Svelte Medical Systems Announces FDA Approval to Initiate a Pivotal Study of Its Coronary Stent Integrated Delivery System (IDS)

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NEW PROVIDENCE, N.J.--(BUSINESS WIRE)--

Svelte® Medical Systems announced today it received conditional approval from the FDA to begin a pivotal study for the Svelte coronary stent Integrated Delivery System (IDS). Approved by the FDA under an Investigational Device Exemption (IDE), the study will evaluate the safety and effectiveness of the Svelte IDS in approximately 370 patients at up to 30 investigative sites in the US.

“We are pleased to have earned approval from the FDA to initiate our pivotal study and look forward to collaborating with our clinical partners to demonstrate the clinical, procedural and cost savings benefits of our IDS technology,” said Jack Darby, President and CEO of Svelte. “Given the ever-increasing time constraints and cost pressures confronting cardiac cath labs, we are very confident the Svelte IDS offers an impactful alternative to maximize efficiency while providing best-in-class technology and outcomes.”

The Svelte IDS combines a wire, balloon and stent into a single ‘All-In-One’ system. The low profile and highly flexible IDS navigates through the vasculature similar to a traditional guidewire to allow physicians to ‘direct-stent’ coronary artery lesions and eliminate several steps from conventional stenting procedures – thereby reducing procedure time and cost. Data presented at medical symposia suggest the Svelte IDS significantly reduces radiation exposure, contrast use, adjunctive interventional product use and overall procedure time when compared with conventional stent systems.

The Svelte IDS utilizing a bare metal stent received CE Mark certification in 2010 and is commercially available in select European and Latin American markets. The company completed enrollment in the DIRECT study, a First-in-Man evaluation of its drug-eluting stent (DES) utilizing a bioabsorbable drug carrier, and expects to initiate a European-based clinical study in support of CE Mark certification of the system later this year. This DES will be offered on both IDS and conventional rapid-exchange platforms incorporating the company’s proprietary Balloon Control Band (BCB) technology upon commercial release.

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. The Svelte IDS represents the first material advance in stent delivery systems in the last fifteen years and is designed to realize the clinical, time and cost-savings benefits of direct stenting in a single platform.

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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