



FDA advisory committee

Medtronic wins advisory; QRS interval kills unanimous vote

By MARK McCARTY

Medical Device Daily Washington Editor

GAITHERSBURG, Maryland – The application by **Medtronic** (Minneapolis) to expand the indication for one class of its electrophysiology hardware for class II heart failure patients turned out well at Wednesday’s advisory committee hearing despite a lot of negative rhetoric by members of the advisory committee. The firm earned a 3-2 final vote that the benefits of the firm’s devices for this indication outweigh the risks, and the vote may have struck some observers as a surprise given the obvious antipathy toward the application’s supporting studies by some members of the panel. However, the FDA representatives who argued the agency’s case seemed none too fond of the application, either.

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LifeScience Alley, FDA ink MOU to advance regulatory science

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

LifeScience Alley (Minneapolis) and the FDA’s Center for Devices and Radiological Health (CDRH) have signed a memorandum of understanding (MOU) intended to advance regulatory science. With any luck, this could be the first step toward getting devices to market faster - while ensuring safety and efficacy – at a lower cost and more efficiently than the current U.S. regulatory environment allows.

LifeSciences Alley says the MOU formalizes interactions that have been occurring between the organization and CDRH for more than a year regarding the advancement of regulatory science. CDRH Director Jeffrey Shuren, MD, signed the MOU just before his keynote address at the tenth annual LifeScience Alley conference and exposition. Regulatory science refers to the tools, methods,

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Report from Europe

Spinal Modulation system gets CE mark for CIP management

A Medical Device Daily Staff Report

Spinal Modulation (Menlo Park, California), a privately held device company, reported that its Neurostimulator system has received the CE mark for the management of chronic intractable pain (CIP). The Spinal Modulation System utilizes low-level electrical signals to modulate neural structures of primary sensory neurons located within the dorsal root ganglion (DRG). These cell bodies have been implicated in the development and maintenance of chronic pain conditions.

“The Spinal Modulation system has provided substantial benefit to a number of my patients with chronic intractable pain that have not had adequate pain relief with other

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BSX gains FDA approval for Infinion 16 Percutaneous Lead

By OMAR FORD

Medical Device Daily Staff Writer

The American Pain Foundation (Baltimore) points out that there are more than 75 million patients in the U.S. that suffer from chronic pain. Of that number tens of thousands of patients have found that Spinal Cord Stimulator Systems can help with the management of pain. It’s a ripe market, and **Boston Scientific** (Natick, Massachusetts) could gain a huge advantage in the space, as the med-tech firm has reported gaining FDA approval of the Infinion 16 Percutaneous Lead, a component designed to work with the company’s Precision Plus Spinal Cord Stimulator (SCS) System.

Boston Scientific claims that the Infinion 16 Lead is the world’s first 16-contact percutaneous lead and

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Don’t miss today’s MDD Extra: Diagnostics



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*Financings roundup***CVS Caremark reveals final results of preferred security offering***A Medical Device Daily Staff Report*

CVS Caremark (Woonsocket, Rhode Island) reported the expiration and final results of its previously reported tender offer as of 5 p.m. on Dec. 7, 2011 for any and all of its \$1 billion outstanding 6.302% enhanced

*Deals roundup***FTC approves LabCorp's acquisition of Orchid***A Medical Device Daily Staff Report*

Laboratory Corporation of America Holdings (LabCorp; Burlington, North Carolina) said it has reached an agreement with the U.S. Federal Trade Commission allowing LabCorp to complete its acquisition of **Orchid Cellmark** (Dayton, Ohio). Under the terms of the proposed consent decree that was accepted by the FTC for public comment, LabCorp is required to divest certain assets of Orchid Cellmark's U.S. government paternity business following closing of the acquisition. LabCorp has reached agreement to sell those assets to **DNA Diagnostics Center** (DDC), a privately held provider of DNA paternity testing.

LabCorp commenced a tender offer for all outstanding shares of Orchid at a price of \$2.80 per share net to the seller in cash without interest and subject to applicable withholding taxes (*Medical Device Daily*, Aug. 16, 2011).

As previously reported, LabCorp's cash tender offer for all outstanding shares of common stock of Orchid Cellmark is scheduled to expire at 5 p.m., EST, Dec. 9, unless further

capital advantaged preferred securities. The tender offer commenced on Nov. 29.

The settlement date for notes validly tendered on or prior to the expiration date is expected to be Dec. 8, 2011. In addition to the total consideration, holders of notes accepted for purchase will receive accrued and unpaid interest on those notes from the last interest payment date with respect to the notes to, but not including, the settlement date.

Barclays Capital and Deutsche Bank Securities acted as the dealer managers for the tender offer. ■

extended (*MDD*, Dec. 2, 2011).

LabCorp makes diagnostic technologies and genomic testing.

In other dealmaking news, **Diversified Service Options** (DSO; Jacksonville, Florida), a subsidiary of Blue Cross and Blue Shield of Florida and the holding company for First Coast Service Options (FCSO), reported its agreement to acquire Highmark Medicare Services (HMS), a subsidiary of **Highmark** (Pittsburgh).

"HMS is an outstanding organization, and we are proud to have the opportunity to welcome the company to our DSO family. Both FCSO and HMS have excellent reputations in the government-sponsored health care industry," said Sandy Coston, CEO of DSO and FCSO. "This acquisition will allow DSO to dramatically increase our business volume which will be of great benefit in providing more cost-effective services for our Medicare claims administration business. We expect both FCSO and HMS to continue to deliver high quality services to which our customers are accustomed."

Both HMS and FCSO will continue to operate as separate, independent organizations, as wholly-owned DSO subsidiaries.

Highmark is an independent licensee of the Blue Cross Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. ■

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*Restructuring roundup***Maquet restructures U.S. sales and services organizations***A Medical Device Daily Staff Report*

Maquet (Wayne, New Jersey) said it has restructured its U.S. Sales and Services Unit to meet the broader needs of customers across all areas of clinical care. As part of this restructuring, the company says it now offers a comprehensive disease therapy team dedicated to servicing customers who are building a hybrid operating room (HOR).

According to the company, a HOR is an operating suite housing all of the equipment and monitoring devices necessary to perform open heart surgeries, such as coronary artery bypass grafting, and percutaneous coronary interventions and procedures, including angioplasty and stenting.

An estimated 100 hospitals in the U.S. currently have a HOR, and the number is expected to increase by 15% or more over the next few years, according to Maquet. With HHOR's a top investment made by hospitals today and roughly 60% of all U.S. hospitals planning for one, HOR's represent a rapidly growing market.

"In a Hybrid OR, the cath lab doubles as an operating room so a patient undergoing a cardiac catheterization procedure can be quickly moved to surgery if required," said Niv Ad, MD, chief of cardiac surgery and director of cardiac surgery research at **Inova Heart and Vascular**

Institute (Fairfax, Virginia). "Hybrid OR's offer the potential for improved patient outcomes, as they allow physicians to perform a full range of procedures within one setting and eliminate the need to move a critically ill patient to a different room of the hospital."

Maquet's new hybrid surgery group will partner with **Philips** (Andover, Massachusetts) and **Siemens** (Malvern, Pennsylvania) to provide comprehensive therapy solutions for this growing market, including a surgical table that can be fully integrated with the imaging system, as well as ceiling booms, cardiac perfusion pumps, intra-aortic balloon pumps, anesthesia systems, surgical lights and OR data integration for advanced surgical suite control. Sophisticated, and fully integrated, this HOR is now available from a single source supplier, Maquet noted.

The company has also launched a new website at MAQUET-HybridOperatingRoom.com intended to provide information about planning, implementing, building and equipping a highly complex Hybrid OR.

"Maquet is the single-source provider of comprehensive Hybrid OR solutions, with more than 10 years of experience leading the development of Hybrid OR's for medical centers around the world," said Raoul Quintero, president of Maquet's U.S. Sales and Service organization. "With the creation of our new hybrid surgery group and through our partnerships with the most advanced imaging partners, we are committed to helping teams of clinicians effectively plan for and introduce this new approach into their hospitals." ■

*HIT roundup***GE, Microsoft to launch JV for healthcare transformation***A Medical Device Daily Staff Report*

GE Healthcare's IT business (Barrington, Illinois) and **Microsoft** (Redmond, Washington) reported plans to create a joint venture aimed at helping healthcare organizations and professionals use real-time, system-wide intelligence to improve healthcare quality and the patient experience.

The new company, which has yet to be named, will be headquartered near the Microsoft campus in Redmond, Washington, with significant presence in Salt Lake City, Utah and additional cities around the world.

Launch of the new joint venture is subject to customary conditions, including regulatory approvals, and is expected in the first half of 2012.

Upon formation, the new company will develop and market an open, interoperable technology platform and innovative clinical applications focused on enabling better population health management to improve outcomes and the overall economics of health and wellness.

As healthcare providers and payers around the globe shift from episodic single-patient care to continuous

population management, new requirements have emerged for integrated care processes, greater insight and engaging patient experiences. These delivery system reforms, including a shift toward new payment models, require healthcare providers to address gaps and integrate data across silos of care delivery to help enable better care coordination and performance improvement.

This new venture will combine Microsoft's deep expertise in building platforms and ecosystems with GE Healthcare's experience in clinical and administrative workflow solutions, empowering healthcare professionals and organizations with the intelligence and capabilities to respond to the rapidly evolving and complex healthcare landscape.

"The complementary nature of GE Healthcare's and Microsoft's individual expertise will drive new insights, solutions and efficiencies to further advance the two companies' shared vision of a connected, patient-centric healthcare system," said Jeffrey Immelt, chairman/CEO of GE. "The global healthcare challenges of access, cost and quality of care delivery are creating a new focus on the performance and accountability of healthcare delivery systems – in every country, at every level of care. This venture will demonstrate what is possible when leading

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Product Briefs

- **Abbott** (Abbott Park, Illinois) reported the initiation of ABSORB II, the first randomized, controlled, multi-center clinical trial to evaluate the safety, efficacy and performance of the Absorb bioresorbable vascular scaffold (BVS) compared to the company's Xience Prime everolimus eluting coronary stent system. About 500 patients with coronary artery disease will be enrolled at about 40 investigational sites in Europe and New Zealand. Absorb is a bioresorbable scaffold designed to treat a patient's blocked vessel and then fully dissolve, leaving the vessel free of a permanent metallic implant. Because a permanent implant is not left behind, naturally occurring vessel functions may be restored. The primary endpoints of the trial are change in dimension of the lumen (interior of the vessel) over time and vasomotion (vessel movement) at the treated vessel segment, which will be assessed based on changes in the vessel diameter in response to a stimulus. Absorb is made of polylactide, a proven biocompatible material that is commonly used in medical implants such as dissolvable sutures. Studies to date have shown that the Absorb device restores blood flow by opening a blocked vessel and providing support to the vessel until the device dissolves after about two years.

- **Exactech** (Gainesville, Florida) reported the full market launch of its Gibralt spinal system. The Gibralt spinal system is a comprehensive solution for posterior stabilization and an adjunct to fusion of the cervical and upper thoracic spine. Gibralt features top loading polyaxial screws, hooks, offset connectors, and rod-to-rod connectors which can be constructed into a multitude of configurations based individual patient anatomy. The low-profile pedicle screw with 80 degrees of motion is designed to reduce the risk of tissue impingement in the thoracic spine, and the EZ Set tulip head allows the tulip head to be easily positioned and set for rod insertion. The Tightlok thread technology of the thread provides high biomechanical strength, resisting screw pullout.

- **OraSure Technologies'** (Bethlehem, Pennsylvania) subsidiary, **DNA Genotek** (Ottawa), a provider of products for biological sample collection, stabilization and preparation, reported FDA clearance for DNA Genotek's Oragene-Dx collection device. Oragene-Dx is a saliva DNA collection and stabilization device. DNA Genotek's lead product line, Oragene, provides a system for the collection, stabilization, and transportation of DNA from saliva. Oragene provides reliable collection of high quality DNA samples using a simple, non-invasive method and the ability to transport and store collected samples for extended periods at ambient temperatures. Oragene-Dx is suitable for use in FDA-cleared molecular diagnostic applications and was cleared using results from the eSensor Warfarin

Sensitivity Saliva Test.

- **X-spine** (Miamisburg, Ohio) reported FDA clearance of the Axle-PEEK interspinous fusion system. The Axle-PEEK system consists of spinal implants FDA-cleared for the treatment of degenerative disk disease (DDD). The system expands on X-spine's Axle line of interspinous fusion devices by incorporating an insert manufactured from PEEK-Optima provided by Invibio Biomaterial Solutions. The Axle-PEEK implants can be placed through a smaller incision and with less disruption of tissues than traditional spinal fusion devices. With this clearance, X-spine uniquely offers spine surgeons a choice of implant materials, either titanium or polymer, in a single device. X-spine makes implants and instrumentation for surgery of the spine. Invibio makes biomaterials, advanced technical research and consultative solutions to medical device manufacturers across a wide range of markets.

Med-Tech Notes

Neoprobe changes name to Navidea

Neoprobe (Dublin, Ohio) said it will change its name to **Navidea Biopharmaceuticals**. The company is also scheduled to begin trading under a new ticker symbol (NAV) on the NYSE Amex exchange at market open on Jan. 5.

In connection with the sale of the neoprobe GDS medical device business and related brand name (Neoprobe) to Devicor Medical Products in August (*Medical Device Daily*, Aug. 18, 2011), the company commenced a corporate re-branding initiative reflecting its business pursuits in the precision diagnostics space. Navidea was chosen as the new name to reflect the company's dedication to "NAVigating IDEAs" that translate cutting edge innovation and precision diagnostics technology into novel products to advance patient care.

"Our new corporate identity signifies the company's transformation into a biopharmaceutical company focused on development and commercialization of precision radiopharmaceutical diagnostics for cancer and other significant disease areas," said Mark Pykett, Neoprobe president/CEO. "We plan to reveal a more complete view of the Navidea brand and an updated website in January in connection with the legal change in our corporate name and as we begin trading under our new ticker symbol, NAV. In the meantime, we wanted to provide advance notice of the change. As Navidea, we will continue to focus our efforts on the approval and commercialization of Lymphoseek and on our development efforts surrounding RIGScan. In addition, we plan to actively move forward with other pipeline development opportunities, including the in-licensing or acquisition of other promising agents."

Neoprobe is focused on the making precision diagnostics and radiopharmaceutical agents.