

Deals roundup

Medtronic set to pay up to \$500 million to buy Invatec

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

Med-tech giant **Medtronic** (Minneapolis) said Monday it will pay up to \$500 million to acquire **Invatec** (Brescia, Italy), developer of devices for the interventional treatment of cardiovascular disease, and two affiliated companies, **Fogazzi** (also Brescia), which provides polymer technology to Invatec; and **Krauth Cardiovascular** (Hamburg, Germany), which distributes Invatec products in Germany.

Medtronic has agreed to make an initial payment of \$350 million and additional milestone payments of up to \$150 million.

According to the company, Invatec's array of stents, angioplasty balloons and accessory products complement therapies and products in Medtronic's CardioVascular business, adding a robust peripheral franchise and pipeline,

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Boston Atrial Fibrillation Symposium

Symposium examines latest treatments of atrial fibrillation

By LARRY HAIMOVITCH

Medical Device Daily Contributing Writer

BOSTON –The 15th annual Boston Atrial Fibrillation Symposium was recently held here. While controversy was at a minimum, there were several interesting topics that held the attention of the more than 1,000 participants, which drew attendees from EP industry clinicians, aspiring entrepreneurs and the investment community.

In recent years, there has been considerable progress in managing this disease, which afflicts 2.3% of the population over the age of 40, 6% of those over 65 and nearly 10% of those over 80. However, paraphrasing the inimitable words of Winston Churchill, from a talk he gave discussing Russia in October 1939, atrial fibrillation yet remains "... a riddle, wrapped in a mystery, inside an enigma ..."

This year's programs covered the gamut of treatment

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Report from Europe

Bmeye, Masimo get CE mark for noninvasive cardio monitor

A Medical Device Daily Staff Report

Bmeye (Amsterdam, the Netherlands), the developers of combined noninvasive, beat-to-beat blood pressure and cardiac output monitoring, and **Masimo** (Irvine, California), the inventor of Pulse CO-Oximetry and Measure-Through Motion and Low-Perfusion pulse oximetry, jointly reported the CE mark certification and the European launch of the Bmeye ccNexfin, noninvasive cardiovascular monitor with Masimo Rainbow SET Pulse CO-Oximetry technology.

The combination of two noninvasive technologies – Bmeye for cardiovascular monitoring and Masimo Rainbow SET for hemoglobin and oxygen saturation monitoring – provides real-time, beat-to-beat measurements of cardiac, circulatory, and pulmonary parameters, which may enable clinicians to detect impending cardiovascular crisis before organ injury ensues.

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Washington roundup

FDA announces meeting on 510(k) process next month

By MARK McCARTY

Medical Device Daily Washington Editor

FDA has announced that it will hold a meeting next month on the 510(k) process, which has been under increasingly intense scrutiny since the blow-up over the Menaflex application, sponsored by **ReGen Biologics** (Franklin Lakes, New Jersey) last year. ReGen's application went to an advisory committee hearing in 2008 (*Medical Device Daily*, Nov. 18, 2008), but several members of Congress had intervened on the firm's behalf, including Rep. Frank Pallone (D-New Jersey), sparking cries of corruption of the process.

Pallone then reversed field, holding a hearing last year in the House Energy and Commerce Committee's health subcommittee during which he stated he was working on a bill that would tighten the requirement for

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Don't miss today's MDD Extra: Cardiology

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*Court report***Oregon jury awards dad \$5.5M for destroyed shoulder joint****A Medical Device Daily Staff Report**

An Oregon jury has awarded a Portland father of four \$5.5 million for a destroyed shoulder joint that was damaged by a pain pump device not approved by the FDA.

Attorneys representing Matthew Beale, 38, and his wife Krista Beale, say **I-Flow** (Lake Forest, California) knowingly marketed its On-Q Painbuster, an infusion pain pump, to orthopedic surgeons even though the FDA rejected approving the device for lack of safety data. The award includes \$1.275 million in damages to Krista Beale. The FDA issued a warning to doctors that it had never approved the use of such pain pumps in shoulder-joint surgeries in November 2009.

"I-Flow did not test the safety of the pump, did not have FDA approval and did not warn doctors that this device was not safe for shoulder-joint surgeries," said Tom Powers, one of the Beales' attorneys with the Portland-based law firm Williams, Love, O'Leary & Powers, PC. "If you don't know, you test. If you can't test, you warn. The last thing you do is mislead or lie."

I-Flow had submitted requests to receive FDA approval for the use of its pain pump for shoulder surgeries three times, according to the Beales' attorneys. The FDA rejected those requests three times for lack of safety data. But I-Flow issued a statement on June 2, 1998, claiming that the agency had approved its pain pump for orthopedic use.

Lead trial attorney John Coletti of the Paulson Coletti firm in Portland said there may be many more people suffering from similar debilitating injuries caused by the I-Flow pump across the country. "This is one of those issues

Coming Wednesday in MDD Perspectives**Is it time for a healthcare legislation reboot?**

With the recent Republican pick up of the Senate seat formerly held by the late Democratic stalwart Ted Kennedy for more than four decades, giving the Republican party the ability to muster a filibuster in the Senate, the future of current healthcare legislation may be in jeopardy, and that might be a very good thing. It's time to think about hitting the reset button in favor of a much more bipartisan piece of legislation. Read about it in tomorrow's edition of MDD Perspectives, an op-ed e-zine that provides fresh commentary and opinions on issues that you can't find anywhere else. And best of all, it's free. If you don't already subscribe to this complimentary e-zine, go to medicaldevicedaily.com to sign up.

that flies under the radar of media, and even some physicians," Coletti said. "We hope that news of this verdict will help spread the word about this problem."

According to the attorneys, Beale routinely participated in football, racquetball, golf and coaching his son's baseball teams and originally injured his shoulder throwing a football, suffering a minor tear in his bicep tendon.

After routine arthroscopic surgery, his doctor prescribed an I-Flow pain pump, which killed the cells that create cartilage in his shoulder joint, Beale's attorneys said. Within months, his cartilage was completely destroyed and his shoulder could no longer produce more cartilage.

According to court documents, his doctor had no idea

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*Agreements/contracts***GE Hitachi chosen to develop U.S. supply of radioisotopes****A Medical Device Daily Staff Report**

GE Hitachi Nuclear Energy (GEH; Wilmington, North Carolina) has been selected by the U.S. Department of Energy's National Nuclear Security Administration (NNSA) to help develop a U.S. supply of a radioisotope used in more than 20 million diagnostic medical procedures in the U.S. each year.

NNSA has chosen GEH to help create a reliable U.S. supply of molybdenum-99 without the use of highly enriched uranium (HEU) to respond to a shortage from repeated, unplanned outages at facilities where it currently is produced.

Molybdenum-99 is the precursor of technetium-99m, the radioisotope most widely used in nuclear medicine diagnostic procedures, including the detection of cancer, heart disease and thyroid disease, along with the study of brain and kidney function and the imaging of stress fractures, according to the Society of Nuclear Medicine.

GEH's new technology does not rely on the fissioning of HEU, advancing a key non-proliferation initiative for the U.S. Because GEH's technology can be used in existing nuclear reactors, the need to build new reactors dedicated to isotope production is reduced.

"NNSA is committed to supporting technology that offers a new path forward for the creation of a reliable, domestic supply of molybdenum-99 without the use of HEU," said NNSA Administrator Thomas D'Agostino. "This pragmatic approach addresses a critical U.S. medical community need while supporting President Obama's goal of reducing the risk posed by global use of HEU."

Deploying GEH's isotope production technology potentially could meet at least 50% of the projected U.S. supply needs for molybdenum-99/technetium-99m to help ensure patient access to vital medical diagnostic procedures. GEH will conduct research and development to confirm its technology at commercial scale and determine the infrastructure and logistics needed to support commercial operation.

"We are seeking some short-term solutions that have long-term potential, and the GEH technical solution provides a path forward that is quite attractive to meet both these needs," said Robert Atcher, MD, PhD, past president of the Society of Nuclear Medicine, who evaluated GEH's isotope technology.

With a half-life of only 66 hours, molybdenum-99 must be delivered to hospitals on a frequent and consistent basis. Molybdenum-99 decays into technetium-99m, the radioisotope most widely used in common diagnostic procedures. Technetium-99m is used in about 80% of all nuclear medicine procedures, including evaluation of the heart, kidneys, lungs, liver, spleen, bones and blood flow.

In other agreements/contracts news:

- **Babcock & Wilcox Technical Services Group** (B&W TSG; Lynchburg, Virginia) has been awarded approximately \$9 million from the National Nuclear Security Administration (NNSA) for the company's medical isotope production program. Awarded under a cooperative agreement, the funding will be used for further development of B&W TSG's patented reactor technology for medical isotope production using low enriched uranium.

- **Symmetry Medical** (Warsaw, Indiana) has entered into an exclusive five-year supply agreement with **OrthoPediatics** (also Warsaw). Symmetry will serve as a manufacturer of implants, instruments and cases, and provide engineering resources, inventory management, warehousing and full supply chain management services through Symmetry's Total Solutions offering, which is ideal for companies like OrthoPediatics. New product development services will be provided by Symmetry's Design and Development Center. Finished products and kitted sets will be shipped direct from Symmetry to distributors and hospitals.

Revenues to Symmetry from the exclusive supply of products, supply chain management and product development services agreement are expected to total about \$3 million in 2010. In addition, Symmetry will receive fees for inventory management, warehousing, and supply chain management services.

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*Financings roundup***Quest Diagnostics to expand share repurchase to \$750M****A Medical Device Daily Staff Report**

Quest Diagnostics (Madison, New Jersey) said that its board increased the company's share repurchase authorization by \$750 million.

"The expansion of our share repurchase program reflects the company's financial strength and our ability to continue generating strong cash flows, and, in addition to continuing to invest in the growth of our business, provides another means to return value to our shareholders," said Surya Mohapatra, PhD, chairman/CEO.

During 2009, the company repurchased about 10 million shares of common stock for \$500 million, fully using its previous authorization. The company had about 183 million shares outstanding as of Dec. 31, 2009.

Quest provides diagnostic testing, information and services.

In other financing news, **Prognosys** (College Park, Maryland), a company developing rapid, multiplexed diagnostics for multiple diseases, has joined the **University of Maryland's** (College Park) Maryland Technology Enter-

prise Institute (Mtech) Technology Advancement Program (TAP) incubator.

One of the company's first products, supported by a \$100,000 phase 1 contract from the National Institutes of Health's National Heart, Lung and Blood Institute, is a test for multiple cardiovascular diseases built on Prognosys' barcode platform. The product is designed to diagnose patients with acute cardiovascular diseases in emergency rooms, enabling physicians to make quick decisions based upon whether a patient tests for acute vascular clots, deep venous thrombosis, pulmonary emboli, or potentially acute coronary syndrome.

"When a person goes to a hospital with chest pain, the triage nurse or physician may initially have no idea what a patient has," says Kenneth Gabriel, president of Prognosys. "A blood sample is taken and shipped to the lab, where technicians work to process samples, but some tests can take up to two days for results, and in some cases patients die. Our test can be done in the ambulance on the way to the hospital, with results in as little as ten minutes."

Prognosys' technology involves embedding multiple sensors on a barcode that react to certain indicators and show results when scanned with a standard bar code reader. Results are then sent through the company's software to a Web-based portal accessible by nurses and physicians or to a handheld device. ■

People in the News

- **Cardinal Health** (Dublin, Ohio) said that James Mongan, MD, has joined the company's board of directors and will serve on the board's audit committee. Mongan was president/CEO of Partners HealthCare System from 2003 until his retirement in December 2009. Cardinal Health makes medical and surgical products, including gloves, surgical apparel and fluid management products.

- **Henry Schein** (Melville, New York) has named Bradley Sheares, PhD, to the company's board. Sheares most recently was CEO of Reliant Pharmaceuticals. Henry Schein's four business groups – dental, medical, international and technology – serve dental practitioners and laboratories, physician practices and animal health clinics, as well as government and other institutions.

- **PolyTouch Medical** (Misgav, Israel) has named William Edelman as chairman of the company. Edelman most recently was president/CEO of TYRX. PolyTouch Medical makes hernia mesh placement technologies.

- Erika Nemeth was promoted to Country Manager for **Synexus** (Manchester, UK). Previously, Nemeth was operations manager for Hungary. Sunexus is a company focused on the recruitment and running of clinical trials at its own dedicated research centers.

Agreements*Continued from Page 3*

- **Tri Hospital MRI Center** (Port Huron, Michigan) has selected **Merge Healthcare** to provide a radiology information system (RIS) that includes integrated business workflow from scheduling through billing. As a joint venture of Port Huron Hospital, St. Joseph Mercy Hospital and St. John River District Hospital; the center serves St. Clair, Sanilac and Huron counties. Fusion RIS brings integrated billing capabilities to radiology businesses by combining two distinctly separate radiology information and accounting applications into one system. ■

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Court

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that the I-Flow pain pump he used was not FDA approved, nor did he know the pump actually caused the permanent damage to Beale's shoulder joint. His doctor would later discover that nearly 49 patients he had treated with the I-Flow pain pump had similar complications after surgery, the documents noted.

"Matt was in so much pain from the bone rubbing on bone, he could not shake his clients' hands or pick up his baby without enduring a shock-wave of pain," Coletti said. "He will have to endure a complete shoulder-replacement surgery knowing that it's unlikely to permanently resolve his chronic pain or help him regain his active lifestyle."

In other legalities:

- Toe Myint, MD, a Tory, Michigan doctor, was convicted Friday by a Detroit jury of conspiracy to commit healthcare fraud in a \$4.2 million Medicare fraud scheme, reported Assistant Attorney General Lanny Breuer of the Criminal Division; U.S. Attorney Barbara McQuade of the Eastern District of Michigan; Special-Agent-in-Charge Andrew Arena of the FBI's Detroit Field Office; and Daniel Levinson, Inspector General of the Department of Health and Human Services (HHS).

After a weeklong trial in Detroit, the jury convicted Myint of one count of conspiracy to commit healthcare fraud. The conspiracy count carries a maximum prison sentence of 10 years. Myint was acquitted on charges of filing three specific false claims. Prior to trial, 10 of Myint's co-conspirator defendants pleaded guilty to a variety of Medicare fraud related charges.

Evidence at trial showed that Myint was the physician at **Sacred Hope Center** (Southfield, Michigan), a clinic that purported to specialize in providing infusion therapy to Medicare beneficiaries. Evidence established that Myint ordered medications for patients that he knew were not needed. Specifically, he signed patient files ordering infusions and injections of corticosteroids and other medications, despite being aware that the patients did not need the drugs and that Medicare was being billed for the drugs.

Trial evidence established that patients were not referred to Sacred Hope Center or Myint by their real physicians for any legitimate purpose, but rather were recruited to come to the clinic through the payment of kickbacks. In the six months between September 2006 and March 2007, Myint and his co-conspirators caused nearly \$4.2 million to be submitted to the Medicare program for services that were unnecessary and never provided.

- The law office of Howard G. Smith reported that it is investigating potential claims against **Stryker** (Kalamazoo, Michigan) concerning possible breaches of fiduciary duty and/or other violations of law by the company's board of directors. The investigation concerns public statements issued by Stryker between Jan. 25, 2007 and Nov. 13, 2008, regarding the company's business, operations, financial

performance and prospects.

Last week another firm, Robbins Umeda, said it had begun investigating possible "mismanagement" of Stryker, also concerning company statements issued during that time period (*Medical Device Daily*, Jan. 22, 2010).

According to a shareholder lawsuit filed Jan. 15, 2010, in the U.S. District Court for the Southern District of New York, during the foregoing period Stryker and certain of its executive officers failed to disclose and/or misrepresented, among other things, that certain Stryker manufacturing facilities were in non-compliance with federal regulations concerning the manufacture and sale of medical devices, that certain Stryker-manufactured products subjected the company to risks and losses due to product recalls, and that the company's reported earnings, gross profits and gross margins were materially overstated and its regulatory compliance costs were understated.

Robbins Umeda said that Stryker insiders took advantage company insiders took advantage of the stock's 52-week high of \$75 a share (split-adjusted) in November 2007, when they sold their personally-held shares generating more than \$300 million in proceeds prior to the stock's 52% decline to \$36.11 on Nov. 20, 2008. ■

Med-Tech Notes

Naviscan PEM added to First Coast arsenal

First Coast Oncology (Jacksonville, Florida) has significantly enhanced its ability to treat breast cancer with the addition of a Naviscan PEM (Positron Emission Mammography) scanner. The facility will be among the first in the nation to use both a PEM scanner and the AccuBoost image guided breast irradiation procedure to optimize their therapy treatment.

The Naviscan PEM scanner uses PET (Positron Emission Tomography) technology to produce high-resolution tomographic images at 2 millimeter resolution, allowing physicians to visualize breast tumors about the size of a grain of rice. The scanner is the size of a mammography unit and consists of two high-resolution detector heads which are placed in close proximity to the breast. Compared to the higher-force compression necessary for mammography, the Naviscan PEM scanner uses gentle breast immobilization.

AccuBoost is a technique for whole breast irradiation that is designed to target and deliver a boost dose accurately and reliably to the lumpectomy cavity margin. With PEM's three-dimensional metabolic perspective, physicians will be able to better visualize the region of interest prior to deploying the AccuBoost system, which lowers dose to healthy tissue as radiation is focused on the intended target sparing exposure to the heart, lungs and the uninvolved breast.

Deals

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while enhancing its coronary product offering. Medtronic noted that Invatec has brought four drug-eluting balloons to market, covering the coronaries and lower-extremity vessels – the only company worldwide with this distinction. “It is a pioneer in the development and commercialization of lesion-specific solutions, including therapies for below-the-knee and carotid artery disease,” according to Medtronic.

“Medtronic’s acquisition of Invatec will accelerate the growth of our CardioVascular business, adding important new products for the coronary and peripheral vascular markets,” said Scott Ward, senior VP at Medtronic and president of the CardioVascular business.

According to the company, cardiovascular interventions represent the world’s largest sector of the medical device market, generating \$10 billion annually on a global basis. A significant growth opportunity within this sector is peripheral vascular disease, a large and underserved market currently estimated at \$2 billion annually and growing faster than 10% a year, Medtronic noted. Roughly 20 million people in the U.S. and Western Europe alone suffer from peripheral vascular disease, which causes pain, reduces mobility, inhibits wound healing and leads to about 250,000 amputations a year, the company said.

“Invatec brings to Medtronic an established international business with a European center of technology development and manufacturing, as well as a strong history of delivering products and high-value solutions to the interventional market,” said Andrea Venturelli, co-founder, CEO and technical officer of Invatec.

Invatec’s core competencies include polymer processing, metallurgy, surface treatments and drug coatings. The company is vertically integrated with full in-house capabilities to design, develop, manufacture and assemble its 35 product families (seven in the U.S.) currently offered in more than 70 countries.

Just last week Invatec reported receiving FDA clearance to market its REEF HP, a PTA Balloon Catheter, for use in peripheral high-pressure dilatation procedures. The “lesion-specific” design of the balloon material is particularly useful in hard-to-dilate situations, the company said. The REEF HP balloon is made from Invatec’s Flexitec XF, a durable material with a large working pressure range of up to 22 atm, offering “excellent control” during high-pressure procedures. The low compliant balloon offers a uniform dilatation force and strong shape retention to dilate resistive lesions with greater stability and success, according to the company (*Medical Device Daily*, Jan. 21, 2010).

“Our integration into Medtronic creates a tremendous opportunity to leverage Medtronic’s global scale and scope across geographies and functions, from R&D to sales and marketing, to advance the interventional treatment of cardiovascular disease,” said Invatec co-founder Stefan Widensohler, VP of global sales and marketing.

Larry Biegelsen, an analyst at Wells Fargo Securities in New York, wrote in a note to investors that “the acquisition enhances [Medtronic’s] exposure to the peripheral vascular disease market.” Longer term, Invatec plans on launching its drug-eluting balloon in the U.S., though it has not started clinical trials yet, Biegelsen noted.

Last spring *MDD* reported that the drug-coated balloon is showing great promise in two small trials conducted to date making endovascular intervention below-the-knee possible where surgery is not, especially in the case of the diabetic patient, a population that makes up 80% of such cases.

The two trials by Scheller, et al., in the coronary area and Tepe, et al., in the peripheral area, published in the *New England Journal of Medicine* in 2006 and 2008, respectively, contradict notions that balloons are not as effective as stenting in smaller arteries, and significantly, show that these balloons are effective to fix problems of in-stent restenosis.

Key to Invatec devices is the FreePac formulation that combines paclitaxel with a compound “made of a 100% natural element that can be extracted from the body, so it is absolutely hemo- and bio-compatible,” Mario Landini, VP of clinical affairs for Invatec, told *MDD* last year (*MDD*, May 27, 2009).

Venturelli and Widensohler founded Invatec in 1996. The company employs about 900 people, predominantly in Brescia, and Frauenfeld, Switzerland.

In other dealmaking activity:

- **Critical Homecare Solutions** (CHS; Conshohocken, Pennsylvania), a **Kohlberg & Company** (Mt. Kisco, New York) portfolio company, said it has agreed to be acquired by **BioScrip** (Eden Prairie, Minnesota) in a deal valued at roughly \$358 million.

Privately owned CHS provides home infusion therapy and nursing services, with a total of 68 infusion and nursing locations. For the pro forma last twelve-month period ended Sept. 30, CHS generated revenues of about \$252 million.

BioScrip, a specialty pharmaceutical healthcare organization, will acquire all of the outstanding capital stock of CHS for \$358 million in cash, stock, debt and warrants. After the transaction, Kohlberg & Company designees will assume two seats on BioScrip’s board of directors. The deal is expected to be close by March 31.

- **ActivStyle** (Minneapolis), a supplier of home medical equipment throughout the U.S., reported the acquisition of **Advocate Medical Services** (Tampa, Florida). Advocate provides medical supplies to customers who suffer from spinal cord injuries, spina bifida, urological incontinence and retention, chronic wounds and ostomies.

Advocate will significantly expand ActivStyle’s expertise in the catheter supply market, the company said. With the transaction, Advocate will have access to a broader product line and the financial support of a larger parent organization.

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Afib

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options for AF, with significant emphasis on catheter ablation. About one year ago, the first AF ablation catheter, the Navistar Thermocool, was granted FDA approval (*Medical Device Daily*, Feb. 9, 2009). Developed by the **Biosense Webster** (Diamond Bar, California) division of **Johnson & Johnson** (J&J; New Brunswick, New Jersey), it was cleared for the treatment of drug refractory recurrent symptomatic paroxysmal (PAF, intermittent early stage) atrial fibrillation.

Catheter ablation, which before that approval was practiced on an "off-label" basis, was now legitimized by that approval and it remains the mainstay of device-based treatment of AF.

Hugh Calkins, MD, a renowned electrophysiologist (EP) and professor of medicine at **Johns Hopkins Heart & Vascular Institute** (Baltimore) provided a comprehensive review of AF clinical trials in his talk titled "Current Status of Clinical Trials of AF Devices Seeking FDA Approval."

He identified 120 trials that address AF, including the following:

- 83 trials for catheter ablation (72 involving "new" technology) with 50 single center trials and 33 multi-center trials
- 50 of those trials performed outside the U.S., the rest in this country
- 49 trials hospital funded, 25 funded by industry and three by the **National Heart, Blood & Lung Institute** (Bethesda, Maryland)

According to Calkins, the next likely FDA approval will be the Arctic Front balloon catheter, originally developed by **CryoCath** (Montreal). This company, which was acquired by **Medtronic** (Minneapolis) for about \$400 million (*MDD*, Dec. 22, 2008), was a pioneer in the development of a cryo-energy, rigid balloon catheter to perform a pulmonary vein isolation (PVI) procedure. PVI is one of the cornerstones of the treatment of AF.

The CryoCath Sustained Treatment Of Paroxysmal Atrial Fibrillation (STOP AF) pivotal clinical trial compared the cryo-balloon catheter to traditional anti-arrhythmic drug therapy. The trial enrolled 270 patients at 20 centers in the U.S. Calkins noted that the required 12-month follow-up was completed in July 2009 and that the final data will likely be presented at the upcoming mid-March annual meeting of the **American College of Cardiology** (Bethesda, Maryland) being held in Atlanta.

A second completed pivotal study is the **Ablation Frontiers** (Carlsbad, California) Tailored Treatment of Permanent AF (TTOP AF) trial, which completed its enrollment in May 2009. It employs standard radio frequency energy with some novel ablation catheters. Calkins estimated that the mandatory one-year follow-up period will be completed around mid-year 2010, with results released sometime after that.

Whereas the STOP AF trial treated patients with PAF, the

TTOP AF trial enrolled patients suffering from permanent (later stage, chronic) AF, who were randomized 2:1 In favor of ablation. 24 centers enrolled a total of 210 patients.

As previously reported (*MDD*, Feb. 9, 2009) Ablation Frontiers was acquired by Medtronic in February 2009 for an initial payment of \$225 million plus an additional payment for PMA approval, which *MDD* estimates at \$175 million.

A third trial discussed by Calkins is being sponsored by **CardioFocus** (Marlborough, Massachusetts). Its technology, which also addresses PAF, features a compliant balloon that can be maneuvered easily into the pulmonary veins, ablative laser energy and direct endoscopic visualization. Thus, the slogan used at its tradeshow booth "See what you ablate, ablate what you see."

The company, which attained CE mark approval in June 2009, has now treated a total of 89 patients, including 16 in its U.S. feasibility trial. The early data, three months post-treatment, is very promising with better than 90% of the pulmonary veins chronically isolated as the result of only a single procedure.

Its excellent results are fostered by the direct visualization from the built-in endoscope and the advantage of a compliant balloon in making contact with the well-documented anatomical variation of the pulmonary veins. Its results are particularly impressive because only a single balloon catheter was used to treat these patients, with no touch-up with other devices permitted during the procedure.

In the U.S., a ten-center feasibility trial is now underway, with a total of 100 patients to be enrolled. The company could launch its pivotal trial in late-2010.

In a talk titled "Balloon-Based Systems for AF Ablation: Outcomes and Complications," Vivek Reddy, MD, from **Mount Sinai Medical Center** (New York) noted that balloon-based approaches to the treatment of PAF are "very promising" and are eagerly awaited by the EP community.

There were several papers and an evening symposium discussing the **Endosense** (Geneva, Switzerland) TactiCath RF ablation irrigated catheter, which Reddy described as the "first force sensing ablation catheter."

Virtually every speaker discussing this device noted that today's catheters lack force control against the wall of the heart, often resulting in either insufficient or excessive tissue contact. Many EPs believe that inadequate tissue contact is the main culprit in a high (30%-40%) ablation procedural failure rate, while also being a major contributor to oft-very lengthy procedures. Meanwhile, excessive force is clearly the cause of two major risks of catheter ablation: tamponade, or fluid accumulation in the sac of the heart and esophageal perforation, a potentially disastrous event.

The TactiCath addresses these drawbacks, providing a highly sensitive sensor to evaluate in real-time the force of the catheter against the heart's tissue.

The superlatives flowing at the company's dinner symposium were impressive. Noted EP physician Karl Heinz

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Europe

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The ccNexfin with Masimo Rainbow SET uses a single sensor finger cuff (Bmeye) and finger sensor (Masimo Rainbow SET) to capture and continuously measure beat-to-beat blood pressure, mean arterial pressure, cardiac output, stroke volume, systemic vascular resistance, derivative of pressure, noninvasive hemoglobin, oxygen saturation and perfusion index. These detailed data allow clinicians to predict and proactively address the early signs of hemodynamic instability during critical situations rather than reacting to late indicators and their effects.

"ccNexfin is a unique noninvasive, beat-to-beat, and user friendly cardiovascular monitor that delivers a patient's full hemodynamic profile based on real-time data," said Rob de Ree, CEO of Bmeye. "Masimo Rainbow SET Pulse CO-Oximetry plays an integral role in the delivery of this rich hemodynamic data stream by providing critical information about oxygen delivery at the tissue level, which is an essential component of accurate hemodynamic assessment."

Assessment of hemodynamic status is a cornerstone of critical care medicine, routinely used to evaluate, diagnose, and direct therapy to manage the care of at-risk and critically-ill patients. Hemodynamic monitoring allows clinicians to assess the cardiovascular system and identify early circulation changes that reflect small changes in the way the heart is working to deliver blood and oxygen to tissues and organs.

ATS bioprosthesis implanted in Switzerland

ATS Medical (Minneapolis) reported the first commercial implants of the ATS 3f Enable Aortic Bioprosthesis were recently performed at the **University of Berne Hospital** (Berne, Switzerland) by Lars Englberger, MD, Mario Stalder, MD, and Professor Thierry Carrel. The procedures were completed using a sutureless technique and the patients are recovering with no complications.

The ATS 3f Enable valve is the first surgical aortic valve replacement approved for commercial use that is implanted using a sutureless technique. The Enable valve combines the ATS 3f Aortic Bioprosthesis with more than eight years of proven clinical performance and a self-expanding Nitinol frame to hold the valve in its optimal position eliminating the need for conventional sutures. This design allows the Enable valve to be folded into a small diameter and placed through a minimally invasive incision. The Enable valve preserves native stress distribution and provides a large orifice area with laminar flow for excellent hemodynamics.

Carrel, chief of Cardiac Surgery at the University of Berne said, "The implants went smoothly. There were no paravalvular leaks and the valves provide excellent hemodynamic performance with low single digit gradients. The Enable valve will help us expand our number of minimally invasive procedures."

Mocon reports minority equity investment

Mocon (Minneapolis) has completed its acquisition of a minority equity interest in **Luxcel Biosciences** (Cork, Ireland), effective Jan. 15, 2010. Mocon invested €2.5 million (approximately \$3.6 million) for a 16.9% equity interest in Luxcel.

"This is a very exciting development and one that we greatly welcome. It demonstrates very clearly how innovative Irish companies like Luxcel can set their ambitions high, and devise and implement growth strategies that will see them break into and thrive in international markets"

Luxcel was founded in 2002, as a spin out company from **University College Cork** (Ireland). The company was created to commercialize technology in the fields of phosphorescence-based sensor development and the applications of these sensors for biological testing. Luxcel sensors enable rapid, high throughput screening and detection of bacterial contamination of food samples, non-invasive analysis of gas in food, beverage and pharmaceutical packaging, and provide one of the most specific measures of drug toxicity and metabolism within pharmaceutical research and development.

Fluidigm to bring fluidic circuits to France

Fluidigm (South San Francisco), a developer of integrated fluidic circuits (IFCs), has joined with **IntegraGen** (Evry, France), a provider of genetic research testing services, to bring IFC technology to French researchers. IntegraGen will offer services to its customers using the Fluidigm BioMark System for Genetic Analysis and the Access Array sample preparation system for sequencing. IntegraGen's lab will also be a demonstration site for researchers investigating Fluidigm's technology.

Fluidigm instrumentation, combined with its microfluidic-based chips, provide high-performance, high throughput gene expression, genotyping, digital PCR, and sample preparation for next-generation sequencing.

"With this wonderful partnership, researchers will be able to immediately utilize IntegraGen's premiere services based on Fluidigm technology and enjoy the benefits of integrated fluidic circuits. In addition, Fluidigm will have a demonstration site for our European customers to observe and understand our easy workflow and other unique capabilities of our technology," said Dominique Remy-Renou, Fluidigm's vice president of European Sales and Support. ■

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Washington

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the device clearance process.

FDA reported in September that it had commissioned the Institute of Medicine to conduct a study of the 510(k) process (*MDD*, Sept. 25, 2009) despite the fact that the Government Accountability Office had already conducted such a study and found fault with the agency only for not ushering through an exhaustive examination of high-risk devices that were already on the market prior to the enactment of the Medical Device Amendments of 1976 (*MDD*, Jan. 21, 2009).

Donna-Bea Tillman, PhD, the director of the Office of Device Evaluation (ODE) at the Center for Devices and Radiological Health, told *Medical Device Daily* last year that she is not waiting for input to make changes (*MDD*, Nov. 17, 2009). Tillman indicated that some applications that would previously have been reviewed as 510(k)s will henceforth become PMAs, but she also noted that ODE had issued a number of 522 orders for dynamic spinal stabilization systems. The 522 is an order for more substantial post-market review. Among the firms that have received a 522 order, all dated October 5, 2009, are **Medtronic Sofamor Danek** (Memphis, Tennessee), **Depuy Orthopedics**, and **Zimmer** (both Warsaw, Indiana).

In a Jan. 22 statement, the agency notes that the Feb. 18 meeting will consist of discussions of four general topical themes. One of those categories is described as "issues related to predicate devices," while a second discussion will address scientific evidence relating to novel technologies. The third and fourth points of discussion will be "issues related to practices the FDA has adopted in response to a high volume of submissions," and postmarket surveillance designed to elicit "new information about marketed devices."

The meeting, which will take place at the Hilton Hotel in Gaithersburg, Maryland, will commence at 8:00 a.m. and is scheduled to run until 5:00 p.m. Registration closes Feb. 5 for live attendance, but the hearing will be webcast.

CDRH announces priorities for 2010

The Center for Devices and Radiological Health announced last week its priorities for this year, offering an ambitious agenda for a group that has been under fire recently from health advocates and Congress.

Not unexpectedly, CDRH intends to tweak the 510(k) process despite having commissioned the IOM report on the program by early next year. According to the sparsely detailed CDRH document, any planned changes to the 510(k) program will start rolling out by Sept. 30. In March, CDRH leaders will hold an all-hands meeting to supplement the results of next month's public meeting on the clearance process, described in the story above. By the end of May, the CDRH working group for the 510(k) program will forward its recommendations to the Center director, a post

now formally held by Jeffrey Shuren, MD (*MDD*, Jan. 21, 2010).

Another of the goals, the description of which offers no detail, is that CDRH will "take steps to address Class III devices currently allowed to enter the market through the 510(k) process."

Innovative medical devices are also in the agency's sights. CDRH intends to complete a phase I assessment of the "quality of clinical studies submitted in support of PMAs" and by November, "begin to take steps to improve the quality of clinical data submitted" for PMA applications.

The agency has also formally codified an imperative hinted at by associate commissioner Joshua Sharfstein at last year's annual meeting of the **Advanced Medical Technology Association** (Washington), during which Sharfstein indicated an interest in devices for unmet needs. This may include those that are re-engineered for pediatric populations, a move backed by Congress in the FDA Amendments Act of 2007. The 2010 strategic plan also calls for the various centers at FDA to "identify two or more devices that have been associated with safety problems across multiple centers" by the end of June, and within three months of that date, "identify and publicly announce steps CDRH will take to address" the identified devices.

Diagnostics are also on the agency's agenda. According to the strategic plan, CDRH will work with the other centers at FDA "to assure the appropriate regulatory oversight of therapeutics and diagnostics when their safety and efficacy are intimately tied to one another." This includes a June 30 deadline to "develop and draft formal mechanisms to address personalized medicine issues" between the centers and a Dec. 31 target for methods to identify and track diagnostics applications that deal with personalized medicine.

Pryor, Cardin ink nanotech safety bill

Nanotechnology safety has been an ongoing issue for several years now, and two members of the Senate Health, Education, Labor and Pensions (HELP) Committee have offered a bill to deal with some of those issues.

According to a Jan. 21 statement posted at the web site for Sen. Mark Pryor (R-Arkansas), the Nanotechnology Safety Act of 2010 would establish a program at FDA "to assess the health and safety implications of nanotechnology in everyday products, and develop best practices for companies who employ nanotechnology." The legislation would set aside \$25 million each year for five years starting in 2011.

Pryor said in the statement that nanotech "is one of the most important and enabling technologies being developed right now, and it has hundreds of promising applications," but that "as these products are developed

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Afib

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Kuck, MD, of **St. George Hospital** (Hamburg, Germany) said that this technology is “the last missing piece of information that we need to improve our ability to treat AF.”

Kuck has been working closely with the company and was the principal investigator of its TOCCATA (TOuCh+ for CAThether Ablation) trial, which enabled the company to gain its CE mark approval.

His ebullience for this technology was absolutely evident by his statement that “there is no doubt in my mind that force sensing catheters will eventually become a standard of care”.

Reddy closed his talk with his own emphatic comment that “force sensing is here to stay!”

In the U.S., Endosense plans to initiate the TOCCASTAR AF trial in 2010, enrolling symptomatic PAF patients in both the U.S. and Europe. Now that J&J has FDA approval for its Navistar Thermocool catheter, it is likely that the trial will be randomized 1:1 between TactiCath and Thermocool.

There are also interesting developments in the realm of surgical treatment of AF. At an evening symposium sponsored by surgical ablation market leader **Atricure** (Cincinnati), several noted AF experts participated in an FDA clinical trial development and site recruitment meeting.

The purpose of this gathering was to kick off the DEEP AF (Dual Epicardial/Endocardial Ablation for Persistent AF Patients) trial, which will begin this year as a feasibility study at five U.S. centers and treat 30 patients. If successful, it will be broadened into a full scale pivotal trial that could lead to a PMA approval.

The concept of DEEP AF is that patients with persistent AF are by far the most challenging to treat and cure, that the success rates with catheter ablation (endocardial) or surgery (epicardial) have been mediocre and that perhaps a combined hybrid approach might be more successful.

The world’s expert in performing hybrid procedures, Mark La Meir, MD, a cardiac surgeon at the **Centre for Heart Disease, University Hospital** (Brussels, Belgium) spoke at this gathering and rhetorically asked the audience: “Why not combine endo and epicardial ablation and take the advantages of both procedures and eliminate the disadvantages of each of the procedures through collaboration?”

La Meir and his EP colleague Laurent Pison, MD, have been doing precisely that, performing a hybrid procedure on longstanding or persistent AF patients. While they only treated 29 patients to date (half of which had persistent AF), and have data on 19 patients six-months post-procedure, 17/19 or 89% are in sinus rhythm and cured of their AF. This success rate is considerably better than has been seen for either catheter ablation or surgery on their own.

In an interview with *MDD*, both physicians were extremely pleased with their early results and expressed confidence in the future potential of hybrid procedures.

“I think that this a fantastic procedure for patients with persistent atrial fibrillation,” said La Meir. “We expect that we will be doing many more of these procedures in the future.”

Another hybrid approach to treating AF is being explored by **nContact Surgical** (Morrisville, North Carolina), which recently reported the initiation of a feasibility clinical trial designed to evaluate the safety and efficacy of a combined surgical and catheter procedure, a so-called convergent procedure. Whereas Atricure is targeting persistent AF, the nContact trial will treat patients with symptomatic paroxysmal AF. ■

Washington

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and used, we must understand any potential risks to human health, safety or the environment.” He said the bill “will help ensure public safety and confidence in the marketplace, and it will support companies that employ nanotechnology materials.”

However, there is something in it for the voters in the sponsors’ states. Pryor and co-sponsor Sen. Ben Cardin (D-Maryland) note in the statement that FDA “already has facilities in place, such as the National Center for Toxicological Research” in Jefferson, Arkansas, that could work with the agency’s new consolidated headquarters in White Oak, Maryland, “that could conduct the scientific studies required under the bill.”

The statement also notes that at present, “there are over 600 known commercial uses of nanotechnology” and that in 2004, “the National Science Foundation estimated new nanotechnology-based products would contribute 2 million jobs and \$1 trillion dollars in revenue to the world’s economy by 2015.” ■

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Deals

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• **Acacia Research Corporation** (Newport Beach, California) said that a subsidiary has acquired the rights to a patent for intraluminal device technology.

“As Acacia’s licensing success grows, more patent owners are selecting us as their partner for the licensing of their patented technologies,” said Paul Ryan, the company’s CEO/chairman. “Acacia is rapidly becoming the leader in technology licensing and we continue to grow our base of future revenues by adding new patent portfolios.”

This patented technology generally relates to securing intraluminal devices, such as stent grafts, in the body, the company noted. ■

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Product Briefs

- **Abbott** (Abbott Park, Illinois) has submitted a PMA application for the Architect HIV Ag/Ab Combo assay to the FDA for expedited review. Upon approval, the assay is expected to be the first test available in the U.S. to simultaneously detect the combined presence of HIV antigens (proteins produced by the HIV virus) and antibodies (proteins produced by the body to fight HIV antigens), which would allow for the early detection and ongoing monitoring of the virus. The ARCHITECT HIV Ag/Ab Combo assay is designed for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV1 group M and group O) and/or type 2 (HIV-2) in adult and pediatric serum and plasma. The assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. It is also intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection in pregnant women.

- **Calibra Medical** (Redwood City, California) said has received FDA clearance for the Finesse, the company's insulin patch-pen. Measuring roughly 2 inches long, 1 inch wide and inch thick, Finesse is a small plastic device designed to adhere to a patient's skin. Finesse is able to hold and deliver prescribed amounts of insulin over multiple days while remaining firmly in place throughout a patient's daily activities, including showering, exercising and sleeping. Finesse is operated discreetly through a patient's clothing and is designed to quickly deliver many common dose amounts.

- **EDAP TMS** (Lyon, France) said it will meet with the FDA to discuss alternatives to the cryo comparative arm and guidelines for a submission of an amended protocol for the U.S. ENLIGHT trial. The study is currently evaluating high intensity focused ultrasound (HIFU) treatment using cryo as the comparative treatment arm. The company makes Ablatherm, which it calls the most advanced and clinically proven choice for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment.

- **LTW Technologies** (Phoenix) said it has received five FDA clearances for its multi-wavelength LED Lightwave therapy device. The Lightwave series uses a light therapy combination of red light therapy, blue light therapy and infrared therapy. LTW says the following indications are

Medtronic's Melody valve gains FDA HDE approval

A Medical Device Daily Staff Report

In what it calls a significant development for congenital heart disease patients, **Medtronic** (Minneapolis) said that its Melody Transcatheter Pulmonary Valve has received FDA approval under a Humanitarian Device Exemption (HDE). This medical device is the first transcatheter heart valve to receive FDA approval.

The Melody is the first heart valve to be implanted through a catheter, or tube, in a leg vein and guided up to the heart. This new approach to the treatment of adults and children with previously implanted, poorly functioning pulmonary valve conduits can delay the need for open-heart surgery. Conduits are surgically implanted valves used to treat congenital heart defects of the pulmonary valve. Patients with congenital heart defects have narrowed, leaky, or missing pulmonary valves that impede the proper flow of blood from the heart's right ventricle to the pulmonary artery, which then sends the blood on to the lungs for oxygenation. Conduits can have a limited lifespan and often require replacement. The Melody is intended to provide another option to conduit replacement.

"The FDA's approval of Melody allows patients to undergo a much less invasive procedure to treat their heart condition," said Jeffrey Shuren, MD, director of the FDA's Center for Devices and Radiological Health. "Congenital heart defects represent the number one birth defect worldwide and this approval represents a new, first-of-a-kind treatment option for some of those patients."

As a condition of the FDA's approval, Medtronic will conduct two post-approval studies to assess long-term risks and benefits as well as to evaluate the physician specialization needed to perform the implantation procedure, also called generalizability. One study will continue to follow 150 participants from the initial clinical trial for five years, and the second study will enroll more than 100 new participants to be evaluated over five years, in order to evaluate and assess the training program. Safety and benefit assessments will be part of both studies. The FDA also requires that Medtronic maintain a database of Melody recipients.

now added to the existing uses for the Lightwave deluxe series: Red light for use in dermatology for treatment of superficial, benign vascular and pigmented lesions; Red and Blue light for emitting energy in the Red and Blue region of the spectrum to treat dermatological conditions, specifically mild to moderate acne vulgaris; and Blue light for dermatological conditions and moderate inflammatory acne vulgaris.

MDD'S CARDIO EXTRA

ADDITIONAL DEVELOPMENTS IN ONE OF MED-TECH'S KEY SECTORS

TUESDAY, JANUARY 26, 2010

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Keeping you up to date on recent headlines in cardiovascular healthcare.

Scientists discover new way to generate abundant functional blood vessel cells from stem cells . . .

A team of scientists at **Weill Cornell Medical College** (New York) has developed a new technique and described a novel mechanism for turning human embryonic and pluripotent stem cells into plentiful, functional endothelial cells, which are critical to the formation of blood vessels. Endothelial cells form the interior "lining" of all blood vessels and are the main component of capillaries, the smallest and most abundant vessels. In the near future, the researchers believe, it will be possible to inject these cells into humans to heal damaged organs and tissues, Weill Cornell said. According to the researchers, the new approach allows scientists to generate virtually unlimited quantities of durable endothelial cells – more than 40-fold the quantity possible with previous approaches. Based on insights into the genetic mechanisms that regulate how embryonic stem cells form vascular endothelial cells, the approach may also yield new ways to study genetically inherited vascular diseases. The study appears in the advance online issue of *Nature Biotechnology*. "This technique is the first of its kind with serious potential as a treatment for a diverse array of diseases, especially cardiovascular disease, stroke and vascular complications of diabetes," said Shahin Rafii, MD, the study's senior author. Human embryonic stem cells have the potential to become any one of the more than 200 types of adult cells. However, the factors and pathways that govern their differentiation to abundant derivatives that could be used to repair organs have remained poorly understood. A major challenge for Rafii's lab has been to improve their understanding, and hence control, of the differentiation process (how stem cells convert to various cell types), and then to generate enough vascular endothelial cells – many millions – so they can be used therapeutically. To meet this challenge, the scientists first screened for molecular factors that come into play when stem cells turn into endothelial cells. Their findings led them to a strategy that significantly boosts the efficiency of producing these cells. Then, the researchers tracked the differentiation process in real-time using a green fluorescent protein marker developed by Dr. Daylon James, the study's first author and assistant research professor in the Department of Reproductive of Medicine at Weill Cornell Medical College. They found that when they exposed stem cells to a compound that blocks TGF-beta (a growth factor involved in cell specialization) at just the right time during cell culturing, the propagation of endothelial cells dramatically increased. They also found that the cells worked properly when injected into mice. The cells were quickly assimilated into the animals' circulatory systems, and functioned alongside normal vasculature. To achieve long-lasting clinical benefits, there remain additional hurdles to exploiting endothelial cells generated *in vitro*. A fundamental prerequisite to using vascular cells in regenerative medicine has been the proper assembly *in vivo* of new blood vessels from stem-cell-derived cells, according to Dr. Sina Rabbany, who is an adjunct professor at Weill Cornell Medical College and professor of bioengineering at Hofstra University. Rabbany emphasizes that, in addition to manipulating biological factors implicated in endothelial cell differentiation, the impact of blood flow on endothelial cells is critical to engineering durable, vascularized organs. With the plentiful supply of endothelial cells that the new methods provide, Rabbany's team is working to build biological scaffolds that model the microenvironment of the vasculature, so that the vessels they generate will be functional and long lasting in patients. The new endothelial cell culture is currently being validated in ongoing research at Weill Cornell using a number of stem cell "lines," or "families" of stem cells. The scientists hope to transfer their methods to the clinic within the next five years.

WorldHeart reports first implant of Levacor VAD in BTT study . . . WorldHeart

(Salt Lake City) reported that the first U.S. implant of the Levacor Ventricular Assist Device (VAD) was performed at **Integrus Baptist Medical Center** (Oklahoma City) last week. This is the first implant in the Levacor VAD bridge-to-transplant (BTT) study, which is expected to enroll 160 patients, pursuant to a recently approved U.S. investigational device exemption application. INTEGRIS is the first of the initial ten BTT clinical study sites. The recipient is a 59-year-old woman suffering from severe cardiomyopathy, or a weakened heart muscle. "The device implant was remarkably smooth with a relatively short procedure and the patient is recovering quickly from her surgery," said Craig Elkins, MD, cardiac surgeon and Integrus' surgical principal investigator for the study. "We are excited to participate in the study and pleased to offer to our patients this new technology." According to the company, the Levacor VAD is the only fully magnetically levitated, bearingless, implantable centrifugal pump to move into clinical trial. By using magnetic levitation to fully suspend a spinning rotor, the Levacor VAD's only moving part, the pump is designed to eliminate wear and to provide unobstructed clearances for blood flow across a wide range of operation, the company said.

Men with erectile dysfunction have higher risk of CVD . . . In the first study of its kind, **New England Research Institutes** (NERI, Watertown, Massachusetts), in collaboration with the Division of Cardiology, **San Francisco General Hospital** and the **University of California, San Francisco** tested whether erectile dysfunction (ED) can be used to reclassify patients according to their future risk of developing cardiovascular disease (CVD) beyond traditional risk factors (smoking, high blood pressure, high cholesterol, etc). Results of the 12-year research study are published in the Jan. 26 issue of the *Journal of the American College of Cardiology* and show that ED may be a warning sign of a future cardiovascular event like heart attack, stroke, atherosclerosis, coronary artery bypass graft surgery, and congestive heart failure. However, while ED is significantly related to CVD independent of traditional risk factors, it does not improve the prediction of who will and will not develop CVD beyond these risk factors. "This is an important study because it is the first to explicitly test whether ED can predict the future development of CVD beyond a predictive tool called the Framingham risk score," said Andre Araujo, PhD, director of Epidemiology at NERI and lead researcher of the study. "Although the answer is no, this is not necessarily surprising given how strongly the Framingham risk score is related to CVD. Our data indicate that ED is as strongly related to the development of CVD as the Framingham risk score." The study followed 1,057 men (ages 40-70) from the Massachusetts Male Aging Study – a prospective observational study of aging, health, and endocrine and sexual function – over an average of 12 years. These men were free of diabetes and CVD at the start of their study participation. However, during the follow-up years, 261 new cases of CVD occurred. ED predicted the development of CVD, independent of age, traditional risk factors, and Framingham risk score. Men with ED showed a 40% higher risk of developing CVD compared to men without ED. "Even though the study showed that ED does not improve risk prediction beyond the Framingham risk score, an ED assessment can be done at very low cost and presents no risk to patients (unlike other novel CVD screening tests)," Araujo said. "Previous work from our study shows that a simple single question ED measure correlates well with an independent physician's assessment. Therefore, health professionals should consider asking about ED in their older male patients. Also, when a patient presents with ED, health professionals should work the patient up for CVD as there may be a window of opportunity for men to improve their health before a CVD event occurs." This work was supported by grants from the **National Institute on Aging**, the **National Institute of Diabetes and Digestive and Kidney Disorders**, and an unrestricted educational grant to NERI from **Bayer Healthcare** (Levrekusen, Germany).

Heart problems linked to post-Katrina stress . . . Chronic stress following Hurricane Katrina in 2005 contributed to a three-fold increase in heart attacks in New Orleans more than two years after levee breaches flooded most of the city, according to researchers at **Tulane University School of Medicine** (New Orleans). Those suffering heart attacks post-Katrina also were significantly more likely to receive coronary interventions, particularly angioplasty to reopen clogged coronary arteries, which suggests these patients may have more severe disease, according to new data. Previous studies have found short-term increases in heart attacks and other cardiac events occurring in the immediate hours to weeks after major disasters such as earthquakes or volcano eruptions. "Our data show that the effects of an acute major disaster are not limited to its immediate aftermath, but can linger on for a prolonged duration," said lead researcher Dr. Anand Irimpen, associate professor of clinical medicine in the Heart and Vascular Institute at Tulane. The study analyzed the number of heart attack patients admitted to **Tulane Medical Center** in downtown New Orleans two years before the storm and two years after the hospital reopened in February 2006. Researchers compared the two groups (pre- and post-Katrina) based on specific demographic and clinical data such as lab test results, health insurance, first-time hospitalization, smoking status, substance abuse and employment. There were 246 admissions for heart attacks, out of a total census of 11,282 patients, post-Katrina compared with 150 admissions out of a total 21,229 patients in the two years before the storm. In addition to a three-fold increase in heart attacks and a 120% increase in coronary interventions, the post-Katrina group had significantly higher prevalence of unemployment, lack of medical insurance, medication noncompliance, smoking, substance abuse, first-time hospitalization and people living in temporary housing. There were no significant differences in the racial, gender or age distribution of the two groups. Based on these data, the authors believe reduced access to preventive health services and chronic stress due to prolonged loss of employment, insurance coverage and housing played an important role in the development of heart attacks.

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