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An Overview of the Latest Updates from Technology & Industry

Medtronic Data Proves Corevaive Performance

New clinical data demonstrate positive long-term performance and durability for the Corevalve transcatheter aortic valve replacement system from Medtronic, Inc. Two-year results from the pivotal 18- French Corevalve multicentre prospective study provide important additional evidence supporting wider use of this transcatheter aortic valve.

The Corevalve system received the CE (Conformité Européenne) mark in March 2007. It is not yet available in the United states for clinical trial or commercial sale or use. The Corevalve system, designed to replace a diseased aortic valve without open-heart surgery or surgical removal of the native valve, has now been implanted in more than 10,000 patients worldwide in 32 countries outside the United states. Typically delivered through the femoral artery, Corevalve is used in 75 percent of transarterial transcatheter valve replacement procedures.

Agfa Ink New Heartstation ECG Deal

Agfa HealthCare has announced Western Maryland regional Medical Centre's recent upgrade to the newest version of IMPAX Heartstation ECg Management system to enable the rapid diagnosis and treatment of patients with posterior wall heart attacks. The Cumberlandbased hospital is using the recently released features of IMPAX Heartstation to digitally review and archive 15-lead ECg studies. Compared to more commonly found 12-lead ECg equipment, 15-lead ECg provides more complete data for detecting heart attacks in the right and posterior ventricle walls. IMPAX Heartstation's features analyse and prioritise 12- and 15-lead ECg exams as they come into the system and alert healthcare providers if a patient is experiencing a life-threatening or other critical condition.

Nevotm Stent Contlnues to Show Solid Results

At 12 months the NEvOTM sirolimuseluting coronary stent has continued to demonstrate excellent safety and efficacy outcomes compared to Taxus® Liberte® according to new data presented from the NEvOTM rEs-l clinical trial. Through 12-month follow-up, there have been no episodes of stent thrombosis reported in the NEvOTM arm, whereas two such events have been reported through 12 months in patients treated with the Taxus® Liberté ® stent, and a third event in this arm was reported after 13 months. Additionally there have been no cases of cardiac death or out-of-hospital myocardial infarction (MI) for patients receiving NEvOTM.

While the trial was not powered for clinical endpoints and thus no statistically - significant differences were observed, the rates of death, MI, the need for repeat revascularisation, and the occurrence of stent thrombosis numerically favoured NEvOTM over Taxus® Liberté® to an even greater degree at 12 months than they had at six months. similar trends were observed in the pre-defined subgroups of patients with diabetes and patients with lesion lengths less than or greater than 20 mm.

At the six-month primary endpoint of this prospective, randomised clinical trial, NEvOTM was reported to be superior to Taxus® Liberté® in in-stent late lumen loss, which is tissue growth within a stent. specifically, in -stent late lumen loss was reduced by 64 percent in the NEvOTM arm as compared to the Taxus® Liberté® arm (0.13 mm compared to 0.36 mm, p<0.001).

In-stent late lumen loss reduces the diameter of the lumen thus restricting blood flow through the stent and can potentially lead to major adverse coronary events, also known as MACE. NEvOTM was also superior in reducing restenosis, a reblockage in a stent. Angiographic restenosis was reduced 86 percent (1.1 percent in the NEvO arm compared to 7.8 percent in the Taxus Liberte arm, p=0.002).

Blotronik Announce Trust Trial Results

BIOTrONIK published final results of the landmark TrUsT Trial (Lumax-T/Lumos- T safely redUces rouTine Office device Follow-up) in the July 27, 2010 issue of Circulation. BIOTrONIK Home Monitoring® is the industry's first and most advanced wireless remote monitoring system for patients with cardiac devices.

The article, "Efficacy and safety of Automatic remote Monitoring for ICd Follow- Up: The TrUsT Trial," demonstrates the benefits of home monitoring in the safe reduction of conventional clinic follow- up visits, as well as in the early detection of patient clinical events, including

asymptomatic atrial fibrillation. Further, home monitoring can extend the time between routine in-office follow- ups, and is the only system having FdA and CE approval to claim these benefits. developed by a steering committee of U.s. electrophysiologists, with 1,450 patients enrolled and randomised in 102 North American sites, TrUsT is the first large-scale prospective cardiac rhythm management study to prove remote monitoring and rapid detection of symptomatic and asymptomatic cardiac events in a prospective, randomised trial. TrUsT used BIOTrONIK home monitoring, an automatic, wireless system that performs daily telemetric surveillance of the patient and reports the technical status of the implanted device without requiring patient activation.

Tide Trial Halts Pending fda Review

glaxosmithKline confirmed today that it will suspend enrolment of new patients in the Thiazolidinedione Intervention with vitamin d Evaluation (TIdE) clinical trial at the request of the U.s. Food and drug Administration (FdA) pending FdA review of recommendations from its advisory committee meeting. Patients already enrolled may continue in the trial.

This post-marketing study is designed to examine the comparative cardiovascular safety of rosiglitazone (Avandia) and pioglitazone (Actos) in patients with type 2 diabetes. It was mandated by the FdA and is being conducted by an independent academic research group, population health research institute based at McMaster University. gsK will work with the TIdE steering committee to send a summary of recent safety data and a summary of the FdA advisory committee meeting on Avandia to all TIdE investigators and institutional review boards to ensure they have the latest information for patients.

St. Jude Medical Completes Lightlab Purchase

st. Jude Medical, Inc. completed its acquisition of LightLab Imaging, Inc. for approximately 90 million dollars in cash. LightLab is involved in the development of Optical Coherence Tomography (OCT), a high-resolution diagnostic coronary imaging technology. The acquisition of OCT technology accelerates the expansion of st. Jude Medical's cardiovascular growth platform by providing the company with a comprehensive product offering that will allow the company to compete in, and potentially expand, the intravascular imaging market. The IvUs market is estimated to be 500 million dollars for 2010 and to grow 10 to 15 percent annually. during the second half of 2010, st. Jude Medical expects the OCT platform to contribute an additional 20 million dollars in revenue to its cardiovascular business. The OCT market is expected to grow at a double-digit compounded annual rate over the next five years and is expected to capture IvUs market share.

The combination of both OCT and the complementary Fractional Flow reserve (FFr) technology will provide physicians with comprehensive lesion assessment information; FFr provides physiological data to help physicians determine which lesions to treat, and OCT provides anatomical images which can help guide stent selection and deployment as well as provide post-stenting information to help ensure the procedure went smoothly.

Boston Scientific Announces First Patient for Multisense Trial

Boston scientific Corporation announced enrollment of the first patient in its MultisENsE clinical trial. The trial is designed to evaluate multiple physiologic sensors in the Company's COgNIs™ cardiac resynchronisation therapy defibrillators (CrT-ds). Boston scientific plans to use the trial data to help develop a clinical alert that identifies the early onset of worsening heart failure. The first patient was enrolled by Paul Coffeen, M.d., Austin Heart, Austin, Texas, where Jeffrey Whitehill, M.d., Medical Chair, Electrophysiology department, is the site's principal investigator. When combined with the company's LATITUdE® patient management system, CrT-d sensors would be able to monitor a patient outside of a clinical setting and permit the LATITUdE system to deliver early notification to the physician when the patient's heart failure worsens.

"Heart failure is a complex disease and physicians use a number of diagnostics to assess a patient's condition and disease progression," said John Boehmer, M.d., Medical director, Heart Failure Programme and Professor of Medicine, Penn state Hershey Medical Centre and principal investigator of the MultisENsE trial. "A multi-sensor design in an implantable device, with the predictive power of multiple data points, would enable physicians to take clinical action sooner to avoid hospitalisation due to heart failure."

Sanofi-Aventis Partners for Diabetes

sanofi-aventis and the Juvenile diabetes research Foundation (JdrF) announced today a unique partnership to develop therapeutic treatments for people with type 1 diabetes at different stages of the disease – both those living with the disease and the newly diagnosed – as well as preventing diabetes in those at risk. Toward those

goals, the partnership will focus on therapeutics such as immune therapies and beta cell regeneration.

Under the newly announced partnership, sanofi-aventis and JdrF will jointly provide academic investigators and non-profit medical research organisations with funding to conduct research projects in regeneration and immune therapy. This partnership will provide sanofi-aventis with options to the intellectual property developed by researchers who receive funding through the programme.

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