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For Immediate Release

Data Published in *Journal of Diabetes Science and Technology* from First-in-Human Study Evaluating the Feasibility of Integrated Insulin Delivery and Glucose Monitoring Using an Insulin Patch Pump

- *Study assessing PharmaSens all-in-one insulin patch pump provides first evidence that combining glucose sensing and insulin administration in a single, wearable device is possible*
- *Next-generation niia device has potential to make diabetes management simpler, more effective and more affordable for insulin users*

Biel/Bienne, Switzerland, April 10, 2026 — PharmaSens AG, a Swiss developer of next-generation insulin patch pump systems, announced that the *Journal of Diabetes Science and Technology* (*JDST*) has published data from the first clinical study evaluating a combined insulin patch pump with integrated insulin delivery and continuous glucose monitoring (CGM). Findings from the clinical feasibility trial of the wearable PharmaSens *niia* device demonstrate for the first time ever that development of an insulin patch pump that combines glucose sensing at the site of insulin delivery is feasible.

"People with diabetes want technology that works quietly in the background and fits into everyday life," said Marcel Both, CEO of PharmaSens. "This feasibility study shows that combining continuous glucose monitoring and insulin delivery into a single, discreet patch device is not only desirable, but achievable. With our integrated technology approach and deep experience in diabetes care and medical device engineering, PharmaSens is uniquely positioned to be the first company to bring such a device to people with diabetes."

The American Diabetes Association's (ADA) recently published "2026 Standards of Care" designates automated insulin delivery (AID) systems as "the preferred insulin delivery system" for all people with type 1 diabetes (T1D) and intensive insulin-treated type 2 diabetes (T2D). Data show that these systems, which currently comprise an insulin pump, a separate CGM and an algorithm, are more effective than multiple daily injections (MDI) at helping users achieve glycemic targets. However, among the 11M intensive insulin users in Europe and the United States, only 13% (1.5M) are using an AID system.

The PharmaSens all-in-one device addresses the profound need for alternatives to current multi-device diabetes-management systems, including AIDs, whose high complexity, Bluetooth connectivity issues and cost limit adoption and undermine glycemic outcomes.

"PharmaSens is committed to developing an all-in-one insulin therapy system that reduces the daily burden of diabetes and empowers insulin users to achieve better glycemic control," said Robert Gabbay, MD, PhD, former chief scientific and medical officer for the American Diabetes Association and a PharmaSens advisor. "This type of innovation has the potential to fundamentally reshape and improve how diabetes is managed in everyday life."

The data published today in *JDST* are from an early feasibility, single-arm study that evaluated an investigational device comprising the PharmaSens *niia essential* insulin patch pump equipped with SynerG™, a glucose sensor developed by Pacific Diabetes Technologies that was integrated with the *niia* device's insulin infusion cannula. A total of 18 adults, all of whom had been living with T1D for at least six months, were enrolled in the trial.

In the main phase of the study, 15 participants wore the device for 72 hours, undergoing two mixed meal tests (MMTs) and one supervised free-living day at a hotel. All participants used a Dexcom G6 CGM System and separate blood glucose monitor (BGM) to guide glycemic treatment decisions, and received manual bolus insulin dosing to help ensure safety. The main phase was initiated after a pilot phase, during which three individuals wore the investigational device for 10-12 hours while undergoing an MMT.

The primary trial endpoint was accuracy of the combined investigational device, assessed by the Mean Absolute Relative Difference (MARD) between its blood glucose readings and those measured by a validated glucose analyzer (Yellow Springs Instruments, YSI). Secondary endpoints included pump performance, the number of insulin delivery failures and device survival duration. Data from three pilot-phase participants and 14 main-phase participants were available for analysis.

Key results from the study include:

- The aggregated MARD for the investigational PharmaSens device vs. YSI reference was 11.6% with a total of 594 data points from 17 devices. A MARD target of <10% is generally considered ideal for CGM devices, and in the context of this early feasibility study, these results are encouraging and provide compelling evidence supporting the successful development of an all-in-one system.
- Error grid analysis compared against YSI reference showed 83% of readings were clinically accurate, falling within Zone A, and 100% were within clinically acceptable Zones A and B, supporting the device's accuracy for glucose monitoring.
- No insulin delivery failures or adverse events were reported with the investigational PharmaSens device.

“The PharmaSens niia insulin pump offers an excellent platform by which insulin delivery and CGM may be combined, and this study has demonstrated the feasibility of such an approach,” said Professor David O’Neal, study principal investigator and director of the Diabetes Technology Research Group at St. Vincent’s Hospital Melbourne, where the study was conducted. “A safe, reliable, ‘all-in-one’ device could substantially reduce the physical and psychological burden of managing diabetes, while also lowering the cost and environmental impact associated with using separate glucose monitoring and insulin delivery devices.”

PharmaSens plans to initiate a second feasibility study in Q2 2026, evaluating a next-generation *niia* insulin patch pump that integrates the patented *niia* platform technology with SiBionics’ advanced CGM technology. PharmaSens and SiBionics announced a strategic partnership in June 2025 to jointly develop the next-generation *niia*.

About PharmaSens

PharmaSens AG, a privately owned Swiss company, is dedicated to simplifying diabetes management and broadening the reach of insulin pump therapy. The PharmaSens team has a wealth of experience in diabetes care and medtech device engineering, having contributed to the development of multiple insulin pump generations. Over several years of research and development, PharmaSens has built a patented international portfolio of distinctive and innovative products. For more information, please visit PharmaSens.com.

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