained with reduced user interaction, with a study goal of three or fewer boluses per day.

STRIVE Key Data Highlights

Enhanced glycemic performance, even with limited bolusing

The STRIVE study demonstrated clinically meaningful improvements in glycemic outcomes with Omnipod 6 during the Crossover Phase.

- Improved time in tight range (70–140 mg/dL) with Omnipod 6 vs. Omnipod 5:
 - Type 1 diabetes (≥14 years): 54% vs. 47% (+7 pts)
 - Type 2 diabetes: 48% vs. 43% (+5 pts)
- Improved time in range (70–180 mg/dL) with Omnipod 6 vs. Omnipod 5:
 - Type 1 diabetes (≥14 years): 77% vs. 73% (+4 pts)

- Type 2 diabetes: 76% vs. 73% (+3 pts)
- Maintained safety profile:
 - Time <54 mg/dL and <70 mg/dL were non-inferior
 - No instances of diabetic ketoacidosis (DKA) or severe hypoglycemia

The STRIVE study demonstrated strong glycemic performance even when users bolused less during the Bolus Optional Phase.

- Strong time in range and time in tight range with fewer boluses:
 - Type 1 diabetes (≥14 years): 76% time in range and 54% time in tight range with 2.2 fewer boluses/day
 - Type 2 diabetes: 74% time in range and 46% time in tight range with 2.5 boluses per day
- These findings suggest Omnipod 6 may be especially helpful for people with diabetes who do not always bolus. This will be further tested in the upcoming STRIVE 2 study, which will evaluate Omnipod 6 among people who bolus fewer than four times per day and are not meeting clinical targets for HbA1c.

EVOLUTION 3 Study Overview:

Insulet also shared results from EVOLUTION 3, the pre-pivotal study evaluating the safety and effectiveness of the Company's breakthrough FCL system for adults with type 2 diabetes.

EVOLUTION 3 enrolled a demographically diverse cohort comprised of 36 participants (adults aged 18–75 years old) with type 2 diabetes using insulin with HbA1c<14%. Participants were intensively managed with basal-bolus therapy and had high baseline utilization of continuous glucose monitoring. Yet they still had high baseline HbA1c of 8.1%.

EVOLUTION 3 Key Data Highlights

Fully Closed-Loop for type 2 diabetes improved time in range and reduced daily insulin with no weight gain

- Insulet's FCL for type 2 diabetes delivered 64% time in range, a 12% improvement with low hypoglycemia (0.15%) in a diverse, intensively managed population.
- Total daily insulin was reduced from 86U to 58U with no weight gain.
- Participants also reported high satisfaction (86% satisfied or highly satisfied) and reduced burden with FCL.

This data is part of the broader clinical program used to support the development of the FCL AID system designed for people living with type 2 diabetes. The EVOLUTION 2 results were shared earlier this year at the 19th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD), and Insulet recently announced the first enrollment of participants in **EVOLVE**, the randomized controlled pivotal trial supporting a

planned 2027 510(k) filing to the FDA and expected 2028 commercial launch. Building on this experience from FCL for type 2 diabetes, early clinical work is underway to advance the science for FCL for type 1 diabetes as well.

Sharing STRIVE and EVOLUTION 3 at ADA

The studies will be discussed at ADA this weekend, including on Sunday, June 7 from 10:15 – 11:00 AM CT in the Product Theater. Dr. Ly will be joined by Dr. Sufyan Hussain, MA, MB BChir, MRCP, PhD and Dr. Gregory Forlenza, MD, MS, for an Insulet sponsored presentation, The Omnipod Difference: Patient Centered Simplicity and Breakthrough Algorithm Performance.

* Insulet's Omnipod 6 and FCL System for type 2 diabetes are investigational devices. Limited by federal (or United States) law to investigational use. These products have not been reviewed by the FDA or any other regulatory agency.

About Insulet Corporation:

Insulet Corporation (NASDAQ: PODO), 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](https://www.insulet.com) or [omnipod.com](https://www.omnipod.com).

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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 18, 2026 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.

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Source: Insulet Corporation