Svelte Medical Systems Announces Completion of 6-Month Follow-up in the DIRECT II Drug-Eluting Stent Study

May 29, 2014

New Providence, NJ – Svelte® Medical Systems today announced completion of primary endpoint 6-month follow-up in DIRECT II (Direct Implantation of Rapamycin-Eluting stents with bioresorbable drug Carrier Technology), a prospective, randomized, multi-center clinical study comparing the safety and efficacy of the Svelte drug-eluting coronary stent Integrated Delivery System (IDS) to Medtronic's Resolute Integrity™ drug-eluting stent. DIRECT II builds upon the positive results of the DIRECT I first-in-man study where the Svelte drug-eluting coronary stent IDS continues to demonstrate durable outcomes with 0% clinically-driven MACE reported through 2-years.

Providing the lowest crimped stent profile on the market, the Svelte IDS facilitates use of the trans-radial approach and 'slender' stenting while minimizing procedure time and cost. The IDS combines a thin-strut cobalt chromium stent with a fully bioresorbable drug carrier made of amino acids found naturally in the human body and the well-studied compound sirolimus (rapamycin) mounted on an integrated-wire delivery system. The system also incorporates proprietary Balloon Control Band (BCB) technology providing uniform and controlled balloon growth, even at high pressures, to safely perform direct stenting as well as high-pressure post-dilatation.

"We are pleased to complete follow-up in DIRECT II and look forward to sharing the study outcomes with the interventional community later this year," said Jack Darby, President and CEO of Svelte Medical Systems. "Our drug-eluting IDS represents the first advance in coronary stent delivery in more than 18-years, offering the ability to reduce access site size and maximize procedural efficiencies while providing durable long-term outcomes as good or better than the current market-leading drug-eluting stents."

The DIRECT II study enrolled 159 patients at 18 clinical sites in Europe to assess the primary endpoints of Target Vessel Failure (TVF) and in-stent Late Loss (LL). All patients were scheduled to receive 6-month clinical and angiographic follow-up, with clinical follow-up continuing through 5-years, with a subset of patients receiving optical coherence tomography (OCT) imaging at 6-months. The study was undertaken in support of CE Mark certification of the Svelte drug-eluting coronary stent IDS.

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. 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 Jack Darby, President and CEO, Svelte Medical Systems, Inc., via e-mailjdarby@sveltemedical.com or phone 908-264-2012.