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TCT 2011

Boam: firms eye harmonization 'somewhat later' in development

By MARK McCARTY
***Medical Device Daily* Washington Editor**

SAN FRANCISCO – This year's edition of Transcatheter Cardiovascular Therapeutics isn't exactly swimming with regulatory personnel, but one of the more strategically important sessions took place yesterday morning, when regulators and industry met to discuss the current state of harmonization-by-doing (HBD) between FDA and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). A couple of members of industry and a couple of physicians sounded off on what they felt is a dysfunctional approach to regulatory convergence, but one prominent FDAer told

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Resolute DES shows strong data across multiple studies

By AMANDA PEDERSEN
***Medical Device Daily* Senior Staff Writer**

Medtronic (Minneapolis) is resolute to demonstrate the strong performance of its Resolute drug-eluting stent (DES) this week at the **Cardiovascular Research Foundation**'s (CRF; New York) annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium for interventional cardiovascular specialists - and rightfully so. The stent continues to shine across multiple studies, according to two new data analyses presented Tuesday at TCT in San Francisco.

The first analysis, RESOLUTE Pooled Diabetics, focuses on outcomes in patients with both coronary artery disease and diabetes, two common comorbidities. The second, RESOLUTE Pooled Safety, focuses on safety outcomes across all patient types. Medtronic also presented the final,

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Report from Europe

Biosensia secures new €1.2M investment to advance platform

A *Medical Device Daily* Staff Report

Biosensia (Dublin, Ireland), a point of care diagnostics company, reported that it has secured €1.2 million investment in its most recent funding round, as part of the company's plans to advance its regulatory and commercial strategy for its platform in Europe and the U.S.

The funding round was led by ACT Venture Capital, and included existing investors Seroba BioVentures and Atlantic Bridge.

The funding will be used to secure CE mark and FDA regulatory approval for Biosensia's products in Europe and the US and advance its commercial partnership strategy. There is a significant unmet need for more convenient, accurate and affordable point of care solutions, and

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NewCo on the block

Svelte Medical Systems offers All-In-One DES application

By OMAR FORD
***Medical Device Daily* Staff Writer**

Med-tech start-up **Svelte Medical Systems** (New Providence, New Jersey) reported the treatment of the first patient in the Direct-on-a-wire Implantation of Rapamycin-eluting stent with bio-Eroding Carrier Technology (DIRECT) study at **Auckland City Hospital** (Auckland, New Zealand).

DIRECT is a First-In-Man, multi-center clinical study designed to assess the feasibility of Svelte's novel All-In-One system, which combines a thin-strut cobalt chromium stent with a fully bio-erodable drug carrier and the well-studied sirolimus (rapamycin) drug, mounted on Svelte's novel fixed-wire delivery system. A little more than 30 patients will be involved in the study – which the company hopes to

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use to put it on the path of gaining CE mark approval.

"The whole concept of the technology is to be able to take out as many steps and ancillary products in a procedure to make it quicker to make it less expensive and also make it safer for the patient," Mark Pomeranz, president/CEO of Svelte told *Medical Device Daily.*

Pomeranz said, "our next generation drug-eluting stent system is designed to couple the benefits of enhanced deliverability and time and cost savings with the low restenosis rates associated with the latest generation drug-eluting stents. "The non-inflammatory and non-thrombogenic drug carrier has high mechanical integrity, yet fully erodes within a year. These unique properties should provide important clinical benefits, and we are very excited to put this new technology in the hands of our outstanding group of clinical investigators."

The All-In-One system is low profile and highly flexible, navigating through the vasculature similar to a traditional guidewire, allowing physicians to 'direct-stent' coronary artery lesions and eliminate several steps in their current stenting procedures, thereby reducing procedure time and cost.

"For the All-In-One system - the stent and balloon are mounted on a guidewire," Pomeranz said. "In a normal procedure you put a guide wire down, you then come in with a balloon catheter and you pre dilate the lesion; opening it up for a stent; you come in with a stent and in many cases you have to come in and put in another balloon to post dilate after the stent is implanted."

As a fixed-wire design, the Svelte All-In-One system achieves lower profile and greater flexibility, 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 technology providing uniform and controlled balloon growth, even at high pressures, to safely facilitate direct stenting and use of the system for post-dilatation.

"The Svelte All-In-One drug-eluting platform offers a novel and potentially improved method of stent delivery coupled with a unique, bio-friendly drug carrier, which can have positive and meaningful clinical and practical impact for both patients and physicians," said Mark Webster, MBChB, an interventional cardiologist at Auckland City Hospital and principal investigator for the DIRECT study.

The firm is estimating that a CE mark for the application could be close to two years out with an FDA approval further down the line.

"We anticipate by late 2013 that we'll have CE mark," Pomeranz said. "It will probably take us until the back half of 2016 - best case scenario - to get that device approved in the U.S.

A bare metal stent version of the Svelte 'All-In-One' system, has already received CE mark in August of last year, and is commercially available in select European and Latin American markets.

Svelte Medical Systems was founded in 2007 by the Fischell family. Pomeranz joined the company sometime in 2008.

"To date, the company has raised through our series A financing, $24 million and we're looking to raise about $30 million in our Series B round," Pomeranz said.

The company, which has 10 full time employees, completed the funding round last year (*Medical Device Daily*, April 9, 2010). ■

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"The five-year results from ENDEAVOR IV confirm that long-term clinical outcomes should be an essential consideration when making decisions related to stent selection," Kandzari said. "Interventionalists treating patients with coronary artery disease now have ample data to distinguish the important differences between the performance of these two drug-eluting stents."

Kandzari also presented a five-year update to a pooled analysis of safety data from the Endeavor clinical program at TCT. The analysis, ENDEAVOR Pooled Safety, involved 2,132 patients who received an Endeavor DES as participants in one of six studies, including ENDEAVOR IV.

ENDEAVOR Pooled Safety shows that at five years of follow-up, treatment with the Endeavor DES resulted in a significant reduction in TLR and CD/MI, and was associated with no increased risk of stent thrombosis in comparison to a bare-metal stent control group including 596 patients from ENDEAVOR II.

"These findings are even more relevant because most patients in both groups were off dual-antiplatelet therapy by one year after stent implantation," Kandzari said. His paper, "Dual antiplatelet therapy duration and clinical outcomes following treatment with zotarolimus-eluting stents," appeared in the October edition of *JACC: Cardiovascular Intervention*. "The Endeavor DES exhibits a safety profile that not only is durable through late-term follow-up but that also distinguishes it from comparative devices." ■

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argued that HBD is "a very important initiative," for several reasons, including that "someday it may extend beyond the U.S. and Japan, because truly we need to become more global in our thinking." ■

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