



Quanta Receives FDA 510(k) Clearance for the SC+ Hemodialysis System Setting the Stage for US Market Launch

Alcester, Warwickshire, UK, 8 January 2021: Quanta Dialysis Technologies Ltd (“Quanta” or “the Company”), a British medical technology pioneer developing innovative dialysis products and services for the global market, today announces it has received 510(k) clearance from the US Food and Drug Administration (“FDA”) to market its small and simple, high performance hemodialysis system SC+. This critical milestone enables Quanta to bring to the American market its portable device that can provide a dialysis dose equivalent to today's standard of care, but in a compact, easy-to-use format suitable for a range of care settings.

“Kidney failure is one of the costliest health conditions for the American health system. The imperative for better value in healthcare, coupled with new challenges driven by COVID-19, has amplified the need to reimagine how hemodialysis is delivered across a variety of settings,” said John E Milad, CEO, Quanta. *“This will be a pivotal year for Quanta as we build our US presence and bring our next generation hemodialysis system to a community ripe with need.”*



The SC+ System in the US

There are more than half a million patients requiring hemodialysis in the United States. The vast majority of these patients receive dialysis three-times-a-week, with a minority receiving more frequent therapy. Unlike other portable hemodialysis systems, SC+ can deliver the higher dialysate flow rates typically used to provide conventional three-times-a-week prescriptions, while also offering the flexibility for more frequent, longer and gentler treatments tailored to patients' needs. The small, lightweight design of SC+ makes the device portable, allowing for dialysis treatments to be brought to patients, and the simple, intuitive user interface makes dialysis accessible to a broad range of healthcare professionals.

In preparation for commercial launch, Quanta continues to develop its US team and operations. Following the appointment earlier this year of the Company's President of North America, John Lipman, Quanta has also recently hired a Head of Chronic Sales and a Head of Clinical Support, while also building a dedicated US-based team that includes training, customer care and technical staff to support the Company's customers and users.

To complement SC+, Quanta will introduce a suite of related products and services. This includes an optional, portable water purification module that will enable SC+ to be easily moved around and to be operated in a wide range of settings, both with and without a centralized water system, and a secure, cloud-based digital health offering that will simplify and automate treatment data capture and reporting, negating the need to create and store manual records.

Brigitte Schiller, M.D., Chief Medical Officer of Satellite Healthcare in San Jose, CA, and member of Quanta's Medical Advisory Board, said: *"SC+ is a welcome new technology that addresses the need for simpler, more portable dialysis systems that can deliver treatment flexibility. Innovations such as this can facilitate more individualized care and improved patient experience, playing an important role in the transformation of the current care model."*

Andrew Lazar, M.D., Chief of Nephrology at Ahuja Medical Center, in Cleveland, OH, said: *"I'm excited about the cartridge-based technology and high dialysate flow rates of SC+. The versatility, portability and simplicity of this device, combined with a modular approach to water purification, offer something for many different care environments. I can use SC+ in skilled nursing facilities, SLED or on regular floors in the hospital. Dialyzing five days a week isn't always an option, and SC+ provides much-needed clinical flexibility."*

Following extensive clinical piloting with the National Health Service (NHS) in England, SC+ became commercially available in the UK last year, playing a vital role in supporting the increased need for more simple, flexible dialysis devices in the hospital and the home, particularly during the rise of the COVID-19 pandemic. As reported in a recently published [study](#) (Komenda et al, Kidney Medicine 2020), SC+ combines the power and performance of larger conventional dialysis machines with the convenience of a compact, portable, user friendly device, making SC+ a much-needed addition to existing dialysis treatment options.

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About Hemodialysis

Hemodialysis is a life sustaining treatment for patients with kidney failure to help normalize blood chemistry and remove waste products and excess fluids.

About Quanta and SC+

Headquartered in the UK, Quanta is an international commercial-stage, technology-enabled dialysis innovator that aims to improve dialysis experiences and to help people live more freely through products and services that are easy-to-use, versatile and empowering.

Quanta's lead product, SC+, is a small and simple, high performance hemodialysis system designed to provide greater freedom and flexibility in the delivery of life sustaining dialysis treatments. SC+ is commercially available in the UK, where it has been successfully used to treat patients across a range of care settings, from the ICU and the clinic to the home.

The innovative and patented technology behind SC+ is based on a design breakthrough that allows all dialysate fluid management to be conducted on a small, lightweight, disposable cartridge. The simple-to-use and digitally connected design of SC+ is intended to empower more patients to take control of their lives with selfcare and home dialysis. Meanwhile, as a compact, portable and versatile device, SC+ provides flexibility to deliver dialysis across a wide range of use environments and prescriptions.

For more information, please visit our website: quantadt.com