Svelte Medical Systems Announces Final Patient Treated in the DIRECT Drug-Eluting Stent Study

May 15, 2012

New Providence, NJ – Svelte® Medical Systems today announced completion of enrollment in the DIRECT (Direct Implantation of Rapamycin-eluting stent with bio-Eroding Carrier Technology) study conducted at four investigational sites in New Zealand. DIRECT is a First-In-Man, multi-center clinical study designed to assess the feasibility of Svelte's novel 'All-In-One' system which combines a thin-strut cobalt chromium stent with a fully bio-absorbable drug carrier and the well-studied sirolimus (rapamycin) drug mounted on a fixed-wire Integrated Delivery System (IDS). The system 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.

"The Svelte system proved highly deliverable across a range of coronary lesions, including some which were rather challenging for a first-in-human study. The unique delivery system and bioabsorbable drug carrier, coupled with a proven drug compound, make for a truly novel drug-eluting stent platform. We look forward to sharing the robust 30-day clinical outcomes from the DIRECT study," said Mark Webster, MBChB, an interventional cardiologist at Auckland City Hospital and principal investigator for the DIRECT study. Interim analysis and case studies from the DIRECT study will be presented by Dr. Webster at the EuroPCR course in Paris, France May 15-18.
The Svelte drug-eluting stent system is designed to couple the benefits of procedural time and cost savings realized through an IDS with the low restenosis rates associated with the latest generation drug-eluting stents. The non-inflammatory and non-thrombogenic bioabsorbable drug carrier further offers the potential to positively impact patient safety and reduce long-term needs for dual anti-platelet therapy.

"Completing enrollment in the DIRECT study represents an important accomplishment for our company. We will continue working diligently to demonstrate the clinical and economic benefits our system provides patients, physicians and payers, and sincerely thank the DIRECT study investigators and their teams for their efforts on behalf of the study," said Mark Pomeranz, President and CEO of Svelte Medical Systems.

Data from Europe demonstrate the Svelte IDS significantly reduces radiation exposure, contrast use, adjunctive interventional product use and overall procedure time when compared with conventional stent systems. The Svelte IDS utilizing a bare metal stent platform received CE Mark certification in August of 2010 and is commercially available in select European and Latin American markets. The company expects to initiate a European-based clinical study in support of CE Mark certification for its drug-eluting

stent platform later this year and plans to offer both an IDS and conventional rapid-exchange delivery platform incorporating its 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.

For additional information please contact Mark Pomeranz, President and CEO, Svelte Medical Systems, Inc., via e-mail mpomeranz@sveltemedical.com or phone 908-264-2195.