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Advent completes CE mark submission for av-Guardian

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Clinical data generated for submission process to be presented at international scientific congress in 2018.



Singapore – Advent Access (Advent), one of Singapore's most innovative medtech companies, announced that it has completed the regulatory submission and key audits for the CE Mark in the European Union (EU) for its award-winning av-Guardian technology. The submission represents a significant step towards commercialisation of av-Guardian.

The av-Guardian is the world's first medical implant to pioneer the concept of having a "guardian guide-door" for dialysis needles to enter a specially created dialysis vein, an arteriovenous fistula (AV fistula), without the implant being in contact with the vein. AV fistulas are widely recognised as the "lifeline" through which hemodialysis patients gain access to their blood for cleaning via a dialysis machine.

Hemodialysis is administered to patients with end stage renal disease (ESRD). In the US alone, it is estimated that nearly 500,000 patients with ESRD depend upon hemodialysis with total Medicare expenditure of US$26.7 billion in 2015. 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, leading to inadequacy of the treatment or damage to the AV fistula lifeline. Advent's av-Guardian aims to engineer a high-quality tissue track to enable reliable and less-painful vascular access to the AV fistula such that dialysis therapies can become more comfortable and effective.

Earlier in 2018, Advent completed the analysis of av-Guardian's first clinical study. The results have been submitted as part of the CE Mark dossier and will be presented at an internationally-renowned scientific congress later in 2018. Advent is currently conducting a second clinical study to evaluate the potential for av-Guardian to assist in self-cannulation and, ultimately, to enable more patients to benefit from home or self-hemodialysis.

Peh Ruey Feng, Founder and Chief Executive Officer of Advent Access, said**:** "Filing for CE registration ahead of our initial schedule marks an important milestone in Advent Access' approach to disrupting dialysis modality for patients with kidney failure globally. We are excited by the potential of av-Guardian to be the solution for one of the biggest unmet needs in the provision and advancement of hemodialysis – ensuring easy and reliable use of an AV fistula to improve patient outcomes and comfort."