BioWorld MedTech

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Sees revenue bump

Accenture gives visually impaired clarity through artificial intelligence solution

By Omar Ford, Staff Writer

Accenture plc is using artificial intelligence to help visually impaired people improve the way they experience the world around them and enhance their productivity in the workplace. The Dublin-based company is testing the Drishti artificial intelligence solution in India. Drishti means "vision" in Sanskrit. The technology was developed as a part of Accenture's focus on Tech4Good, a program the company

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Inside

Minimally invasive technology to address ICH

Nico-sponsored ENRICH trial doubles in size

By Katie Pfaff, Staff Writer

Nico Corp. recently doubled its ENRICH trial sites based on interest in the study of early intervention with clot removal among patients being treated for intracerebral hemorrhage (ICH). The study will compare intervention with the company's Brainpath approach technology during minimally

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Raman shift may guide neurosurgeons to stray brain cancer cells

By David Godkin, Staff Writer

Montreal-based ODS Medical Inc. has developed a fiber-optic probe that detects stray cancer cells during brain tumor surgery with close to 100 percent accuracy and sensitivity. Now they're testing the Raman spectroscopy probe in clinical

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Looking at cancer treatment

Invitrocue and Genome Institute of Singapore launch joint innovation lab

By David Ho, Staff Writer

HONG KONG – With a new state-of-the-art laboratory, Singapore is leading the Asia-Pacific in the use of phenotypic and genomic data for cancer treatment.

See Invitrocue, page 8

Device tax could reappear in 2018

'Skinny repeal' bill dies in Senate; less ambition an option

By Mark McCarty, Regulatory Editor

The so-called "skinny repeal" bill that would have peeled back a small number of aspects of the Affordable Care Act tanked in the Senate early in the morning of July 28, but Julius Hobson of the D.C.-based law firm of Polsinelli said the two major parties can still avail themselves of

See Senate, page 6

Should help with postoperative pain

Cousin Biotech set to launch first parietal prosthesis for release of analgesic substances

By Bernard Banga, Staff Writer

PARIS – Cousin Biotech Sarl, of Wervicq Sud, France, recently embarked on the regulatory phase prior to marketing a parietal prosthesis capable of an extended release of analgesics. The

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BioWorld Medtech's Neurology Extra

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

Read this week's edition

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.

Cousin Biotech

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company said this new generation of implant will help reduce the risk of postoperative pain for patients who undergo hernia operations.

Hernia repair is the second most practiced digestive surgery in France. Every year, 180,000 operations (140,000 inguinal hernia operations and 40,000 interventions following eventration) are performed. Closure of the orifice is achieved with the aid of a parietal repair implant in polypropylene or polyester netting.

However, 12 percent of patients suffer postoperative pain immediately or for more than three months after the intervention. Current techniques such as tissue infiltrations only ensure a short-term analgesic or even adverse effects. "We have therefore designed a new biostable parietal implant capable of being loaded with analgesics and progressive release in situ. This enables pain relief after the intervention," Cousin Biotech CEO François Tortel told *BioWorld Medtech*.

His company was founded in 1995 by the Cousin family group, specializing in technical textile weaving. Cousin Biotech has 120 employees today and allocates 10 percent of its revenue to R&D.

"We keep innovating so we can do what others do not and provide original surgical solutions in order facilitate the work of surgeons and bring comfort to patients," said Tortel.

Cousin has applied for 65 patents, 28 of which are used in a portfolio comprised of 400 implantable medical devices for abdominal wall repair and also spinal surgery.

"Every year we invest $137,000 in patenting to protect our innovations," said Tortel. This innovation policy has borne fruit with some world firsts for the company. It claims the first parietal prosthesis with balloon expansion for umbilical hernia treatment in 2007 and the first self-adhesive wall repair in 2010.

New generation of parietal repair implant

"For seven years we have been working on the development of a functionalized parietal implant in partnership with two university laboratories in the region of Hauts-de-France," said François Henin, general director of Cousin Biotech.

Consequently, the Inserm U 1008 unit of the University of Law and Health of Lille and the Laboratory of Materials and Transformation (UMET) of the National Center for Scientific Research (CNRS) of the University of Sciences and Technology of Lille have designed and patented the manufacturing process, on an industrial scale, of biomaterial containing cyclodextrin within the progressive and delayed release properties of therapeutic molecules.

Cousin's new parietal repair implant includes a mesh textile support made of polyethylene terephthalate (PET) subjected to special chemical treatment with the aid of a cyclodextrin polymer produced from starch. This so-called cage molecule, known for its capacity to form reversible inclusion complexes with active ingredients, will trap and encapsulate an amide long-term local anesthetic (ropivacaine) in its action cavities before releasing it at a slower pace.

"The hydrophobic cavity of the cyclodextrin molecule measures between 5 and 9 Angstroms, and its hydrophilic external width

The company has 2,000 meters^2 of white rooms; Cousin Biotech Sarl

> *"This new generation of textile parietal prosthesis is capable of achieving extended release of analgesics for surgical hernia treatment.*
>
> François Tortel
> CEO, Cousin Biotech

is between 13 and 17 Angstroms," said Professor Bernard Martel, director of UMET. In practice, during installation, the surgeon places the ropivacaine on the Biotech implant, which has been functionalized with the cyclodextrins. The focus of the technology developed by Cousin Biotech is to prolong the painkilling efficiency of ropivacaine by capturing a large amount of the active molecule (reservoir effect) in order to subsequently release it in a prolonged way.

"This allows the painkilling effect to be supported but without exceeding the toxic dose. Indeed, any active ingredient has an effective dose and a "toxic" dose, which forms what we call a therapeutic window," Guillaume Vermet, one of the R&D engineers of implantable medical devices at Cousin Biotech, told *BioWorld MedTech*.

Convincing body of testing since 2009

Cousin Biotech's engineers have adapted the dosage protocols to the existing packaging of the ropivacaine ampoules (10 mililiters) and in accordance with the size of the parietal prosthesis from the Biomesh range (from the implant circle with a 7 centimeter diameter to a 30 cm by 50 cm rectangle). The surgeon can therefore proceed to inject a ropivacaine ampoule of 10 cm^3 (10 ml) for small sized parietal ampoules (less than 14 cm). Two ampoules of ropivacaine, thus 20 cm^3, can be injected for average sized meshes (between 14 and 21 cm) or even 3 ampoules, thus 30 cc of ropivacaine for large meshes (exceeding 21 cm).

Since 2009, functionalization parameters have been studied in

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Nico

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At conclusion of the current trial, the company plans to continue educating physicians on the treatment regimen, and will work toward creating a standardization approach for centers that offer the procedure. More than 6,000 procedures by 500 neurosurgeons, residents and fellows have received training in the U.S., U.K., Canada and Australia.

The company has raised $50.08 million in six funding rounds between January 2008 and June 2016. Series C financing was led by River Cities Capital Funds and participated in by CHV Capital, The Halo Group and Twilight Venture Partners. River Cities and The Rose-Hulman Institute of Technology participated in venture capital funding, and Square 1 Bank participated in debt financing.

In addition to a wait-and-see approach, ICH can be treated with diversion or surgery to reduce pressure in the brain. Ireland-based Medtronic offers its Pipeline flex device, which covers affected area and diverts blood flow away. Bochum, Germany-based Phenox's P64 flow modulation device also diverts flow after hemorrhage. ♦

Cousin Biotech

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order to obtain an implant that meets requirements in terms of flexibility, mechanical properties, cytocompatibility and absorption of active agents. Then, the inclusion of ropivacaine was studied within the cyclodextrin cavity in solution by nuclear magnetic resonance and capillary electrophoresis. Adsorption isotherms were made in order to evaluate their respective loading ratios on the modified textile.

"This ratio corresponds with the therapeutic doses applied locally in the present protocols," said Nicolas Blanchemain, manager of the Inserm U 1008 unit.

The first conclusive mechanical tests took place in 2012 and showed that the mechanical properties of Cousin Biotech parietal implants were similar after their functionalization by cyclodextrins. One year later, the in vitro pretests showed that these functionalized implants were safe. As a result, the release kinetics revealed that 90 percent of the analgesic was released in the first hours.

"Then in 2014, we evaluated the therapeutic activity of implants loaded with analgesics in rats," said Hénin.

Last year, cytocompatibility tests were carried out on Biomesh A2 parietal repair implants industrially produced by Cousin Biotech.

"In 2017, we successfully carried out chemical tests in accordance with ISO 10993-18 norms in order to confirm the chemical safety of this new combined medical device," said Vermet.

The med-tech continues to undertake the biological evaluation process of its parietal implant with the release of an analgesic in accordance with norm 10993-5.

A production tool capable of satisfying demand

The company currently has the capacity to industrially produce this new parietal implant in its 2,000 meter^2 area of white rooms, which are spread throughout its factory of half a hectare in Wervicq Sud. This year, Cousin invested $1.7 million in new production equipment with 70 percent of its turnover coming from export to 61 countries, notably the U.S., Russia, India, China, Australia and South Korea.

"We intend that from 2019, we will be the first to market this new generation of parietal implant to be used in 2 million hernia operations per year worldwide," said Tortel. The market is estimated to be $750 million in the U.S. alone where 800,000 inguinal and ventral hernia repairs are carried out each year. ♦

Regulatory front

The **FDA** has classified the adjunctive cardiovascular status indicator as a class II device thanks to a petition by **Flashback Technologies** of Boulder, Colo., for the company's Cipher Ox Compensatory Reserve Index (CRI) tablet. The new device type is described as the adjunctive cardiovascular status indicator. Another device type that successfully navigated the de novo process for a class II designation is the oral removable palatal space occupying device, which was prompted by an application by **Scientific Intake** for its Sensor monitored alimentary restriction therapy (SMART) device. The cranial motion measurement device de novo petition was filed by **Jan Medical Inc.** of Mountain View, Calif., for the company's model 1100 Brainpulse device, while the de novo petition for the closed-loop hysteroscopic insufflator with cutter-coagulator was filed by **Iogyn Inc.** of Cupertino, Calif., for three models of the Iogyn device. Iogyn was acquired by **Boston Scientific Inc.** of Marlborough, Mass., in 2014.