



Svelte Medical Systems Announces Enrollment Complete in the DIRECT II Drug-Eluting Stent Study

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NEW PROVIDENCE, N.J.--(BUSINESS WIRE)--Svelte® Medical Systems today announced enrollment of the final patient in the DIRECT II (Direct Implantation of Rapamycin-Eluting stents with bioabsorbable drug Carrier Technology) clinical study. DIRECT II is a prospective, randomized study comparing the safety and efficacy of the Svelte drug-eluting coronary stent Integrated Delivery System (IDS) to the Medtronic Resolute Integrity™ drug-eluting stent in 159 patients at 19 investigative sites. The study builds on the positive results of the DIRECT I first-in-man study which evaluated the Svelte drug-eluting coronary stent IDS in 30 patients in New Zealand. The Svelte system met all study endpoints in DIRECT I while demonstrating in-stent neointimal volume obstruction of 2.7% at 6-months, a one-third to one-half reduction in volumetric obstruction observed in similar studies with market-leading drug-eluting stents. Clinical outcomes reflected the strong angiographic findings, with 0% clinically driven MACE reported through 18-months.

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Providing the lowest crimped stent profile on the market, the fixed-wire Svelte drug-eluting stent IDS navigates the vasculature similar to a traditional guidewire and facilitates use of the trans-radial approach. The system combines a thin-strut cobalt chromium stent with the well-studied compound sirolimus (rapamycin) and a new class of bioabsorbable drug carrier composed of naturally-occurring amino acids (PEAs) which elicit a reduced inflammatory response compared with competitive (PLGA) technologies. Proprietary Balloon Control Bands (BCBs) envelop the balloon shoulders to provide a smooth leading edge during delivery and uniform, controlled balloon growth during deployment to safely perform direct stenting as well as high-pressure post-dilatation. A rapid-exchange system incorporating these proprietary technologies will also be available at commercial launch.

“We are pleased to have completed this rigorous evaluation of the Svelte drug-eluting stent IDS following the strong and sustained outcomes of the DIRECT I study,” said Stefan Verheye, MD, PhD and co-director of the Antwerp Cardiovascular Institute at the Middelheim Hospital in Antwerp. “As continued emphasis is

placed on downsizing access sites and improving procedural efficiencies as well as clinical outcomes, this system presents an important option to interventional cardiologists.” Pr. Verheye shared interim findings from the DIRECT II study at the TCT meeting in San Francisco in October.

Primary endpoints of the DIRECT II study were 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 continued through 5-years. A subset of patients will receive optical coherence tomography (OCT) imaging at 6-months.

“We thank all investigators for their contributions to the DIRECT II study and look forward to bringing our technology to the wider interventional cardiology community,” said Jack Darby, President and CEO of Svelte Medical Systems. “Our IDS and RX systems are uniquely designed to facilitate use of the trans-radial and direct stenting approach to PCI, two segments of the market which are not currently served by dedicated technologies, yet have demonstrated significant clinical benefits and procedural efficiencies which are critical in today’s healthcare landscape.”

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-mail jdarby@sveltemedical.com or phone 908-264-2012.

Contacts

Svelte Medical Systems, Inc.

Jack Darby, 908-264-2012

President and CEO

jdarby@sveltemedical.com