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Svelte Medical Systems Announces Treatment of First Patient in the DIRECT II Drug-Eluting Stent Study

NEW PROVIDENCE, N.J.--(BUSINESS WIRE)--Svelte® Medical Systems today announced treatment of the first patient in the DIRECT II (Direct Implantation of Rapamycin-Eluting stents with bioabsorbable drug Carrier Technology) study at Middelheim Hospital in Antwerp, Belgium. DIRECT II is 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. The study builds on the positive 6-month results of the DIRECT I first-in-man study which evaluated the Svelte drug-eluting coronary stent IDS in 30 patients in New Zealand. In DIRECT I, the Svelte drug-eluting coronary stent IDS met all study endpoints and demonstrated in-stent neointimal volume obstruction of 2.7% as assessed by intravascular ultrasound (IVUS), which is one-third to one-half the volumetric obstruction observed in market-leading drug-eluting stent first-in-man studies.

Providing the lowest crimped stent profile on the market, the Svelte drug-eluting coronary stent IDS combines a thin-strut cobalt chromium stent with a fully bioabsorbable drug carrier made of amino acids which are also found naturally in the human body and the well-studied compound sirolimus (rapamycin) mounted on a fixed-wire delivery system. Low profile and highly flexible, the Svelte IDS navigates the vasculature similar to a traditional guidewire, facilitating use of the transradial approach and general downsizing of the access site, while allowing access to more difficult to cross and distal lesions. The system also includes 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, thereby minimizing procedure time and cost.

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"The Svelte IDS offers a unique approach to percutaneous coronary intervention and we look forward to evaluating the performance of the drug-eluting platform in this highly scientific clinical study," said Stefan Verheye, MD, PhD and co-director of the Antwerp Cardiovascular Institute at the Middelheim Hospital in Antwerp. "We have experience with the bare-metal version of the IDS, and the system's low profile and unique balloon technology have allowed us to direct stent both simple and complex lesions."

The DIRECT II study will enroll 159 patients at up to 20 clinical sites in Europe and Brazil to assess the primary endpoints of Target Vessel Failure (TVF) and in-stent Late Loss (LL). All patients are scheduled to receive 6-month clinical and angiographic follow-up, with clinical follow-up through 5-years. A subset of patients will also receive optical coherence tomography (OCT) imaging at 6-months.

"We are excited to have the DIRECT II study underway and wish to thank our outstanding group of investigators for their collaboration in this effort," said Jack Darby, President and CEO of Svelte Medical Systems. "We believe our

drug-eluting IDS, with its proprietary balloon and drug carrier technologies, represents an easy to use, best-in-class offering which will deliver procedural efficiencies and associated cost savings while demonstrating long-term clinical outcomes consistent with market-leading drug-eluting stents."

Non-randomized data presented previously suggest the Svelte IDS significantly reduces radiation exposure, contrast use, adjunctive interventional product use and overall procedure time compared with conventional stent systems. Another randomized clinical study, ACES, is currently enrolling patients to demonstrate the positive clinical benefit and impact on resource utilization of the bare metal Svelte IDS compared with conventional coronary stent devices in patients with lesions eligible for direct stenting in a randomized setting.

Final 6-month data from the DIRECT I first-in-man study will be presented at medical symposia later this year. Following CE Mark certification of the drug-eluting IDS, the company also plans to commercialize its drug-eluting stent on a conventional rapid-exchange delivery platform incorporating its proprietary balloon control band and drug carrier technologies.

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.

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