Svelte Medical Systems Announces Start of the FAASTER Post-Market Registry Study

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New Providence, NJ – Svelte® Medical Systems today announced the start of the FAASTER (**F**irst **A**ssessment of the **A**crobat **S**tenting **T**echnique **E**uropean Post-Market **R**egistry) study in clinical sites across Europe. FAASTER is a real world, multi-center registry assessing the procedural success and resource utilization associated with the Svelte coronary stent mounted on an Integrated Delivery System (IDS) in relation to target lesion and vessel complexity (as defined by NAVI-score) and selected catheter approach (diagnostic or guiding). Up to 1,500 patients will be evaluated in the study.

The Svelte IDS is low profile and highly flexible, navigating through the vasculature similar to a traditional guidewire, allowing physicians to 'direct-stent' coronary artery lesions and eliminate several steps from conventional stenting procedures, thereby reducing procedure time and cost. "We have used the Svelte IDS across a wide range of clinical applications in our lab, including frequently stenting through diagnostic catheters, and appreciate the system's versatility and reliability. Capturing data on a larger scale through the FAASTER study will help us better understand the clinical benefits of the system in a variety of patient subsets," noted Jacques Berland, MD of the Department of Cardiology, Clinique Saint Hilaire, Rouen, France.

Data presented at last month's Euro PCR meeting in Paris, France suggest the Svelte IDS significantly reduces radiation exposure, contrast use, adjunctive interventional product use and overall procedure time when compared with conventional stent systems. "The FAASTER registry is part of our ongoing efforts to collect valuable customer feedback and assess the clinical utility of our system," said Mark Pomeranz, President and CEO of Svelte Medical Systems. "We hope to more broadly demonstrate the clinical and economic benefits associated with the use of our 'All-In-One' integrated delivery system."

The Svelte IDS utilizing a bare metal stent received CE Mark certification in 2010 and is commercially available in select European and Latin American markets. The company recently completed enrolment in the DIRECT study, a First-in-Man evaluation of its drug-eluting stent (DES) utilizing a bioabsorbable drug carrier, and expects to initiate a European-based clinical study in support of CE Mark certification of the system later this year. This novel and exciting DES will be offered on both IDS and conventional rapid-exchange platforms incorporating the company's proprietary Balloon Control Band (BCB) technology upon commercial release.

Headquartered in New Providence, New Jersey, Svelte Medical Systems (www.sveltemedical.com) is a privately-held company engaged in the development of highly deliverable balloon expandable stents. The Svelte IDS represents the first material advance in stent delivery systems in the last fifteen years and is designed to realize the clinical, time and cost-savings benefits of direct stenting in a single platform.

Statements made in this press release that look forward in time or that express beliefs, expectations or hopes regarding future occurrences or anticipated outcomes or benefits, are forward-looking statements. A number of risks and uncertainties, such as risks associated with product development and commercialization efforts, results of clinical trials, ultimate clinical outcomes and benefit of the company's products to patients, market and physician acceptance of the products, intellectual property protection and competitive product offerings, could cause actual events to adversely differ from the expectations indicated in these forward looking statements.