World's First Integrated Delivery System Meets All Endpoints in the DIRECT II Randomized, Controlled Drug-Eluting Coronary Stent Study

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Washington, DC – Svelte Medical Systems today reported that its drug-eluting coronary stent Integrated Delivery System (IDS), a new approach to Percutaneous Coronary Intervention (PCI) and the first advance in coronary stent delivery in nearly 20-years, met all DIRECT II study 6-month angiographic and clinical endpoints. The IDS also exhibited reduced procedure and device times, with trends toward reduced fluoroscopy time and contrast use, confirming results seen in prior studies in which the IDS demonstrated procedural time and cost savings.

DIRECT II is a prospective, randomized, multi-center clinical study comparing the safety and efficacy of the Svelte drug-eluting coronary stent IDS and the Medtronic Resolute Integrity™ drug-eluting coronary stent in 159 patients undertaken in support of CE Mark certification of the Svelte system. Non-inferiority to Resolute Integrity in the primary efficacy endpoint of in-stent Late Lumen Loss (LLL) at 6-months was clearly established (0.09$\pm$0.31 mm with Svelte IDS vs. 0.13$\pm$0.27 mm with Resolute Integrity, p-value for non-inferiority = <0.0001). Clinical outcomes were similarly positive, with 6-month Target Lesion Revascularization (TLR), target lesion failure, target vessel failure, myocardial infarction and major adverse cardiac event (MACE) rates in the Svelte IDS arm half those observed in the Resolute Integrity arm. Six-month TLR with the Svelte IDS was 0.9%, affirming results seen in the DIRECT First-In-Man study in which 0% TLR and MACE are now sustained through 28-months.

"The results of the DIRECT II study confirm the safety and effectiveness of this interesting new concept for coronary artery stenting," said Stefan Verheye, MD, PhD and co-director of the Antwerp Cardiovascular Institute at the Middelheim Hospital in Antwerp. "The Svelte IDS can be delivered through smaller catheters and facilitates radial artery access, two increasingly important approaches to PCI demonstrating improved procedural outcomes and greater patient comfort."

The Svelte IDS represents the first change in coronary stent delivery since the advent of the rapid-exchange catheter. Utilizing an integrated wire design which provides the lowest crimped stent profile on the market, the IDS is designed to optimize trans-radial interventions (TRI) and a 'slender' approach to PCI by downsizing catheter sizes used during intervention. TRI is used in the majority of PCI in Japan and parts of Europe, and its use in the US is growing rapidly, increasing from less

than 5% of procedures in 2007 to 25% today. In the DIRECT II study, 67% of patients were treated via TRI.

“We thank the DIRECT II investigators, many of them first-time users of the IDS, for their contribution to this study which confirms the safety and efficacy of our system,” said Jack Darby, President and CEO of Svelte Medical Systems. “Achieving this important milestone brings us closer to offering clinicians and patients an entirely new approach to PCI which compliments TRI and slender stenting while simplifying the treatment of challenging lesions and extracting hard and soft procedural costs.”

Data from the DIRECT II study were presented this week during the 2014 Transcatheter Cardiovascular Therapeutics (TCT) conference. Both the IDS and a conventional rapid-exchange (RX) platform incorporating Balloon Control Band (BCB) technology will be offered with the Svelte drug-eluting stent and are expected to be commercially available in Europe in 2015.

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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