

## FOR IMMEDIATE RELEASE

### **CeQur Simplicity™, a Wearable Mealtime Insulin Delivery Device, Obtains FDA-Clearance for 4 Days of Wear to Further Simplify Diabetes Management**

*The CeQur Simplicity patch is now FDA-cleared for up to 4 days of wear. Each patch replaces up to 12 injections further simplifying mealtime insulin management.*

**Horw, Switzerland, June 18, 2024** - CeQur®, a medical device company dedicated to simplifying insulin delivery for individuals on multiple daily injections, announces the FDA's recent 510(k) clearance of CeQur Simplicity for an extended wear duration from 3 to 4 days. This update marks an advancement in mealtime insulin management to the longest wearable insulin delivery patch, providing people with diabetes discretion, additional convenience, and injection-free dosing.

A pivotal analysis of over 26,000 people with Type 2 Diabetes (T2D) on Multiple Daily Injections (MDI) from the IQVIA database indicated that only 21.3% achieved the ADA-recommended A1C goal of less than 7%.<sup>i</sup> This study represents a large portion of insulin users and >90% of people with T2D on multiple daily injections who are still using pens or syringes. This data also underscores the need for more effective insulin delivery solutions like CeQur Simplicity, which now, with its extended 4-day wear time, aims to improve dosing adherence and simplify diabetes management even further.

The new 4-day clearance for CeQur Simplicity represents a significant improvement, increasing the device's wear time by 33% and reducing the number of applications. Each patch now replaces up to 12 mealtime injections, equating to over 1000 less injections annually, offering a substantial benefit for individuals managing diabetes.

This extended wear time underscores CeQur's commitment to improving the lives of those managing diabetes, offering more freedom and flexibility. CeQur Simplicity, with the promise of "Mealtime Insulin, Simplified," provides a discreet and easy-to-use solution for those seeking an alternative to traditional mealtime insulin injections. With this clearance, CeQur Simplicity sets itself apart as a unique, bolus-only insulin therapy, promoting better adherence and an enhanced quality of life. Recent real-world studies have demonstrated 94% patient satisfaction and an average A1C reduction of 1.29%.<sup>ii, iii</sup>

"We are excited to share that there are now ~5000 people with diabetes using CeQur Simplicity for their mealtime insulin delivery," said Bradley Paddock, President and CEO at CeQur. "With the 4-day clearance, we hope to make it even easier for people with diabetes to take their mealtime insulin."

This extension is built on the success of the initial launch and the positive reception from users who have experienced the benefits of the 3-day wear patch. In response to growing demand, CeQur has successfully increased its manufacturing capacity with a fully automated manufacturing line

to support 100,000 patients and is increasing the size of its sales force, ensuring wider accessibility and support for the diabetes community.

“Our Market Access team has been working diligently, and as a result of their activities, nearly 70% of commercial lives are on formulary coverage and more are being added regularly,” Chris Arapoff, VP of Health Economics & Reimbursement, reported. The average patient’s copay is now less than \$40/month.

CeQur will showcase the 4-day wear CeQur Simplicity insulin patch at the American Diabetes Association’s 84<sup>th</sup> Scientific Sessions in Orlando. Attendees are invited to Booth #1223 for demonstrations and to learn more about the impact of this innovative diabetes management solution.

### **About CeQur Simplicity™**

CeQur Simplicity is a simple, 4-day wearable Insulin Delivery Device for discreet, convenient and injection-free bolus dosing. One CeQur Simplicity patch holds up to 200 units of rapid-acting insulin administered in two-unit increments and replaces, on average, twelve daily mealtime injections over four days. Clinical research has shown that nearly 90% of patients using CeQur Simplicity reported following their insulin regimen better as compared to multiple daily injections.<sup>iv</sup> The patch is clinically proven to improve glycemic control, with patients achieving significantly improved A1C and time-in-range (TIR) goals.<sup>v, vi</sup>

### **About CeQur®**

CeQur is commercializing advanced, simple-to-use insulin-delivery devices that make it easier for people living with diabetes to adhere to therapy and stay in control of their disease. The Company’s simple, wearable devices provide freedom from multiple daily insulin injections.

More information can be found at [www.cequr.com](http://www.cequr.com).

- i. Shah, V. et al, 2024. Obesity and Disparity in Glycemic Outcomes are Prevalent Among Adults with Type 2 Diabetes (T2D) on Multiple Daily Injections (MDI) of Insulin: A Large US Retrospective Cohort Study. Poster presented at ATTD 2024 poster #532. March 6-9. Florence, Italy
- ii. Isaacs, D., Kruger, D., Shoger, E., Chawla, H., Patient Perceptions of Satisfaction and Quality of Life Regarding Use of a Novel Insulin Delivery Device, *Clinical Diabetes*, 2023;41(2):198–207
- iii. Data on File at CeQur
- iv. Zraick V, Dreon D, Nalk R, Shearer D, Crawford S, Bradford J, Levy B. 2016. Patient User Experience Evaluation of Bolus Patch Insulin Delivery System. Poster presented at the American Diabetes Association’s 76th Scientific Sessions. Abstract 995-P. New Orleans, LA, USA
- v. Bergenstal R, Peyrot M, Dreon D, Aroda V, Bailey T, Brazg R, Frias J, Johnson M, Klonoff D, Kruger D, Ramtoola S, Rosenstock J, Serusclat P, Weinstock R, Naik R, Shearer D, Zraick V, Levy B. 2019. Implementation of Basal–Bolus Therapy in Type 2 Diabetes: A Randomized Controlled Trial Comparing Bolus Insulin Delivery Using an Insulin Patch with an Insulin Pen. *Diabetes Technology and Therapeutics* 21 (5):1-13.
- vi. Bergenstal R., et al Comparing Patch vs Pen Bolus Insulin Delivery in Type 2 Diabetes Using Continuous Glucose Monitoring Metrics and Profiles; *Journal of Diabetes Science and Technology* 1–7, 2021