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Advancing data-driven surgery

Mauna Kea adds endomicroscope intelligence to robotic surgery toolkit

By John Brosky, Contributing Writer

PARIS – The Food and Drug Administration granted 510(k) clearance to Paris-based Mauna Kea Technologies SA to apply the Celioflex UHD confocal miniprobes in robotic-assisted surgery procedures.

The first utilization for a microscopic view during robotic surgery is expected to be for optical biopsies, enabling a surgeon to define margins around cancerous tissue in real time, Mauna Kea founder and CEO Sasha Loiseau told *BioWorld MedTech*.

See Mauna Kea, page 4

Inside

Hemophilia-impacted joint diagnosis, management

Bioverativ and Invicro align to image hemophiliac patients' joints, track therapeutics

By Katie Pfaff, Staff Writer

Bioverativ Inc. entered a collaborative effort with Invicro LLC to increase use of imaging technologies to better diagnose and treat joint disease among patients with hemophilia. The

See Bioverativ, page 5

Regulatory

FDA says development tools are IDEs or are available to the public

By Mark McCarty, Regulatory Editor

The medical device development tool (MDDT) notion has gained substantial traction at the FDA, but members of the FDA staff said on a conference call that any such tool that does not go through the formal MDDT program will be treated as a

See Regulatory, page 7

CAGE captures RNA function

First integrated atlas of microRNA expression compiled

By John Fox, Staff Writer

The latest study by the Functional Annotation of the Mammalian genome (FANTOM) group, an international consortium led by Japan's RIKEN Institute, has compiled the first extensive atlas of microRNA expression in human primary cells, which could help development of new cancer treatments.

See MicroRNA, page 8

Have a Mimosa and save a limb

Canadian device shines a light on diabetic foot disease, may prevent amputation

By David Godkin, Staff Writer

Trials are underway at Toronto's St. Michael's Hospital assessing a device designed to alert doctors – and eventually their patients with diabetes – when their feet are showing signs of tissue damage that could lead to amputation. Karen Cross told *BioWorld MedTech* the Multispectral Mobile Tissue Assessment (Mimosa) device uses near infrared light to detect even the smallest irregularities in foot tissue that may affect the health of a patient with diabetes.

"This device is accurate 92 percent of the time," said Cross, one of the co-founders of the start up company Mimosa Diagnostics Inc., which makes the device. "It allows us in real time to monitor what's happening to a patient's feet so that physicians can intervene at an earlier time point. And as a physician and a scientist that's what you really want."

See Mimosa, page 6

Patent Highlights

BioWorld MedTech presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

BioWorld Medtech's Neurology Extra

Production Editor Andrea Gonzalez on one of med-tech's key sectors

Read this week's edition

Mauna Kea

Continued from page 1

Surgeons are obsessed with margins, he said, not only to decide if enough diseased tissue has been taken out but equally to know what healthy tissue should be left alone in sensitive areas, such as the brain or the sphincter.

Measuring less than 3 millimeters at the distal end of a optical fiber cable, the Celioflex probe connects to the Cellvizio platform to render cellular-level images that Loiseau said are particularly well-suited to converge with the rapid advances in artificial intelligence (AI) as robotics evolve toward data-driven surgery.

"We are seeing amazing, explosive growth in AI specifically for medical image interpretation. Our images are highly differentiated and AI can read these very well. We have great proofs of concepts from groups at Stanford [University in Stanford, Calif.] while some others are in the works. We can now safely say to surgeons that they do not need to worry about interpreting images beyond a basic understanding of what looks normal and what looks not normal, because there is assistance for interpretation that will make this easy," he said.

BioWorld MedTech caught up with Loiseau during a visit to California, "not too far," he said, from Intuitive Surgical Inc. in Sunnyvale, Calif., the maker of the best-selling surgical robot.

Mauna Kea noted "there are more than 4,000 da Vinci robotic surgical systems installed around the world, with approximately 750,000 robotic-assisted procedures performed on these systems in 2016."

"There is more than one robotics company and they are all in the same neighborhood," Loiseau said, declining to name potential partner companies.

Combining robotics with data-driven surgery, he explained, means a surgeon will be assisted not only by an electro-mechanical system but also by intelligent computer visioning, optically capable of looking at anatomy, and zooming into tissue to help the surgeon determine what action to take.

With a broad clearance for the FDA to utilize the probe in "body cavities, organs, and canals during endoscopic or laparoscopic surgical procedures, including robotic-assisted procedures," the company's engineers are adapting the Celioflex probe to be grasped and securely handled by a machine.

Agnostic platform

"There will be new robotics platforms coming to market and we want to be sure Cellvizio is adapted for these," he said. "The advantage of our system is an ability to be agnostic to a platform. Over the past few years we have worked tremendously hard to make the system fully integratable. We have the ability to do this now, which we did not have four years ago. Today it is happening and it's incredible. In a near future we believe we will be able to provide a much smaller version, which like a module, can fit within a given platform."

The capabilities of Cellvizio will not be reduced to what Loiseau called a black box that flashes red-green signals. Images from the probe will be displayed for the surgeon to view, along with labels that can be as simple as normal-abnormal or can offer additional information drawn from the AI assessment.

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>
> Sasha Loiseau
> Founder and CEO, Mauna Kea

The goal in applying an AI capability, he said, " is not to do things that the human surgeon is able to do but to do things the surgeon simply cannot do," such as stopping to compare against hundreds of similar cases, review literature or guidelines.

Using robotics, the surgeon is fully immersed with the head in the machine's console looking at the surgery site on a screen. Integrating images from Cellvizio becomes easy with software capabilities for continuous picture-in-picture display.

While the surgeon is focused on one task, Loiseau explained, Cellvizio with an AI capability can simultaneously continue interpreting images and assessing margins to prepare an answer before the next question is asked.

"This demonstrates the maturity in our technology, which is still disruptive, and now is perfectly positioned in a moment when the medical community is recognizing that the world has changed. Doctors are asking us when will they be given the AI-assisted interpretation. That's a wow, very impressive," he said.

"We are still a small company and need to stay focused on where there is a commercial traction, on where it makes sense and where we can become profitable," said Loiseau.

"Right now our focus is in gastroenterology because there is a very exciting market opportunity for us, particularly in the U.S. with attractive reimbursement, recommendations from medical societies, and a good momentum with a new business model," he said.

Pivoting to a new commercial offer has set back the company, he acknowledge, having reported global sales down 26 percent in the first half of 2017, though there was a 12 percent growth in the Americas clinical business reflecting the pay-per-use sales model.

"We have this giant opportunity that opened in the U.S.," he said. "We are going to focus on this, and yes, we will reduce our energy in other regions and there will be a lower level of sales in those regions. And that's what happened."

"There is no surprise that we are taking a hit in many different

See Mauna Kea, page 9

Mauna Kea

Continued from page 4

ways because it is very difficult to fully swing to a new business model where we need to retrain everyone, to address the market in a new way. And yes, these recent quarters have been brutal because we are doing this," he said.

Pay-per-shave.

Abandoning the traditional razors-and-razor blades model for commercializing medical devices, Loiseau said Cellvizio is now offered as a service, making the procedure a variable expense that is within reimbursement levels.

"Today our customer does not buy razors or even razor blades. The customer pays as they shave. For every shave you will pay something, and it includes everything, the razors, the razor blades, maintenance for the razor. Upfront, we invoice nothing. The invoice is purely on utilization. We place the machine, we stock the probes, we train the surgeons and they hit the ground running. We invoice for each procedure that is performed," he explained.

"This model makes the sales cycle easier, it makes the adoption cycle much faster for those doctors who have been wanting to use Cellvizio. Now they know how to take it to the hospital administration and make this work fast, instead of heading into a fight for capital, to fight against the cardiologists or interventional radiologists," he said.

"We expect to emerge from this transition with a very different physiognomy for the company and its sales," he said.

On top of this, Loiseau added, "because of the versatility of the technology we believe there is a lot of market expansion potential through commercial partners, through product development partners, and possibilities for going into different fields of application." ♦

Other news to note

Labfolder GMBH, of Berlin, and the **German Accelerator Life Sciences**, an initiative supported by the German Federal Ministry for Economic Affairs and Energy, reported the initiation of an extensive collaboration supporting the company's expansion into the North American markets. With thousands of users and a growing number of customers in the U.S. already, the newly established Cambridge office will accelerate those efforts and support customer relations.

One Drop Inc., of New York, reported the results of a retrospective study of people with diabetes (type 1 and type 2) using the One Drop Mobile diabetes management app, demonstrating a 1.1 percent to 1.3 percent absolute reduction in A1C in just 4 months. The results were published Aug. 24, 2017, in *JMIR* Diabetes. Using retrospective app-collected data, One Drop in collaboration with U.S. and non-U.S.-based scientists, assessed the A1c change of people using One Drop Mobile. They also assessed the relationship between tracking self-care with the app and changes in A1c.

SRI International Inc., of Menlo Park, Calif., reported the launch of **Ancora Medical Technology**, its latest spin-off venture. Ancora's initial product will be a new type of catheter to administer long lasting post-operative anesthetic. The patented technology is designed to improve the reliability of operative nerve block administration by anesthesiologists, which may help reduce the need for opioid-based post-operative pain relief. Physicians and engineers at Stanford University and SRI International collaborated to invent the improved catheter.

Appointments and advancements

U.S. FDA Commissioner Scott Gottlieb appointed Rachel Sherman to the No. 2 job at the agency, principal deputy commissioner. Sherman has served as associate deputy commissioner for medical products and tobacco at the agency since October 2015. She will continue to function in that role in parallel with her new position.

Bioverativ

Continued from page 5

equity investment round closed in February 2016.

In an Aug. 3 analyst guidance by Cowen Equity Research, revenue from Elocate was projected at $682 million in 2017, and $995 million in 2021, and Alprolix revenues to reach $355 million in 2017, and $370 million in 2021. Cowen said, "Bioverativ's most interesting asset may be BIVV009, an anti-C1s antibody acquired with True North Therapeutics for the treatment of cold agglutinin disease (CAD). BIVV009 is scheduled to enter two pivotal studies during in H2 and we believe this low-risk candidate has >1.5B in peak sales potential. We view Bioverativ as having an attractive, high margin, orphan disease business with a solid financial outlook (12 percent EPS CAGR)." ♦