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Data Published in *Diabetic Medicine* Demonstrate the CeQur PAQ Insulin Delivery Device Improved Glycemic Control Among People with Type 2 Diabetes

-- Patients who transitioned to simple three-day, wearable insulin infusion device eliminated the need for multiple daily injections and reported increased treatment satisfaction –

MARLBOROUGH, Mass., September 5, 2018 -- CeQur® today announced that the journal *Diabetic Medicine* published the findings from two studies evaluating the company's PAQ® Insulin Delivery Device among people with type 2 diabetes. The data demonstrate that the simple three-day, wearable PAQ basal-bolus insulin delivery device significantly improved glycemic control among people with type 2 diabetes who transitioned to the device. Study participants also reported increased treatment satisfaction with the PAQ device as compared to insulin injections.

"Research shows that the majority of people with type 2 diabetes on insulin therapy do not achieve good glycemic control - primarily due to barriers associated with multiple daily insulin injections. Daily insulin injections can be painful or embarrassing for patients and interfere with daily life," said Julia Mader, M.D., of Medical University of Graz, Austria, and the lead author of the publication. "The data from these studies provide further evidence that the PAQ insulin delivery device can eliminate the burden of multiple daily injections and provide a convenient, simple, safe and effective option for insulin delivery among adults with type 2 diabetes."

Two million people with type 2 diabetes in the United States take multiple daily insulin injections to control their blood glucose levels (HbA1c). Clinical practice guidelines published by the American Diabetes Association generally point to HbA1c levels below 7 percent (53 mmol/mol) as reasonable targets to help prevent diabetes complications. An estimated 70 percent of insulin users in the United States do not achieve this goal, primarily due to missed insulin injections.

The PAQ findings published in this month's print issue of the journal *Diabetic Medicine* are from two prospective, open-label, non-controlled studies involving 28 adults with type 2 diabetes. The studies comprised three periods: a baseline (insulin injections), a transition, and a PAQ treatment period (12 weeks). The primary endpoint was change in HbA1c from baseline after 12 weeks. Secondary endpoints included seven-point self-monitored blood glucose, total daily dose of insulin and body weight. Safety was assessed according to examination, hypoglycemic episodes and adverse device effects.

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Twenty-four patients completed the two studies and were safely transitioned from established regimens of daily injections to the three-day, wearable PAQ device. After 12 weeks of PAQ use, results showed significant improvements from baseline with an average reduction in HbA1c of 1.5 percent (±0.9 percent; P<0.0001) or -16 mmol/mol (±9 mmol/mol) and at all seven self-monitored blood glucose readings time points (P ≤0.03). By comparison, participants in the multiple daily injection arm of several recent randomized, controlled studies, experienced an HbA1c decrease of ~0.4 percent or ~4mmol/mol.

“These findings further validate the efficacy and safety of the PAQ basal-bolus insulin delivery device, and demonstrate its potential to remove the barriers to effective insulin therapy and improve outcomes for people living with type 2 diabetes,” said Robert Farra, CEO of CeQur. “We are especially pleased that patients using the PAQ device reported high levels of treatment satisfaction, underscoring the importance of our work to provide an alternative solution to insulin injections.”

Patient-reported outcome measurements indicated that study participants favored the PAQ device over insulin injections. The total Diabetes Treatment Satisfaction Questionnaire (DTSQ) score significantly improved at the end of the PAQ treatment period as compared with baseline (+4.0 ± 6.9 [95% CI 1.3, 6.8]; P=0.005). Patients saw the PAQ device as more convenient than baseline therapy and were more satisfied to continue treatment. PAQ participants’ hyperglycemia score also significantly decreased at week 12 as compared with baseline (–2.11 ± 2.5 [95% CI –3.12, –1.10]; P=0.0002).

About CeQur®
CeQur is developing and commercializing advanced yet 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, three-day, wearable devices provide freedom from multiple daily insulin injections. More information can be found at www.cequr.com.

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Corporate Contact:
Jay Warner
1-508-494-4782
jay.warner@cequr.net

Media Contact:
Michele Parisi
1-925-429-1850
mparisi@forwardhealthinc.com