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ASIA EDITION

AWAK Tech receives Breakthrough Device Designation by USFDA

09 January 2019 | News

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AWAK Technologies (AWAK), a pioneering medical technology company focused on dialysis using regeneration technology for end-stage renal disease, recently announced that the US Food and Drug Administration (FDA) has granted Breakthrough Device designation to its AWAK Peritoneal Dialysis (AWAK PD) device, a wearable and ultra-portable PD system that incorporates AWAK's patented sorbent technology.

A world-first, the AWAK PD device disrupts the mode of delivery in which peritoneal dialysis is currently administered. The device allows dialysis to be performed "on-the-go", overcoming the challenge of long hours of therapy and connection to large-size dialysis machines, currently faced by renal patients. End-Stage Renal Disease affects 650,000 patients per year in the US.

According to the FDA, Breakthrough Device Designation is granted to expedite the development and review of certain devices that demonstrate potential to provide a more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases. To qualify as a Breakthrough Device, there must either be no FDA approved alternative treatments available or the technology must offer significant advantages over the existing approved alternatives.

This designation was granted by the FDA after reviewing the results from the First-In-Human safety trial of AWAK PD device which was successfully completed in October 2018 at the Singapore General Hospital, Singapore's largest acute tertiary hospital. The trial results showed that AWAK PD was able to efficiently remove the accumulation of toxins from the body and patients in the trial did not experience any serious adverse events during dialysis with AWAK PD.

Suresha Venkataraya, Chief Executive Officer, AWAK Technologies, said: "Breakthrough Device Designation is an important milestone in the development of AWAK PD following the recent positive clinical study results. The designation reinforces our belief that AWAK PD has the potential to revolutionise the way in which peritoneal dialysis can be delivered and we look forward to collaborating closely with the FDA on the next stages of our development pathway."