Medical Device Daily™
The Daily Medical Technology News Source
Monday, October 14, 2013 Vol. 17, No. 198 Page 1 of 9

Cleveland Clinic Medical Innovation Summit

Summit moves to new Global Center for Health Innovation

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

The increasingly popular Cleveland Clinic Medical Innovation Summit kicked off today, bringing more than 1,200 executives, investors, entrepreneurs, and clinicians to the brand new Global Center for Health Innovation in Cleveland's downtown. And while there are some obvious changes to this year's summit, the spirit of innovation has clearly not changed.

"With regard to changes, the biggest one of course is moving the location," Thomas Graham, MD, Cleveland Clinic's chief innovation officer, told *Medical Device Daily*. "There is great excitement about being the inaugural meeting at what I believe will be a real jewel of Cleveland's downtown."

See Cleveland, Page 5

USGI gears up for pivotal trial; gains traction from Europe studies

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

A top priority for medical-tech firms in today's healthcare landscape revolves around developing a device that can demonstrate both meaningful data and strong clinical outcomes.

If previous studies of **USGI Medical**'s (San Clemente, California) endoscopic application to treat obesity are any indication – then to coin and old phrase – the firm has its priorities in order. Last week, the company spoke with *Medical Device Daily* about the results of two European studies concerning the firm's POSE procedure and about the recent news that it has obtained conditional approval of an investigational device exemption (IDE) application from the FDA to launch a U.S. multi-center, randomized, sham-controlled study for the weight loss application.

See USGI, Page 6

CFDA striving to close gaps in its device classifications

By KRISTINE YANG
***Medical Device Daily* Contributing Writer**

The China Food and Drug Administration (CFDA) has issued its latest update to its medical device classification list.

The latest regular update to the list on Sept. 27 comes as the national regulatory body works to streamline its workflow and speed up the classification and registration process for medical devices in China.

As part of a reform process it started in March, the CFDA is dealing with a backlog of classification applications while speeding up the way it classifies devices. It now takes less than a year to include new devices on the classification lists, a necessary step to register them in the country.

See China, Page 7

Washington roundup

SCAI criteria pushes troponin behind CK-MB for infarct test

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

Changes in standards of care often have implications for therapeutic and diagnostic devices, and a recent announcement by the **Society for Cardiovascular Angiography and Interventions** (SCAI; Washington) has the potential to reverse a recent trend in testing for patients under care for coronary artery disease. The consensus statement recommends that cardiologists resort principally to tests of the CK-MB protein to detect infarcts in patients just out of bypass or percutaneous intervention, a development that seems likely to boost sales of tests for this protein at the expense of tests for troponin.

The SCAI statement explains that the new standard

See Washington, Page 8

Don't miss today's MDD Extra: Neurology

INSIDE:

THOMSON REUTERS

USGI

Continued from Page 1

The incisionless outpatient procedure has been performed on more than 2,000 patients, mostly in Europe, where it is known as "POSE." The procedure is performed entirely through the mouth without any incisions through the abdomen. Physicians have reported that many of their patients have returned to work without any bandages or signs of surgery within two to three days.

Physicians participating in ESSENTIAL, the U.S. study, will use USGI Medical's g-Cath EZ Suture Anchor Delivery Catheter to place tissue anchors across folds of tissue in strategically-located parts of the stomach to reduce its size and ability to stretch to accommodate a meal. The g-Cath, which is used extensively for general, non-obesity indications, is the first endoscopic suturing technology proven to create a durable, healed fold in the stomach.

"I think anyone from the weight-loss space in terms of endoluminal procedures or surgery for weight loss would look at this data (from the studies in Europe) and say this has the potential to be best in class," John Cox, COO of USGI, told *Medical Device Daily*. "We believe that this type of treatment has the potential to fill that treatment gap between diet and exercise and surgery and offer a weight loss option to millions of patients that really don't have an option because they would fit somewhere in that treatment gap. Our goal is to see if the Essential Trial data, when it becomes available, will meet these expectations. Many thought leaders in obesity believe that patients need more options between diet and exercise and surgery."

Physicians from Spain reported results of two studies showing the positive outcomes and physiological effects of the POSE procedure at the 18th World Congress of International Federation for the Surgery of Obesity & Metabolic Disorders (IFSO) in Istanbul this past August.

Román Turró, MD, reported results of his team's POSE experience at the GI Endoscopy Department at the **Centro Medico Teknon** (Barcelona).

Prospective, institutional ethics-approved data collection began in February 2011 and included results from 137 consecutive procedures performed through July 2013. The first 22 patients who had been followed for 12 months post-procedure at the time of the presentation achieved average excess weight loss of 62% and total body weight loss of 19%.

Importantly, initial safety data were favorable for POSE as well. Of the 137 patients, none were hospitalized with a surgical intervention after undergoing POSE. One patient developed an infection that was treated with antibiotics and two patients suffered intra-gastric bleeding, which was treated endoscopically. The average age of patients included in the safety analysis was 42.8 years and the average body mass index (BMI) was 36.9 at the time of the procedure.

Females accounted for 74% of the patients.

Endoscopies on a subset of these patients also confirmed that the suture anchors remained in place in the stomach 12 months after the procedure.

Separately at IFSO, Silvia Delgado-Aros, MSc, MD, PhD, a member of the Neuro-Enteric Translational Science (NETS) Research Group at the **Institut Hospital del Mar d'Investigacions Mèdiques** (Barcelona), presented physiologic findings showing that POSE led to weight loss, a sustained reduction in caloric intake, normalization of blood sugar levels and improved feelings of fullness and satiety triggered by an improved gut peptide response to food. In this controlled study, patients followed for 15 months reported mean excess weight loss of 63.7%.

"The start of the ESSENTIAL Trial represents a significant milestone for USGI Medical and endoscopic approaches to weight loss," Cox said in a release. "Our efforts to support this study underscore our excitement about the potential of our technology and our commitment to patient safety and outcomes. We look forward to working with many of the country's leading bariatric surgeons and advanced endoscopists, both at top academic medical institutions and well-respected private centers, to enroll patients in this study." ■

Omar Ford;770-810-3125
omar.ford@thomsonreuters.com

Europe

Continued from Page 2

from the Company's Phase I clinical trial conducted at five European centers.

Twenty-four patients suffering from class II-IV HF, as defined by the New York Heart Association (NYHA) functional class criteria, as a result of a previous heart attack have now passed the one-year milestone since their HF was treated using the Revivent System via Less Invasive Ventricular Enhancement or the LIVE procedure. A key indicator for survival in HF patients lies in reducing and maintaining the volume of the left ventricle (LV) to less than 60mL/m2. In the data presented, 24 of 26 patients sustained a reduction in this critical prognostic measure to a mean of 43.9 + 22 mL/m2, a mean 40% decrease. Also reported was a 30.9% improvement in quality-of-life (QOL) scores, which measure psychological and physical aspects that greatly influence a patient's independence.

The Revivent System restores the LV to its more optimal conical shape by creating a fold of tissue that effectively excludes the non-functioning scar tissue created by a heart attack, thereby enhancing the efficiency of the remaining heart. The Revivent System is intended for use in the operating room as a stand-alone procedure or during a concurrent cardiac procedure. The Revivent-TC System, designed for use in the interventional laboratory, replicates the results of the Revivent System, but uses a hybrid transcatheter-minimally invasive technique and removes the need to open the patient's chest. ■