Healionics Awarded $1.7M SBIR Grant from NIH to Advance New Vascular Graft Toward First-In-Human Use

Seattle, WA (November 16, 2017) — Healionics Corporation, a Seattle-based medical device company, has received notice from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of a $1.7M Fast-Track Small Business Innovation Research (SBIR) grant in support of regulatory approval and a clinical study of *STARgraft*™, its innovative synthetic vascular graft. Andrew Marshall, Healionics' Chief Technology Officer, is the Principal Investigator for the project.

Phase I of the grant ($440k) has been released, with $1.3M Phase II funding contingent upon FDA 510(k) clearance (anticipated in late 2018) and earmarked for a post-clearance human study. The clinical study will evaluate *STARgraft* as a vascular access graft for dialysis patients and will be conducted in collaboration with University of Washington Medicine.

In the United States, more than 470,000 patients with kidney failure rely on thrice-weekly hemodialysis treatment to survive. Maintaining a reliable vascular access site for these patients is challenging, and options for such access are limited. Synthetic vascular grafts (artificial blood vessels) are a common method to provide this access, but current grafts suffer from poor reliability due to their tendency to occlude quickly.

Healionics' *STARgraft* is a new synthetic vascular graft that has demonstrated much better reliability than on-market devices in multiple preclinical studies, thus offering the potential to substantially reduce cost, morbidity and mortality among dialysis patients.

"In preclinical studies, *STARgraft* has been shown to consistently overcome the main cause of failure for dialysis access grafts (occlusion at the outflow end)," says Dr. Marshall. "Successful clinical introduction could improve quality of life and outlook for a large fraction of dialysis patients by providing a reliable permanent vascular access option that avoids long-term dependence on infection-prone catheters."

"This non-dilutive funding provides significant leverage for our investors as we near the key milestone of FDA clearance," says Healionics CEO Mike Connolly. "Given the critical unmet need for safe, reliable, and ready-to-use bloodstream access for dialysis patients, *STARgraft* could be a real game changer."

About Healionics Corporation
Healionics is addressing the critical need for improved means of vascular access for patients on dialysis. Our devices are based on our platform *STAR*® technology which provides substrate-independent, precision-engineered, 3D biomaterial scaffolds that enhance the biointegration and function of medical implants. This patented technology is already in human use as an implant for glaucoma treatment, and has shown promising preclinical results for a variety of other implantable devices and applications. www.healionics.com

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