



Advent Access Receives CE Mark Certificate for Pioneering av-Guardian™ Vascular Access System

Singapore, 3 July 2019 – Advent Access (Advent) today announced receipt of the CE Mark certificate for its award-winning av-Guardian™ vascular access system. The certificate indicates av-Guardian™'s conformity with health, safety, and environmental protection standards set by the European Union for a device to be distributed into the European Economic Area.

The av-Guardian™ is the world's first implant technology to pioneer the concept of establishing a "guardian guide-door" to facilitate dialysis needles to optimally access the dialysis vein, an arteriovenous fistula (AV fistula), without being in contact with the vein. The technology is compatible with patients undergoing hemodialysis in various treatment settings – in dialysis centers or at home, regardless of the types of dialysis machine being used.

Providing reliable access to the AV fistula remains one of the most stressful and challenging parts of hemodialysis. Moreover, during this usually painful procedure many complications can often arise due to poor needling, leading to inadequate dialysis or vascular access related hospitalizations.

Peh Ruey Feng, Chief Executive Officer and Founder of Advent Access, said: *"Receiving CE Mark approval for av-Guardian™ is an important milestone in our mission to provide a more comfortable treatment for patients suffering long term end-stage kidney disease and to reduce the cost burden of maintenance dialysis. Our focus now is to work with high-quality manufacturing and distribution partners to realize the impact we can make in potentially changing the way hemodialysis patients receive treatment both in-center or at home."*

The av-Guardian™ technology was recently evaluated in a first-in-man study conducted at Singapore General Hospital and National University Hospital of Singapore, with support from the National Kidney Foundation. The study was a non-randomized, prospective clinical investigation to assess the safety and clinical performance of the av-Guardian™ across 216 hemodialysis sessions in patients with native AV fistulas. The study showed that av-Guardian™ met all safety and performance endpoints. In particular, the av-Guardian™ achieved 94% - 98% successful access to the AV fistula, with 86% - 90% success at the first needle attempt.

Enabling Hemodialysis Patients for the Future of Home Care

Today, an estimated 2.5 million patients suffer from end-stage renal disease (ESRD) and it is estimated that this figure will more than double to 5.5 million patients worldwide by 2030¹. 89% of ESRD patients

¹ Liyanage T, Ninomiya T, Jha V, et al. (2015). Worldwide access to treatment for end-stage kidney disease: a systematic review. *The Lancet*, 385 (9981), 1975-1982.

rely on hemodialysis to sustain their lives until a kidney transplant is received². The hemodialysis market is valued at USD\$71 billion in 2017 and is forecasted to be worth USD\$99 billion by 2025³.

Advent Access is focused on developing solutions to address the rising cost of operating in-center hemodialysis and the limited scalability of dialysis centers when they reach maximum capacity. An effective solution is to empower more patients the freedom to perform hemodialysis at home or independently. However, the foremost barrier freeing the patient from the dialysis center and the nurse, is the patient's ability to self-needle with confidence⁴.

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About Advent Access

Advent Access is a medical technology startup focused on end-stage renal disease management. A Stanford StartX company and spin-off from A*STAR, Advent's mission is to pioneer innovations to significantly reduce dialysis cost and restore quality of life for kidney failure patients. The company's first product is the av-Guardian™ - an award-winning implant technology that aims to improve vascular access reliability, enable less-painful self-cannulation and, in the long run, potentially reduce vascular access related hospitalizations. The av-Guardian™ forms a key component of Advent Access' dialysis-machine agnostic platform to empower patients to perform hemodialysis independently, safely and more affordably - at home or in novel care environments. For more information on Advent Access, please visit www.adventaccess.com

² Gale, J. (2019). Deadly Kidney Ailment Spurs Need for Dialysis, Transplants.

³ Allied Market Research. (2018). Market Worth \$99,747 Million, Globally, by 2025, Says Allied Market Research.

⁴ Anuradha J, Philip F, Alison W, et al. (2015). Self-Cannulation for Haemodialysis: Patient Attributes, Clinical Correlates and Self-Cannulation Predilection Models. *PLoS One*.