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Svelte Drug-Eluting Stent Utilizing New Class of Bioabsorbable Drug Coating Attains 0% Clinically-Driven Events Through 12-Months in First-In-Man Study

NEW PROVIDENCE, N.J.--(BUSINESS WIRE)--Final 6 and 12-month results of the DIRECT first-in-man clinical study were presented by study principal investigator Dr. Mark Webster at the late-breaking clinical trials session of the EuroPCR meeting yesterday in Paris, France. No patients experienced clinically-driven TLR, TVR or MACE at 6-months, with results sustained through 12-months. It is believed the Svelte drug-eluting stent is the first ever to achieve 0% clinically-driven MACE through 12-months in a independent core-lab and DSMB adjudicated clinical study.

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The Svelte drug-eluting stent utilizes a new class of drug coating composed of a fully bioabsorbable, amino acid-based drug carrier mixed with the well-known anti-proliferative compound sirolimus. Amino acids occur naturally in the human body, providing a non-inflammatory and inherently bio-friendly drug-eluting platform. Unlike current-generation bioabsorbable coatings relying on hydrolysis for absorption, amino acids undergo gradual enzyme-based surface erosion with no bulk degradation or pH change activating an inflammatory response.

Invasive imaging at 6-months in the DIRECT study corroborates these clinical outcomes, revealing stent volume obstruction of 2.7%, approximately one-half that observed in current-generation, market-leading drug-eluting stent first-in-man studies. Optical coherence tomography revealed 98% of stent struts were fully covered, indicative of low inflammation and consistent vessel healing.

“We could not be more pleased with the outstanding and unmatched clinical outcomes observed in the DIRECT study,” said Jack Darby, President and CEO of Svelte Medical Systems. “Having no clinically-driven events through 12-months is indicative of the bio-friendly nature of our drug coating, strength of our stent design and precision of our stent delivery system. We congratulate the study investigators, all of whom were first-time users of our IDS, for achieving these results in a challenging first-in-man patient population.”

The DIRECT (**D**irect **I**mplantation of **R**apamycin-eluting stent with bio-**E**roding **C**arrier **T**echnology) study evaluated the Svelte drug-eluting stent mounted on a fixed-wire Integrated Delivery System (IDS) in 30 patients at 4 sites in New Zealand. Providing the lowest crimped stent profile on the market, the Svelte system facilitates use of the trans-radial approach and general downsizing of the access site, while allowing access to more difficult to cross and distal lesions. The IDS 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, thereby minimizing procedure time and cost. This balloon technology will also be available with a rapid-exchange delivery system at commercial launch.

Approximately one-fifth of patients in the study were diabetic while one-half presented with Type B2 or C lesions. Procedural success was 100% and device success was 97%. Study results are published in the current issue of EuroIntervention, the official journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI).

The Svelte drug-eluting stent is currently under evaluation in the DIRECT II study. DIRECT II is a prospective, randomized, multi-center clinical study comparing the safety and efficacy of the Svelte drug-eluting coronary stent mounted on the IDS to Medtronic's Resolute Integrity™ drug-eluting stent. 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 receive optical coherence tomography (OCT) imaging at 6-months.

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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