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PAGE 1 OF 11

Heart Rhythm Society

Atrial fibrillation: progress, but many unresolved issues

By LARRY HAIMOVITCH

Medical Device Daily Contributing Writer

BOSTON – The 30th annual scientific sessions of the **Heart Rhythm Society** (HRS; Washington) took place here last week, with record attendance as the field of electrophysiology (EP) continues to ascend in importance in the healthcare world.

For the third consecutive year, HRS sponsored a two-day “AF Summit,” which once again drew an overflow attendance and was chock full of the latest clinical data on this emerging field.

The importance of atrial fibrillation (AF) to the EP community cannot be overestimated. It is by far the most common arrhythmia treated and clearly is an area with the greatest opportunity to improve patient outcomes, yet remains incredibly frustrating because there are so many

See AF, Page 5

Report from Europe

Siemens positions enhanced interventionalists’ angiography

By JOHN BROSKY

Medical Device Daily European Editor and Staff Reports

If it works for brain surgeons, who else might be interested in full-color digital subtraction angiography (DSA) reconstruction?

Siemens Healthcare (Erlangen, Germany) is shifting the sales focus for its syngo iFlow image enhancement software from neurology, where it has enjoyed a solid take-up, to other ‘body’ interventionalists, such as interventional oncologists and specialists keen on visualizing blood flow for organs and tumors.

Black-and-white photo sequences depicting blood flow have been a staple of medical practice for as long as anyone can remember.

As many as 30 angiographic images that have been digitally subtracted, that is stripped of all background and displaying only blood vessels, are typically taken for a

See Europe, Page 8

AIR2 data bodes well for 1st asthma device therapy

By AMANDA PEDERSEN

Medical Device Daily Staff Writer

A device designed to help adults with the most severe cases of asthma – without the use of drugs – is getting closer to becoming available in the U.S. Results of the Asthma Intervention Research 2 (AIR2) trial of the Alair Bronchial Thermoplasty system, developed by **Asthmatx** (Sunnyvale, California), were reported today at ATS 2009, the international conference of the **American Thoracic Society** (New York), in San Diego. The Alair system is on track to becoming the first device therapy available for asthma patients in the U.S.

According to Asthmatx, the AIR2 results demonstrated statistically significant improvements in quality of life measurements and reductions in asthma attacks (severe exacerbations) and emergency room visits for respiratory symptoms in adults with severe asthma who underwent

See Asthma, Page 7

Quest has ‘Focus’ to identify H1N1 flu strain in patients

By OMAR FORD

Medical Device Daily Staff Writer

What’s something that could potentially slow down the diagnoses of H1N1 otherwise known as Swine flu? Try a public health system that has to wait copious amounts of time to receive test results identifying the virus.

Quest Diagnostics (Madison, New Jersey) aims to speed up the process a bit. The company reported that its **Focus Diagnostics** (Cypress, California) infectious disease reference laboratory has introduced a laboratory-

See Quest, Page 9

A little something Extra

You asked for it . . . you got it. Tacked onto the end of your regular issue today are two pages of *MDD's Cardio Extra*, which we have tagged “Additional Developments in One of Med-Tech’s Key Sectors.” This is now a regular weekly feature of the publication as part of increasing *MDD's* value to you.

INSIDE: DIAGNOSTIC MAKER CITED FOR VALIDATION LAPSES, APPROVAL2
CLARIANT COMPLETES \$10.9M CONVERTIBLE STOCK PLACEMENT3

AHC Media LLC

*Washington roundup***Diagnostic maker cited for validation lapses, approval**

By MARK McCARTY

Medical Device Daily Washington Editor

Diagnostics maker **Merlin Labs** (Carlsbad, California) took in a March 9 letter posted to FDA's web site last week, citing the firm for validation lapses as well as a failure to obtain a PMA, a 510(k), or an investigational device exemption for one or more devices. The heavily redacted warning letter also cites corrective action lapses among other misuses, and while the firm's web site indicates the company focuses mostly on tests for malaria and dengue fever, the site also indicates that Merlin offers a diagnostic for an unspecified type A influenza test.

Under the section dealing with validation, FDA states that the company had "no pre-approved validation protocol" for an unspecified diagnostic, and lacked "pre-established acceptance criteria" for at least one process validation. Among the specific functions noted in this heavily redacted citation are equipment cleaning and pouch sealing. The firm's response to the 483 was seen as faulty for one of these manufacturing processes because it was not accompanied by "a process validation protocol with pre-determined specifications and associated test results." According to the warning letter, Merlin indicated that it "visually inspect[s]" the process in question.

The letter cites a failure to validate a change of design, but the brevity of the citation and the degree of redaction leaves little detail other than that the firm asserted that "the design validation and verification data are in the design history file," but the response included no copies of the data.

FDA indicates that the company failed to undertake procedurally required corrective and preventive action for false positives in connection with a diagnostic, the name of which was yet again redacted. The company's response

**Coming Wednesday
in *MDD Perspectives*****Big-city snob gets a welcome
technology surprise in the sticks**

Medical Device Daily Staff Writer Lynn Yoffee got a healthcare information technology wake-up call recently while making use of rurally based healthcare services. 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.

was that the false positives had not been confirmed and that "the lot in question met specifications," stating that its handling of the situation did not constitute a CAPA, but rather were "improvements based on business decisions."

Merlin's troubles for this citation seemed to largely hinge on the fact that a subsequent complaint involved another false positive, which the company apparently had confirmed and which prompted the unspecified changes to the diagnostic. FDA argues that such changes "would appear to constitute a corrective and/or preventive action" rather than just a business-based improvement.

The warning letter also cites Merlin for problems with equipment calibration and device history records, the responses for which were both deemed adequate. However, FDA said it could not evaluate the firm's response for a citation for employee training, and informed the company that its response to a citation for equipment cleaning

See Washington, Page 6

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Financings roundup

Clariant completes \$10.9M convertible stock placement

A Medical Device Daily Staff Report

Clariant (Aliso, Viejo) reported that it has completed the second tranche of a private placement of convertible preferred stock with Oak Investment Partners (Westport, Connecticut) a multi-stage venture capital firm.

The second tranche for nearly \$10.9 million, combined with \$29.1 million in proceeds from the first tranche that closed March 26, 2009, will retire \$31 million in Clariant borrowings and bolster working capital.

"As we stated in the initial financing announcement, this transaction strengthens Clariant's financials, streamlining our balance sheet and moving us tangibly closer to our goal of sustainable profitability," said Ron Andrews, vice chairman/CEO. "Oak is an excellent strategic partner with deep expertise in life sciences that will help Clariant continue its robust growth and expand our share of the dynamic cancer-diagnostic services market."

Clariant said it intends to retire a \$10 million mezzanine debt facility from **Safeguard Delaware**, a wholly owned subsidiary of **Safeguard Scientifics** (both Wayne, Pennsylvania) a provider of growth capital for entrepreneurial and innovative technology and life sciences companies. The mezzanine debt would have matured Feb. 28, 2010. In addition, the facility carries an annual interest rate of 14% and would have required the issuance of a substantial number of warrants beginning June 1 if it were not terminated before that date.

The purchase price of the Clariant Series A convertible preferred stock was \$7.60 per share, which equates to an effective purchase price of \$1.90 per share of underlying common stock or about market price at the date the financing was agreed upon. Under terms of the private placement, Oak may convert at any time one convertible preferred share into four shares of Clariant common stock. After one year, preferred shares, which do not accrue dividends, convert automatically into common shares if Clariant shares trade above \$4.75 per share for 20 days of a 30 consecutive trading-day period.

After four years, Clariant may redeem any unconverted preferred shares at \$7.60 per share plus any undeclared but unpaid dividends. Upon mutual agreement after the closing of the second tranche, Oak may purchase up to an additional \$10 million of Clariant preferred shares, providing the company access to capital for strategic opportunities that would accelerate the company's growth.

The private placement gives Oak effective control of nearly 21% of Clariant's outstanding shares and reduces Safeguard's position to nearly 47% from nearly 62% at December 31, 2008. With certain exceptions, preferred shares will be voted with common shares on an as-converted basis. Safeguard first took an ownership stake in Clariant in 1996, increasing its position over time. ■

Court report

Scrushy, Siegelman appeal bid in case is deflected by panel

A Medical Device Daily Staff Report

Richard Scrushy, ex-CEO of **HealthSouth** (Birmingham, Alabama) and former Alabama Gov. Don Siegelman have lost another legal round in a 2006 bribery case.

The conviction stemmed from \$500,000 in contributions made by Scrushy to a campaign fund for a state lottery, arguably a payoff for Siegelman reappointing Scrushy to a state hospital licensing board.

The original U.S. District Court conviction was upheld this past March by a 3-judge panel of the U.S. Court of Appeals in Atlanta (*Medical Device Daily*, March 10, 2009).

Siegelman and Scrushy had asked for a review of the case by the full Court of Appeals, but it refused to do so in a decision reported last Friday.

According to a *New York Times* report on the case, attorneys for the two men indicated their plans to appeal the case to the U.S. Supreme Court, with one attorney saying "the chances are good" that the high court would hear the case, because "what the government has to prove to send a political figure to jail is a matter of national interest." ■

Patent watch

Orbital Therapy gets U.S. patent for new breast cancer treatment

A Medical Device Daily Staff Report

Orbital Therapy (Bedford, Massachusetts) reported that it has been issued U.S. patent 7,526,066 for a unique external beam radiotherapy treatment machine optimized for breast cancer patients.

This device currently under development by Orbital Therapy will place the patient in the prone position to increase the separation of the target from the rest of the patient, and virtually eliminate motion caused by breathing. The clinician will have full 360° access to the breast, allowing for modern treatment techniques to be delivered ranging from focal to whole breast irradiation. This device will include integrated shielding, protecting the patient from unwanted exposure to radiation. In addition, the integrated shielding will not require the healthcare facility to set up a traditional vault (bunker) to use the device, and will potentially allow for mobile application. Building a vault can easily cost \$1 million and is a major barrier to adding additional treatment units in remote and congested areas.

"For the first time ever with high energy X-rays, the majority of the patient will be outside of the bunker during the treatment. With continued progress in early detection, patients are more concerned with long term effects caused by unwanted radiation, which is unavoidable on a conventional treatment machine", said Jason Koshnitsky, CEO of Orbital Therapy. ■

Agreements/contracts

Volcano to sell Lumen Xtract thrombus aspiration catheter

A Medical Device Daily Staff Report

Volcano Corp. (San Diego), a developer of products for the diagnosis and treatment of coronary and peripheral artery disease, reported an exclusive worldwide distribution agreement to initiate the formal launch of the Xtract thrombus aspiration catheter, manufactured by **Lumen Biomedical** (Plymouth, Minnesota). The Xtract thrombus aspiration catheter is available for immediate sale in the U.S. and Europe. This marks Volcano's entry into what it believes is at least a \$70 million aspiration market, the company noted.

The Xtract thrombus aspiration catheter is FDA-cleared and is CE marked for use in coronary vessels, as well as some peripheral vascular applications. According to the company, the device incorporates three unique design attributes that enhance its performance. These include a single lumen design to maximize cross-sectional area, and in turn, thrombus suction; a circular, right angle tip for close-up access to clots; and a curved, directional tip to enable full sweep of the vessel. These design features enable physicians to offer a truly new approach for thrombus aspiration, Volcano said.

Scott Huennekens, president/CEO of Volcano, said the agreement with Lumen is "perfectly aligned with our corporate strategy, and builds on the unique value that Volcano offers to the interventional cardiology community." He added, "Volcano does not believe that a one-size-fits-all technology is capable of addressing complex disease states such as AMI, CTO and bifurcations, which continue to challenge clinicians today. Instead, we feel that application-specific tools such as IVUS-guided balloons, forward-looking IVUS catheters and tissue composition technologies can better target and treat the appropriate patient and lesion.

The Lumen Xtract thrombus aspiration catheter now gives Volcano a second-generation aspiration catheter to complement its IVUS and VH IVUS imaging tools in these challenging AMI patients, Huennekens said.

In other agreements and contracts news:

- **MEI Development** (Coral Springs, Florida) reported an agreement with **GE Healthcare** (Chalfont St. Giles, UK) that offers GE's customers the option of MEI's solutions, including development, financial, oncology, women's health and consulting services.

MEI says it provides turnkey solutions for physicians, outpatient facilities and hospitals that are interested in adding and updating imaging technology. MEI offers an array of services including determining project viability, creation and implementation of business planning, procurement of imaging equipment and complete project financing.

- **TriLink BioTechnologies** (San Diego) reported an

agreement with **Osmetech Molecular Diagnostics** (Pasadena, California) to supply reagents for Osmetech's recently launched eSensor Cystic Fibrosis Carrier Detection (CFCD) system and the eSensor XT-8 system for Warfarin sensitivity.

TriLink is providing Osmetech with custom oligonucleotides, which are required reagents for the eSensor detection systems, the companies reported.

TriLink makes custom oligonucleotides, modified nucleoside triphosphates and CleanAmp PCR products for the diagnostic and OEM markets.

- **BD Diagnostics** (Franklin Lakes, New Jersey) and **HandyLab** (Ann Arbor, Michigan) reported an exclusive agreement for BD to commercialize its molecular assays on a new BD MAX system, an automated molecular diagnostic testing platform in development using HandyLab's recently launched Jaguar instrument. BD will focus initially on its BD GeneOhm line of molecular assays to detect major pathogens associated with healthcare-associated infections.

Released by HandyLab in November 2008, the Jaguar system is the first fully integrated bench-top molecular diagnostic system to provide hands-off operation, according to the company. The system incorporates clinical sample preparation, nucleic acid extraction, and microfluidic real-time polymerase chain reaction (PCR) amplification and detection. The self-contained workstation is designed to accommodate on-demand and batch workflows. It requires minimal laboratory space and minimal skill levels to generate up to 24 real-time PCR results in under two hours.

- **SonoSite** (Bothell, Washington) reported that **Medical Simulation** (MSC; Denver) has selected SonoSite's M-Turbo ultrasound as its preferred system for teaching clinicians central line placement procedures for their SimSuite Central Line Management Program.

According to the company, SonoSite's M-Turbo technology enables clinicians to confidently perform central line placement procedures. The system's imaging technologies – SonoMB, SonoHD, and SonoAdapt – provide healthcare professionals with crystal-clear imaging, better edge detection and needle recognition for ultimate visual guidance.

SonoSite develops hand-carried ultrasound. MSC provides full-service simulation training and education services to healthcare personnel, medical societies and medical product manufacturers.

- **RaySearch Laboratories** (Stockholm, Sweden) said it has entered into a long-term development and licensing agreement with **Siemens Healthcare** (Malvern, Pennsylvania). This new collaboration means that RaySearch will provide a number of treatment planning modules aimed at improving radiation therapy. The software modules will be integrated in Siemens' syngo Suite for Oncology, which is Siemens' integrated workflow solution for radiation therapy.

According to the company, the collaboration is expected to start generating revenues for RaySearch during 2011. ■

AF

Continued from Page 1

unanswered questions. This was exemplified by the title of one panel discussion, "Are We Better off than Four Years Ago: What is the Best Approach?"

The rising awareness of AF can be seen by the recent introduction of House Resolution 255, which called for a National Atrial Fibrillation Awareness Month in September 2009. In strongly supporting this initiative, Mark Estes III, MD, president of the HRS said that "currently less than 30% of AF patients receive the recommended treatment. Therefore, an AF Awareness Month will play an important role in not only raising awareness but also improving patient care and ultimately saving lives."

With the average age of an AF patient exceeding 70 years of age and a rapidly aging global population, several speakers cautioned that AF could soon become an "epidemic." Several experts have predicted that between now and 2050, the prevalence or pool of AF patients will nearly triple.

With the success rate of anti-arrhythmic drugs widely estimated at well below 50%, catheter ablation of atrial fibrillation has become a very important weapon in the EP's armamentarium. There were no FDA-approved products in the category until late-February, when **Biosense Webster** (Diamond Bar, California), a **Johnson & Johnson** (New Brunswick, New Jersey) company attained clearance for its Navistar Thermocool catheter. Despite the absence of approved devices, domestic AF ablations have approximately doubled in the past three to four years and are estimated at about 75,000 to 80,000 in the U.S. this year.

During a session titled "Critical Issues in AF Therapy" several speakers noted that the results of catheter ablation are improving but yet have room for much more improvement. For myriad reasons, the true "success rate" is difficult to pinpoint and far more significantly, the measures of success vary widely. This aspect was noted by several speakers, one who succinctly said "there is so much more truth to find out."

One consensus that has clearly emerged is that ablation of the pulmonary veins (PVs) is, in the words of Pierre Jais, MD, **Haut-Leveque Hospital** (Bordeaux Pessac, France), the "cornerstone" of catheter ablation. Jais said that is especially true for a paroxysmal (intermittent, typically early stage) AF. In addition, it is generally accepted that PV ablation using a standard point-to-point radio frequency (RF) catheter ablation is limited by the technical challenges of maintaining catheter stability and all too often results in the recurrence of AF due to the lack of lesion continuity.

There are several unresolved issues in the catheter ablation of the PVs: Two key ones are 1) What other areas of the heart need to be ablated to halt the AF; 2) Are there other approaches or energy sources that will buoy the results of PV ablation or isolation.

With regards to the first question, several speakers dis-

cussed in detail other ablation sites such as the ganglionic plexi (GPs or the autonomic nervous system) and complex fractionated atrial electrograms (CFAEs). With the modest success of PV ablation alone, these two ablation sites are gaining favor in the EP community and in many institutions are becoming the standard of care in AF ablation.

More importantly, the clinical results from adding these additional ablation strategies are positive. According to Warren Jackman, MD, of the **University of Oklahoma Health Science Center** (Oklahoma City), the addition of GPs to an AF ablation can boost the success rate up to an additional 20%. However, this strategy adds to an already long and complex procedure.

According to D. Wyn Davies, MD, **St. Mary's Hospital** (London, UK), the goal of AF ablation ideally should be a "single shot," which he discussed in a comprehensive talk on non-radio frequency energy sources such as cryothermia, laser, high intensity focused ultrasound, irreversible electroporation and others.

A single shot of energy in each PV, which ideally would create complete block of the AF, could also simplify and shorten the procedure. The most commercially advanced of these devices is the CryoCath Arctic Front cryo balloon, which has already been commercialized in Europe and is expected to report results of its U.S. prospective randomized controlled pivotal trial in the U.S. in 2H09. As previously reported (*Medical Device Daily*, Dec. 22, 2008), **Medtronic** (Minneapolis) recently placed a big bet on single shot cryo PV ablation, purchasing CryoCath for nearly \$400 million.

An intriguing player in this space is **CardioFocus** (Marlborough, Massachusetts), whose tagline at its HRS exhibit was "See what you ablate, ablate what you see." This slogan refers to the unique and very useful capability of its catheter to view the ablation zone in the PVs in real-time with direct endoscopic visualization. In addition, cases have been performed, demonstrating direct lesion visualization in real-time.

Physicians who have seen both aspects of this visualization capability believe that it represents a huge advantage over traditional fluoroscopic imaging and also better than intracardiac echocardiography (ICE). It is the only ablation catheter that has this attribute.

An equally if not more important aspect of the company's device is that its balloon, which delivers ablative laser energy at 980 nm, is "compliant," that is, it is soft and will fit into the hugely different shapes and sizes of the patient's pulmonary veins. In contrast, the CryoCath Arctic Front balloon is rigid and while it comes in two different sizes, will not fit well into all PVs. A non-compliant balloon may result in incomplete ablation in the PVs and allow for recurrence of the AF.

Although its clinical data is limited to 18 patients treated since early 2009, it appears very promising, with a

See AF, Page 6

Washington

Continued from Page 2

did not measure up because it lacked specifics on the frequency of cleaning.

At press time, the company had not responded to calls from *Medical Device Daily* for comment.

Respironics recalls apnea monitors

Respironics (Murrysville, Pennsylvania) has announced a voluntary recall of almost 5,000 of the Smart-Monitor line of infant sleep apnea monitors. The move is prompted by the discovery that the unit may fail to sound an audible alarm, although no problem has been noted for the alert light on the unit.

The recall, announced April 26, was prompted by a single report of an alarm failure notification and affects units manufactured between Jan. 16 and Nov. 13, 2008. This is classified as a class III recall due to the risk of serious injury or death, and Respironics is pulling back all units in distribution and calling for all units in use to be returned.

FCC may add spectrum for device wi-fi

The Federal Communications Commission reported recently that it may add to the bandwidth it permits for the operation of wireless medical devices, which may expand use of a variety of devices in a hospital setting.

FCC has had its eye on the spectrum question for some time, announcing more than three years ago its intent to establish what sort of bandwidth medical devices will need in order to allow new technology to move into the healthcare setting (*Medical Device Daily*, Aug. 1, 2006). The current proposal would allow device makers and hospitals to use "wireless micro-power networks" occupying four discrete slots of seven megahertz (MHz) each between 413 and 547 MHz, a bandwidth that is at present partly used for land mobile radio and radar operations. Currently, wireless devices typically operate in the range of 401 to 406 MHz, and the intent of the current proposal is to foster space for the operation of neuromuscular stimulation devices.

NIH swamped by grant applications

In a tough economy, good news often draws much more vigorous responses than is typical, and such seems to be the case for the monies allocated to the National Institutes of Health in the economic stimulus package passed by Congress earlier this year.

The stimulus program has added more than \$8 billion to NIH's typical budget of \$23 billion for research grants, and the agency's Office of Extramural Research (OER) is said to be overwhelmed. A recent story in *USA Today* quotes OER's Cheryl Fells as pleading "help!"

Fells' office handles phone calls from researchers looking for information on how to fill out grant paperwork online, a sure target for increased activity. While the agency

expected as many as 15,000 applications, NIH has been hit with 20,000 applications and the deadline, May 29, has not yet passed.

NIH has roughly \$200 million available for two-year grants in addition to about \$1 billion in funds pegged for construction as an economic stimulus. Another \$300 million will go toward equipment funding, a sum that is said to be likely to increase. ■

AF

Continued from Page 5

95% success rate in chronic isolation at three months post-procedure. In addition, there were no clinical recurrences or adverse events. The success rate compares very favorably to 63% reported in the pivotal trial with the Thermo-cool catheter. The latter required using multiple procedures.

Vivek Reddy, MD, director of cardiac electrophysiology at the **University of Miami Miller School of Medicine** (Miami) presented initial data on this catheter at the **Scripps Clinic** (La Jolla, California) "Percutaneous Catheter Ablation of Atrial Fibrillation" conference in March (*MDD*, March 11, 2009) and noted that the early human data from cases being performed at **Homolka Hospital** (Prague) was very encouraging.

In an interview with *MDD* at HRS, Reddy said "this is by far the most promising technology I have seen for AF catheter ablation. I really like both the direct visualization and the fully compliant balloon and I think it could ultimately be the big winner in this market."

The company, which has been venture capital-backed for several years, is seeking to gain CE mark approval in the coming months and anticipates initiating a human clinical trial in 2009 in the U.S. ■

MED - TECH NEWS AND NOTES

EtQ re-certified to ISO specifications

EtQ (Farmingdale, New York) reported that its development center has been re-certified to ISO 9001:2008 certification, after an extensive audit conducted by Société Générale de Surveillance (SGS).

EtQ's development center is responsible for the development of software platforms and application suites to achieve and maintain compliance with quality, environmental, and health and safety management system requirements.

EtQ is an Enterprise Quality and Compliance Management software for identifying, mitigating, and preventing high-risk events through integration, automation, and collaboration.

Asthma

Continued from Page 1

bronchial thermoplasty delivered by the Alair system.

"The reduction in asthma attacks and improvements in quality of life are consistent with the outcomes from previous trials," said Mario Castro, MD, a professor of medicine and pediatrics at the **Washington University School of Medicine** (St. Louis), and a principal investigator in the AIR2 trial. "These outcomes provide further clinical evidence needed to demonstrate the safety, effectiveness and long term benefits of bronchial thermoplasty."

The AIR2 trial was designed to evaluate the safety and effectiveness of bronchial thermoplasty in adult patients with severe asthma who were symptomatic, despite being treated with high doses of standard of care medications (high dose inhaled corticosteroids and long-acting bronchodilators). The study was a randomized, double-blind, sham-controlled trial and enrolled 297 patients at 30 sites in six countries. The primary effectiveness endpoint was the change from baseline in Asthma Quality of Life Questionnaire (AQLQ) score. Comparing the short and long-term safety profiles for both the treatment and sham control groups assessed safety, Asthmatx noted.

According to the company, the key statistically significant clinical findings of the trial were: improvement in the average AQLQ score at six-, nine-, and 12 months over sham control; four out of five Alair-treated patients responded with a clinically significant improvement in AQLQ compared to 64% of sham controls; 32% reduction in asthma attacks; 84% reduction in emergency room visits for respiratory symptoms; 36% reduction in patients reporting episodes of asthma (multiple symptoms) adverse events; and 66% reduction in days lost from work/school or other activities due to respiratory symptoms.

While investigators were expecting to reach the primary endpoints of the AIR2 trial, Castro told *Medical Device Daily* that he was somewhat surprised at the "pretty marked reduction in severe exacerbations of asthma and emergency room visits," because "typically studies have to be quite large with asthma to meet an endpoint like that."

In fact, those were the results that had the most impact with doctors and patients because they can relate to a number of ER visits more so than some of the other findings, Asthmatx CEO Glen French told *MDD*.

Bronchial thermoplasty is a non-drug procedure for asthma. The treatment is performed through the working channel of a standard flexible bronchoscope that is introduced through a patient's nose or mouth, and into their lungs. The tip of the small diameter Alair catheter is expanded to contact the walls of targeted airways. Controlled thermal energy is then delivered to the airway walls to reduce the presence of airway smooth muscle that narrows the airways in patients with asthma. The minimally invasive procedure, like many other flexible endoscopy procedures, is done under light anesthesia, and the patient

returns home the same day, according to Asthmatx.

Castro told *MDD* that the treatment is actually delivered in three sessions: first in the right lower lobe of the lung; next in the left lower lobe; and the third in the upper lobes. The patient has to wait about two weeks between sessions to ensure that they are stable enough to go through the procedure, he said.

Asthmatx said that in the period immediately following bronchial thermoplasty, there is an expected increase and worsening of respiratory-related symptoms, which are of the type expected following bronchoscopy in patients with asthma. The company said these events typically occur within a day of the procedure and resolve on average within a week with standard care. In the long term, fewer bronchial thermoplasty treated patients reported respiratory adverse events and there was a significant decrease in patients reporting asthma (multiple symptoms) adverse events in the Alair-treated group compared to the sham control group.

"The results from AIR2, similar to the results from two prior randomized clinical trials evaluating the Alair system, demonstrate that patients with severe asthma can experience clinically significant improvements in their asthma control and their quality of life," French said.

The results of this pivotal study have enabled Asthmatx to submit a premarket approval application (PMA) to the FDA for regulatory approval, the company said.

"Participation in the AIR2 trial required an extraordinary level of involvement from all patients, and we were encouraged by the very high level of interest from patients who wanted to participate," Castro said. "This high level of patient interest and involvement in this complex and time-consuming trial reflects the substantial clinical need that exists for new treatment options in this population of patients with severe asthma."

The company has already filed the final module of its PMA application for the system and the FDA has granted it expedited review status (*Medical Device Daily*, Jan. 22, 2009). French said that in early April the agency had some questions related to the submission and that the company is in the process of answering those questions. Assuming its responses satisfy the FDA's inquiries, he said the next step would be to schedule an advisory panel meeting. Assuming that meeting goes well, and if everything else goes according to plan, Asthmatx hopes to introduce the device to the U.S. market early next year, French said. He said the company believes it has a "tremendous amount of clinical research" backing it up and has been collaborating with FDA for nearly a decade, fine-tuning the studies along the way. "This study means everything to the company, in a sense," French said. "It will determine for us if [the device is] sufficient to meet FDA's standards, which we believe it is."

The Alair system has received a CE mark for use in Europe, the company noted. Also, in 2006, bronchial ther-

See Asthma, Page 10

Europe

Continued from Page 1

diagnosis of aneurysm coiling and vasospasm, dural arteriovenous fistula, and arteriovenous malformation, for example.

More recently such images have proven essential in both pre- and post-operative assessments for percutaneous interventions to place a stent, a coil tube to support vessel walls.

Even more recently, with advances in contrast agents, blood flow to a tumor can be studied in detail using DSA.

These sequential X-ray images remain in a grainy black-and-white and surgeons flip through them rapidly to study the blood flow as it enters a surgical target and then exits, to assess the extent of any blockage, or the effectiveness of a procedure to remove such blockage.

"The very experienced interventionalists can fuse a DSA sequence in their heads by flashing through the multiple images to understand the blood flow," said Thomas Hartley, marketing manager for interventional radiology at Siemens.

"But for newer doctors and radiology staff, it takes an effort and there is a learning curve" for decrypting DSA images, he said.

The syngo iFlow process combines the 25 to 30 photos in a DSA sequence into a single image where blood flow is color-coded and renders an easy to understand, almost intuitive view of the contrast-loaded blood flowing through the brain, the leg, or organs.

Vessels appearing in red show the early flow while blue depicts late flow in vessels.

syngo iFlow is a software-based upgrade to the Siemens's Artis zee family of systems used for interventional radiology and cardiology.

"It is not terribly expensive to add this feature," Hartley said. "And it certainly is not expensive if it proves to be clinically useful."

Because the software works with routine DSA sequences, there is no additional exposure to radiation for the patient, which would be the case if blood flow concerns caused the physician to order a 3-D computed tomographic scan.

Hartley said syngo iFlow processes a single frame in less than one second, "so it does not take very long to recompose the series into a single image of the dynamic flow," he said.

The learning curve is not steep, either.

"The radiologists marks a tart and an end point and clicks a button," he said.

"We see a strong potential for clinical procedures outside of neurology, which remains our primary focus," he said, adding that for leg stenosis syngo iFlow should prove clinically significant for pre- and post assessments.

"There is also a whole class of interventionalists working on the liver, kidneys and other blood-intensive organs

that we are targeting," Hartley said.

Syngo iFlow has also proven useful in making more vivid a phenomenon known as "tumor blush", the sudden visualization of a tumor as it fills with a contrast agent, indicating that interventional oncologists may find the software upgrade helpful.

Syngo iFlow holds a CE mark, clearing it for sale in more than 30 countries, and is currently being reviewed in a 510(k) application to the FDA.

An added benefit for an easy-to-understand image of blood flow is for the patient, Hartley said.

New neurosurgery systems from Renishaw

Renishaw (Wotton-Under-Edge, UK), a leader in engineering technologies, is introducing an exciting line of high precision systems for functional and stereotactic neurosurgery at the 15th quadrennial meeting of the World Society for Stereotactic and Functional Neurosurgery (WSSFN) taking place in Toronto from May 24-27.

These include the neuromate surgical robot, and image-guided stereotactic technologies, some of which are still in development.

To mark the introduction, the company will also be hosting a special satellite event at the Toronto Cricket Club on May 24, with two leading neurosurgeons to speak about their experiences with surgical robotics and other new stereotactic technologies, and their vision for their future use.

Dr. Olivier Delalande, pediatric neurosurgeon at the **Fondation Rothschild Hospital** (Paris), will discuss his pioneering use of the neuromate stereotactic robot to perform paediatric procedures, including Stereo Electro-Encephalography for epilepsy, and neuroendoscopic disconnection for hypothalamic hamartoma.

Professor Steven Gill of **Frenchay Hospital** (Bristol, UK), who is well-known for his pioneering work in placing deep brain stimulation leads, will also discuss the clinical applications of new technologies in the targeted delivery of therapeutics and their drive towards the requirement for advanced stereotactic systems.

Renishaw Chairman/CEO Sir David McMurtry said, "Our commitment to the neurosurgical market is built around listening to the needs of our clinical customers and then delivering advanced precision systems to meet their requirements."

Other Renishaw product lines include laser calibration systems for machine performance analysis, 3-D dental scanning and milling systems, linear and rotary position encoders, Raman spectroscopy systems for spectral analysis of materials, and most recently medical devices for neurosurgical applications.

In the year ended June 2008, Renishaw had revenues of £201.2 million and profit before tax of £41.7 million. The Renishaw Group has some 50 locations in 31 countries, employing more than 1,800. ■

Quest

Continued from Page 1

developed real-time polymerase chain reaction (PCR) test to aid in identifying Influenza A H1N1 Swine-origin (H1N1) flu virus.

The company said that the Focus Diagnostics Influenza A H1N1 (Swine Flu) RNA Real-Time RT-PCR Test is the first laboratory testing service to be introduced by a commercial laboratory to aid in the identification of patients infected with the novel H1N1 virus and differentiate patients infected with other seasonal Influenza A strains. The company said that Focus Diagnostics has a track record of being first to market with new laboratory testing services for emerging infectious diseases, such as West Nile Virus, SARS, and chikungunya virus.

"This is potentially a much faster turn around time," Jay Lieberman, MD, Medical Director, Infectious Disease Quest Diagnostics told *Medical Device Daily*. "We can give results within 24 hours. Health departments aren't set up to be laboratories."

Focus Diagnostics validated its new Influenza A H1N1 (Swine Flu) RNA Real-Time RT-PCR Test using clinical specimens submitted to its reference laboratory confirmed as positive for the novel H1N1 influenza virus by public health authorities. Real-time PCR is a highly sensitive testing technique that can detect the presence of a virus' RNA from a patient's nasal or nasopharyngeal specimen. The S-OIV virus responsible for a recent outbreak affecting dozens of countries is a subtype of Influenza virus Type A.

The new Focus Diagnostics test simultaneously detects the presence of Influenza A virus RNA and specifically identifies the presence of the novel H1N1 virus.

Focus Diagnostics will perform the Influenza A H1N1 (Swine Flu) RNA Real-Time RT-PCR laboratory test, in alignment with current public health guidelines, at its reference laboratory in Cypress, California. Physicians, hospitals and other healthcare practitioners may order the laboratory test directly from Focus Diagnostics or through the Quest Diagnostics national laboratory network. Expected turn-around time for reporting results is within 24 hours of receipt of specimen by the Focus Diagnostics laboratory.

"Our new laboratory test will be an important tool to help health care professionals and public health authorities identify infected patients more quickly, promoting earlier diagnosis and treatment," said Jon Cohen, MD, senior VP and CMO, Quest Diagnostics. "This capability could be particularly important if the novel H1N1 virus continues to spread in the U.S. or re-emerges this fall or winter. Public health officials in the U.S. have done an exceptional job of managing the current Influenza emergency, and we continue to work closely with them to assist their preparedness efforts."

In addition to the new Influenza A H1N1 (Swine Flu) RNA Real-Time RT-PCR Test, Quest Diagnostics' regional laboratories, including the Focus Diagnostics reference labora-

tory, perform a broad range of testing services to detect Influenza viruses, including PCR, rapid cell culture, direct immunofluorescence (DFA) and enzyme immunoassay (EIA) techniques. Depending on the laboratory, the company can perform testing on different types of collected specimens, such as nasopharyngeal swabs, nasal secretions, nasal wash (lavage) and aspirations.

The price point for the test will be at \$298 and is sure to be highly demanded.

Quest declined to talk about how many patients had already used the test but did say the volume of patients using it has been growing.

To date there have been at least 8,829 people sickened by the H1N1 in 40 countries, and up to 76 deaths from it.

"[H1N1] still remains a big story, Lieberman told *MDD*. "No one knows what's going to happen with this outbreak." ■

Grants roundup

S&N's Orthopedics unit makes first contribution to OREF

A Medical Device Daily Staff Report

Smith & Nephew's (London) orthopedics business reported today it has made its first contribution to the **Orthopedic Research and Education Foundation** (OREF; Rosemont Illinois) for continuing medical education (CME) grants. Smith & Nephew said in January it entered into a grant administration agreement with OREF under which OREF would serve as an independent grant-making organization for Smith & Nephew's financial support of research and education in orthopedics.

The funds have been contributed by Smith & Nephew to OREF's Clinician Development Program, a comprehensive new system developed by OREF to generate industry support for orthopedic research and education in a way that ensures transparency in the allocation process, relying on the history and experience of OREF as an independent, non-profit foundation. These grants will be available to partially or fully support qualified courses that are accredited by the Accreditation Council for Continuing Medical Education and are designed to help orthopedic surgeons learn new procedures and treatment protocol, refine surgical skills, and gain hands-on experience with new implants and other devices. ■

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*Restructuring roundup***Northfield Labs, Xtent report plans to dissolve companies****A Medical Device Daily Staff Report**

Northfield Laboratories (Evanston, Illinois) reported that it will shut down its business operations and carry out an orderly disposition of its assets.

The company said it made the decision following its review and analysis of the complete response letter received from the FDA at the end of April (*Medical Device Daily*, May 4, 2009). Northfield determined that further clinical development of a reformulated version of its PolyHeme human red cell substitute product, including additional clinical trials, would likely be required before it could again seek to obtain FDA approval. The company concluded that the time and substantial expense required to complete this additional clinical development, together with significant uncertainty that FDA approval would ultimately be obtained, made it unlikely that sufficient additional capital could be raised to support such further product development.

Earlier this month, the company reported that it had terminated substantially all operational and staff employees at its manufacturing facility in Mount Prospect, Illinois, and headquarters in Evanston (*MDD*, May 14, 2009).

The company cautioned that in view of its obligations to creditors, expenses expected to be incurred in connection with the wind down process and uncertainty regarding the realizable value of its non-cash assets, no assurance can be given that any amounts will be available for distribution to shareholders in connection with the winding down of the company's business. Northfield said it has retained counsel to explore the options available to wind down its business.

Since its inception in 1985, Northfield has incurred losses of \$220 million.

Xtent (Menlo Park, California) reported that its board has determined, after consideration of potential strategic alternatives, that it is in the best interests of the company and its stockholders to liquidate the company's assets and to dissolve the company.

In January, the company reported that it planned to engage an investment bank to help the company pursue strategic alternatives. At the same time, it notified 112 employees out of its total employment of 121 that their positions would be eliminated effective March 23 (*MDD*, Jan. 26, 2009).

The company's board has unanimously approved a plan of dissolution that is subject to stockholder approval. The company intends to hold a special meeting of the stockholders to seek approval of the plan and has filed related proxy materials with the SEC. Although the company's board has approved the plan of dissolution, it said it will continue to consider any "reasonable alternative strate-

gic proposals" presented to the company.

Xtent develops customizable drug-eluting stent systems for the treatment of coronary artery disease. ■

Asthma

Continued from Page 7

moplasty was ranked fifth on the **Cleveland Clinic's** "Top Ten" list of medical innovations for 2007 (*MDD*, Nov. 10, 2006). That list marked the first of what has become an annual list from the clinic.

"The treatment we have available for asthma currently is primarily based on education and pharmacotherapy . . . pharmacotherapy in this group of patients has really reached its limits in that it is still not achieving control of asthma symptoms," Castro told *MDD*. He said pulmonologists are looking forward to this device because it is something new they will be able to offer these patients to try to improve the control of their asthma symptoms. He also said doctors are looking for a therapy that is not associated with long-term adverse side effects as the current asthma treatments are.

So far, Castro said, the reaction to the Alair system from his colleagues in the field has been "overwhelming." The last time the company presented data on the device the room was packed and actually spilling out into the hallways, he said.

Castro emphasized the importance of this potential new asthma therapy by noting the seriousness of the problem for these types of patients. These patients are really disabled by their asthma, he said, and their quality of life is quite impaired. ■

M E D - T E C H N E W S A N D N O T E S

Interleukin Genetics meets Amex standards

Interleukin Genetics (Waltham, Massachusetts) said that the Corporate Compliance Staff of the NYSE Amex LLC has accepted the company's plan to meet the Exchange's continued listing standards, and has granted the company an extension to become compliant, through Dec. 31, 2009. As a result of the staff extension, the company was not required to attend a hearing before the Listing Qualifications Panel.

"We are pleased with the decision by the Exchange to continue our listing and look forward to meeting the business goals established by the company in our plan," said Lewis Bender, CEO, Interleukin Genetics. "The decision provides us with a reasonable timeline to achieve our objectives and become compliant with the listing standards. We look to execute on our business strategy and establish our leadership in the personalized health industry."

PRODUCT BRIEFS

- **AdvanDx** (Woburn, Massachusetts) received FDA clearance for GBS PNA FISH for detection of *Streptococcus agalactiae*, aka Group B Strep, from turbid Lim Broths inoculated with vaginal and rectal swabs obtained from pregnant women between 35 and 37 weeks gestation. The 90 minute molecular diagnostic test enables rapid detection of Group B Strep from Lim Broths to help detect colonization in pregnant women. GBS PNA FISH combines the high sensitivity of Lim Broth with the speed, accuracy and ease-of-use of the PNA FISH molecular diagnostic platform to provide accurate Group B Strep detection fit for the routine laboratory workflow. In a recent clinical study, GBS PNA FISH was shown to detect up to 42% more Group B Strep positives than conventional culture methods.

- **Any Lab Test Now** (Atlanta) has partnered with Atherotech, a Birmingham, Alabama-based CLIA-laboratory, to provide the VAP Cholesterol Test direct to consumers at an affordable price. The VAP Cholesterol Test is an expanded cholesterol profile that identifies a greater number of people at risk and is the first cholesterol test to directly measure LDL. The VAP Cholesterol Test is based on ultracentrifugation, the "gold standard" method of measuring cholesterol. The test, which doesn't require fasting, provides direct measurements of LDL, HDL and all relevant subclasses, and includes non-HDL, a highly accurate determination of apoB, and emerging risk factors such as Lp(a), remnants and small dense LDL.

- **bioMérieux** (Paris) said it is building on its Microbiology Lab Automation (FMLA) concept by offering a new tool to its customers, LeanSigma – today's most recognized process and flow improvement methodology. bioMérieux introduced the FMLA concept in 2008 with the goal of providing clinicians with more rapid and standardized results to allow them to prescribe the right treatment to their patients in the shortest time possible. LeanSigma combines

Lean and Six Sigma methods into a single, coordinated process. The audit will make it possible to pinpoint efficiency losses in areas such as the transfer of a sample from one instrument to another, the time it takes for a technician or an instrument to complete a task, certain tools and procedures, or even laboratory ergonomics. Improvement actions can then be recommended to enhance both laboratory reaction times as well as workflow.

- **Biosystems International** (Paris) has started the development of an *in vitro* diagnostic blood test for lung cancer. The antibodies of the test under development were discovered using BSI's monoclonal antibody proteomics platform which has delivered a panel of lung cancer specific antibodies that has been tested on 4 patient cohorts totaling 367 patients and 304 controls and demonstrates > 80% sensitivity and > 80% specificity (for comparison, the PSA test for prostate cancer screening has a sensitivity of 35% and specificity of 63%). To confirm the specificity of the antibody panel to lung cancer, it has also been tested on control cohorts including subjects with non-malignant lung pathologies such as COPD, bronchial pneumonia, and fibrosis, as well as lung tumors of non-pulmonary origin.

- **Concentric Medical** (Mountain View, California) reported the enrollment of the 500th patient in its Merci Registry, a real-world, international, post-market study of its product, the Merci Retrieval System. The company says the Merci Registry has captured a wide variety of data, including acute procedural data, patient care protocols, and longer term outcomes. The acute procedural data, such as recanalization rates and procedural steps, play a critical role in Concentric Medical's ability to continually improve the technical success and ease of use of the Merci Retrieval System. Participating physicians and Concentric Medical are analyzing patient care protocols and longer term outcomes to further the stroke community's understanding of best practices for the acute care and management of stroke victims. The first analyses of these data are expected to be completed and presented later this year.

PEOPLE IN PLACES

- Michael Mainelli was named president/CEO of **Active Implants** (AIC; Memphis, Tennessee). Mainelli previously was president of Stryker Spine and president of Stryker Japan. AIC makes polymer technology for hip and knee segments of the orthopedic market.

- Bryan Olin was named VP of quality for **Cyberonics** (Houston). Olin previously was senior director of quality assurance for Zeltiq Aesthetics. Cyberonics specializes in neuromodulation technology.

- **Thoratec** (Pleasanton, California) reported the election of Paul LaViolette, the former COO of Boston Scientific,

to its board. Thoratec makes therapies to address advanced-stage heart failure.

- **Serica Technologies** (Medford, Massachusetts) reported the appointment of two senior staff members to support the continued clinical development and commercialization of its products in orthopedic and sports medicine, and aesthetic and reconstructive plastic surgery. Paul Weitzel, MD, an orthopedic surgeon and assistant clinical professor at Tufts University School of Medicine, was named VP of medical affairs, orthopedics. Mona Haynes was named chief commercial officer. Haynes most recently was chief commercial officer at Targanta Therapeutics. Serica is a growth-stage medical device company focused on silk-based biomaterial platform technology for human tissue repair and regeneration.

MDD'S CARDIO EXTRA

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

TUESDAY, MAY 19, 2009

PAGE 1 OF 2

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

Chest pain CT Scans validated by long-term study Research from the **University of Pennsylvania School of Medicine** (Philadelphia), presented May 15 at the annual conference of the **Society for Academic Emergency Medicine** (Lansing, Michigan) confirms that screening with coronary computerized tomographic angiography (CTA) is a safe/effective way to rule out serious heart disease in patients presenting with chest pain. Among 481 patients in the trial, after getting a negative scan — no evidence of dangerous blockages in the coronary arteries — none had heart attacks or required bypass surgery or placement of stents in one-year follow-up. The authors say the findings provide a roadmap for appropriately and cost-effectively using this technology, which generates 3D images of the heart and the blood vessels surrounding it. The researchers used the trial to argue for “a national coverage decision that will facilitate coronary CTA in the emergency department.”
(www.uphs.upenn.edu/news/News_Releases/2009/05/ct-scan-chest-pain-diagnosis.html)

Stem cell transplant in mouse embryo yields heart protection A study by researchers at **Mayo Clinic** (Rochester, Minnesota) describes how embryonic stem cells delivered to mouse embryos, in the earliest stages of development, resulted in the mice being able to recover from cardiac injury in adulthood. Mice that received embryonic stem cell treatment recovered cardiac function, while a control group deteriorated, demonstrating ischemic myopathy, myocardial scarring and significant pulmonary congestion, typical in progression towards heart failure. “Preemptive stem cell-based intervention in utero thus provides a strategy to engineer tolerance, and prevent incidence of life-threatening organ failure in the adult,” the authors say, calling this the first evidence that regenerative medicine may be useful in treating myocardial infarction through prophylactic intervention. The study is published in *Stem Cells*.
(Abstract:<http://stemcells.alphamedpress.org/cgi/content/abstract/27/4/971?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=mouse+embryos&searchid=1&FIRSTINDEX=20&volume=27&issue=4&resourcetype=HWCIT>)

Low, high levels of hormone in men with HF increases death risk Men with systolic chronic heart failure (HF) who have low or high levels of estradiol, a form of estrogen, have an increased risk of death compared with men with only moderate levels. Researchers at the **Center for Heart Disease, Military Hospital** (Wroclaw, Poland) examined the relationship between estradiol in the blood and the death in men with HF and reduced left ventricular ejection fraction. The study included 501 men divided into five groups, determined by the level of estradiol in their blood. Lowest mortality was in patients with estradiol levels within the middle quintile; the highest three-year mortality rate was in men in the lowest quintile (about four times higher risk of death) and those in the highest quintile (twice the risk of death) of circulating estradiol levels. The study appears in the May 13 issue of *JAMA* (301[18]:1892-1901).

Selected reports from the 30th Annual Scientific Sessions of the **Heart Rhythm Society** (HRS; Washington) May 13-16 in Boston:

• **Study: ICDs extend heart attack survivors lives by a year** A follow-up study has found that heart attack survivors who receive implanted cardioverter defibrillators (ICDs) live longer the longer they have them, according to the results of late-breaking clinical trial presented at HRS 2009. The study followed for eight years the patients of the 2002 MADIT II trial, finding that patients with ICDs had a 37% lower chance of death from any cause than those without one, translating into 1.2 life-years saved. Ilan Goldenberg, MD, research associate professor within the Heart Research Fol-

low-up Program at the University of Rochester Medical Center (Rochester, New York), said that the results “emphasize the life-saving value of ICDs as chronic therapy for high-risk cardiac patients.”

• **Expert consensus on catheter ablation of arrhythmias issued**

A call for more research concerning the catheter ablation of ventricular arrhythmias (VA) was issued at the scientific sessions via a joint document from the **European Heart Rhythm Association**, a branch of the **European Society of Cardiology** (Sophia Antipolis, France) and the HRS. The document updates a review of indications, techniques and outcomes of catheter ablation for treatment of ventricular arrhythmias, a technique now being offered to increasing numbers of patients. It was written by 20 European and U.S. electrophysiologists and says that there is still “very limited” data establishing the long-term impact of catheter ablation on morbidity and mortality. Questions highlighted by the joint document include: the long term efficacy of catheter ablation, the comparative success rates of drug and ablative therapies, and whether ablation slows the progression of ventricular remodeling in structural heart disease?

• **Study shows relationship between AF, development of Alzheimer's**

. . . . Researchers at **Intermountain Medical Center** (Salt Lake City, Utah) reported a potential connection between AF and Alzheimer's disease. Researchers studied more than 37,000 individuals, using data from the Intermountain Heart Collaborative Study, and found that those with AF 44% more likely to develop dementia than those without AF. Those with AF under age 70 were 130% more likely to develop Alzheimer's. And those with both AF and dementia were 61% more likely to die during the study period than dementia patients without AF. T. Jared Bunch, MD, said that this was the first “large-population” study to demonstrate what has been long suspected. “The Alzheimer's findings — particularly the risk of death for younger patients — break new ground.”

• **Medtronic completes enrollment in TTOP-AF trial Medtronic**

(Minneapolis) utilized the HRS conference to report completing enrollment in the Tailored Treatment of Permanent Atrial Fibrillation (TTOP-AF) trial evaluating the use of its latest radio frequency (RF) ablation technology. The Ablation Frontiers Cardiac Ablation System, for the treatment of continuous AF is comprised of a RF generator and three anatomically shaped mapping and ablation catheters that target three areas of the heart for AF treatment. The system is approved for use in Europe but not in the U.S. Enrollment completion follows Medtronic's recent acquisitions of **Ablation Frontiers** (Carlsbad, California) and **CryoCath Technologies** (Montreal) to form Medtronic's AF Solutions division (*Medical Device Daily*, Feb. 9, 2009/Dec. 22, 2008), saying it will offer a complete line of diagnostic, cryoablation and RF tools to treat AF.

• **Study: ablation superior to drugs for treating AF**

One year after undergoing catheter ablation, 63% of patients with AF were free of any recurrent atrial arrhythmias or symptoms, vs. 7% of those treated according to an international study; 17% of those treated with drugs were arrhythmia-free. The ablation group also scored significantly higher on a quality-of-life scale. Based on the results, the trial was halted early. The study included 167 patients at 19 centers, including 15 centers in the U.S., and the researchers said it is the largest to date to compare ablation to drug therapy for AF. The research was funded by **Biosense Webster** (Diamond Bar, California), which makes the ThermoCool catheter system used in the study. An additional study called CABANA is designed to determine whether ablation patients live longer than patients receiving medication. Researchers will follow about 3,000 patients for three years.

— **Compiled by Don Long, MDD National Editor**

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