Vivasure Enrolls First Patient in Frontier IV Clinical Trial

Galway, Ireland – 13 October 2017 – Vivasure Medical® ("Vivasure") is pleased to announce the successful enrollment of the first patient in the Frontier IV clinical study, a non-randomized multicenter international trial, designed to expand the indications of its proprietary PerQseal® large arteriotomy closure technology. The patient was enrolled by Dr. Peter Crean at the Blackrock Clinic, Dublin, Ireland.

Large arteriotomies (12F+) are vessel punctures created to facilitate endovascular procedures such as transcatheter aortic valve replacement (TAVR), endovascular aneurysm repair (EVAR), balloon valvuloplasty (BAV) and ventricular assist devices (VAD). PerQseal is the world's first fully absorbable, patch-based large-bore percutaneous closure technology.

"Driven by clinical and economic outcomes data, percutaneous access-site management has become an increasingly important aspect of TAVR procedures," said Dr. Christoph Naber of the department of cardiology and angiology, Contilia Heart and Vascular Centre, Essen, Germany, and TAVR principal investigator of Frontier IV. "I strongly believe PerQseal, which is designed specifically to address large arteriotomies, will help improve outcomes for these patients."

"We are very excited to begin the Frontier IV trial as the next phase in our commitment to build the clinical experience with PerQseal," said Gerard Brett, co-founder and CEO of Vivasure. "A percutaneous approach has now become the gold standard for procedures such as TAVR and EVAR, driven by clinical outcomes data. As patient volumes increase, access site management and closure has become an increasingly important aspect of complication and cost reduction. The data from this trial will be used to support our goal of expanding the indication range of the PerQseal technology."

About PerQseal®

PerQseal® utilises a fully absorbable, intravascular patch, which seals large arteriotomies from the inside. It is comprised of a synthetic polymer implant, and an easy-to-use, ergonomically designed delivery system. The implant has a flexible, low-profile intravascular patch and a supporting scaffold. A portion of the scaffold extends through the arteriotomy, and includes a locator which helps maintain the implant in position. After deployment, the implant is rapidly endothelialised and fully absorbed.

About Vivasure

Based in Galway, Ireland, one of Europe's largest medtech hubs, Vivasure is focused on the development of bioabsorbable implant technologies with vascular applications. Vivasure operates a fully integrated R&D and ISO 13485 certified manufacturing facility and is backed by leading international medtech investors.

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