BioWorld MedTech

Clarivate Analytics

The news source of record covering the latest advances in medical technology
Actionable Intelligence • Incisive Analysis

February 8, 2018
Volume 22, No. 27

Possible front-line treatment option

Eneura raises $17M to market neuromodulation device for acute migraine treatment, prevention

By Stacy Lawrence, Staff Writer

Baltimore-based startup Eneura Inc. has raised a $17 million series D round to market its handheld transcranial magnetic stimulation device. Last fall, the FDA cleared the daily, single use device, known as the sTMS mini, for migraine prevention. That makes it the only treatment – drug or device – that's been given a nod from the regulator for both acute migraine treatment and prevention.

See Eneura, page 3

Inside

Post-stroke treatment

Pathmaker inks $5M deal to develop neuromodulation device for muscle spasticity

By Katie Pfaff, Staff Writer

Bio-electronic company, Pathmaker Neurosystems Inc., has entered a collaborative agreement with NIH to develop its noninvasive Myoregulator device for neuromotor disease and treatment of patients with spasticity following stroke. The deal brings $5 million in funding through the CREATE devices program and partnership with NIH's National Institute for Neurological Disorders and Stroke (NINDS).

Boston and Paris-based Pathmaker's

See Pathmaker, page 4

Scientists develop blood test to detect Alzheimer's

By Tamra Sami, Staff Writer

PERTH, Australia – Australian and Japanese scientists have developed a blood test that detects beta amyloid in the brain that could become a biomarker for Alzheimer's disease (AD). The test can detect Alzheimer's in patients years before symptoms of dementia emerge.

Australian and Japanese researchers joined forces to conduct a retrospective study with more than 400 patient samples, and the test was shown to be more than 90 percent accurate in detecting beta amyloid, said Colin Masters, laureate professor of dementia research, and head of the Neurodegeneration Division at the Florey Institute,

See Alzheimer's, page 5

Safeheal provides anchor for colon lining to protect surgical wound sites

By Nuala Moran, Staff Writer

LONDON – Safeheal SAS has overcome the difficulties of anchoring a lining in the colon to develop a sheath that can protect surgical wounds until healing is complete, avoiding the need for patients undergoing colectomy to have a standard of care ostomy to divert feces away from the wound following surgery.

Apart from the considerable safety and quality of life implications, this feat has the significant advantage of avoiding the need for a second procedure to reverse the ostomy, providing cost

See Safeheal, page 6

'Genealogical proteomics' gives insight into diseases

By Anette Breindl, Senior Science Editor

By comparing the proteomes of affected and unaffected family members, researchers have gained new insights into the rare genetic disorder Menkes disease, and found that it has molecular connections to Parkinson's disease (PD).

The team published its findings in the Jan. 31,

See Proteomics, page 7

BioWorld MedTech's Orthopedics Extra

Executive Editor Holland Johnson on one of med-tech's key sectors

Read this week's edition

Pathmaker

Continued from page 1

investigational neuromodulation device was awarded an FDA expedited access pathway review in late 2015, and is currently being studied in IRB-approved multicenter U.S. clinical trials.

Collaboration between Pathmaker and NINDS will be closely linked, with cooperation on development and setting milestones to regulatory approval, Nader Yaghoubi, CEO, Pathmaker, told *BioWorld MedTech*. "This collaborative partnership and funding will support product engineering, multicenter U.S. pivotal trials and regulatory submission for Myoregulator." The device is expected to receive approval next year, the company believes.

Treatment for spasticity

One of few companies to be involved in the NINDS Cooperative Research to Enable and Advance Translational Enterprises for Biotechnology Products and Biologics (CREATE) program, the collaboration is aimed to "increase the likelihood of success" of Myoregulator in order to add to patient options, according to the company.

"Our selection for this program says a lot about the dearth of choices for patients with spasticity. This is a very high unmet need," said Yaghoubi. "Unfortunately for the patient with spasticity, there are limited treatment options and there hasn't been much progress in the last three decades."

Currently, patients are treated with intramuscular injections, often of botox to temporarily paralyze muscles; oral medication; and implantable pumps.

"We think that our noninvasive approach is going to have significant advantages over the current paradigm of treatment," said Yaghoubi.

Myoregulator uses "Doublestim" technology, which delivers noninvasive and simultaneous stimulation to peripheral and spinal areas to reduce spasticity in muscles. The device is planned to treat patients who experience spasticity after stroke, a condition that impacts more than 30 percent of stroke patients due to a muscle tone disorder, which results in reduced motor control and functional movement. Myoregulator is used in a clinical setting such as a hospital, rehabilitation center, or physician's office in 20-minute sessions several times a week for one or two weeks.

The first generation device is placed as needed for each patient in order to "use noninvasive stimulation to suppress hyper-excitable spinal cord neurons that are involved in causing muscle contraction," said Yaghoubi. The first-in-class device is configured with two pairs of electrodes and placed specifically for each patients based on anatomy – at the outflow of the affected muscle at the spinal level and the location of peripheral nerves innervating the affected muscle.

"We think that our noninvasive approach is going to have significant advantages over the current paradigm of treatment.

Nader Yaghoubi
CEO, Pathmaker

Stroke impact

About 795,000 Americans have a stroke each year, according to the CDC, at a cost of $34 billion annually, taking into account health care, medication and lost productivity.

Myoregulator; Pathmaker Neurosystems Inc.

Pathmaker's portfolio includes noninvasive devices intended to treat muscle spasticity, muscle weakness and paralysis tied to the more than 48 million patients across China, Europe and the U.S. who the company suggest experience impairment due to cerebral palsy, multiple sclerosis, Parkinson's, spinal injury stroke and traumatic brain injury.

Last month, Pathmaker also received an undisclosed funding award and services from the nonprofit New England Pediatric Device Consortium to develop its Myoamplifier device for pediatric patients with muscle weakness and paralysis. The noninvasive investigational device is designed to impact impaired neuromotor pathways and combines electrical and magnetic stimulation with its "Triplestim" technology, which simultaneously stimulates cortical, peripheral, and spinal areas to effect particular muscles.

Neuromodulation as treatment

Neuromduation devices seem to have taken off in recent years with applications across several disorders, including mental health, sleep, epilepsy and pain.

In December, Livanova plc, of London, acquired San Diego-based Imthera Medical Inc. in a deal valued at $225 million, garnering Imthera's implantable neurostimulation device for patients with obstructive sleep apnea via hypoglossal nerve stimulation. (See *BioWorld MedTech*, Dec. 6, 2017.) Livanova added the group to its neuromodulation division, which includes a VNS therapy for epilepsy and partial onset seizures refractory to medication. The device was approved for patients 12 and older, and recently won expanded approval for patients aged four and up. (See *BioWorld MedTech*, July 5, 2017.)

Hopkins, Minn.-based Respicardia Inc. also received FDA approval for its implantable Remede system for central sleep apnea, which acts on the phrenic nerve to regulate the diaphragm. (See *BioWorld MedTech*, Oct. 10, 2017.)

Mountain View, Calif.-based Neuropace Inc. received $74 million in financing late last year to commercialize its closed-loop neurostimulation system, Neuropace RNS, for patients with partial onset seizures who seek an alternative to medication. The device, which monitors brain waves and

See Pathmaker, page 8

Pathmaker

Continued from page 4

delivers stimulation when irregular patterns emerge, won an FDA nod in November 2013 for adult patients with refractory partial onset epilepsy arising from one or two brain areas, and who have not controlled seizures with medication. (See *BioWorld MedTech*, Oct. 25, 2017.)

Based on a 2016 Sandler Research report, the market for deep brain stimulation treatment for dystonia, epilepsy, obsessive compulsive behaviors and Parkinson's was expected to reach $906 billion worldwide by 2020. As part of that segment, neurostimulation treatment for depression, epilepsy, Parkinson's and pain is anticipated to grow between 2014 and 2019 at a CAGR of 5.37 percent. ♦

Product briefs

Dilon Technologies Inc., of Newport News, Va., launched its Copilot VL+ video laryngoscope, an advanced airway management device that provides the optimum view of the airway when placing breathing tubes. The device offers a larger, brighter, higher resolution display and LEDs to help the user obtain a better view of the airway, is compact and portable for use in various settings, and is priced for value, according to the company. The system also includes disposable sheaths with anti-fog coating and a smaller footprint for more room to manipulate the endotracheal tube.

Hologic Inc., of Marlborough, Mass., reported the launch of the Fluoroscan Insight FD Mini C-Arm, which provides high-resolution and low-dose rate modes for skeletal imaging. The new system also offers Megaview Image in Review Mode, providing clinicians the option to display and view 50 percent larger images. It offers a variety of improved features designed to arm orthopedists, podiatrists and clinicians with diversified imaging options, more flexible storage and transport, and an enhanced interface.

Masimo Corp., of Irvine, Calif., received the CE mark for Eve, a critical congenital heart disease (CCHD) newborn screening application, for the Rad-97 Pulse CO-oximeter. Eve combines the power of Masimo SET Measure-through Motion and Low Perfusion pulse oximetry with a pre-ductal to post-ductal synchronization algorithm designed to reduce calculation errors. Eve, also available on the Radical-7 Pulse CO-oximeter, simplifies the CCHD screening process by providing visual instructions, animations, an automatic synchronization algorithm and a detailed, easy-to-interpret display of screening results.

San Diego-based **Mesa Biotech Inc.**, a privately held, molecular diagnostic company that has developed a polymerase chain reaction testing platform designed specifically for point-of-care infectious disease diagnosis, received 510(k) clearance and a clinical laboratory improvements amendments waiver from the U.S. FDA for its Accula Flu A/Flu B test. The Accula Flu A/Flu B test will be marketed by Sekisui Diagnostics LLC, of Lexington, Mass., under the Silaris brand.

Myriad Genetics Inc., of Salt Lake City, said results from a large 1,162 patient study of the Myriad Myrisk Hereditary Cancer test will be featured during the poster presentation at the 2018 Genitourinary Cancer Symposium in San Francisco. The key finding is that more than 12 percent of men with prostate cancer had an inherited mutation in a cancer-causing gene. The study objective was to evaluate genetic testing using the 28-gene Myrisk Hereditary Cancer test in 1,162 men with a personal history of prostate cancer.

Qiagen NV, of Hilden, Germany, reported the European launch of its Therascreen PITX2 RGQ PCR Kit, a clinically validated DNA methylation assay that helps predict the response of certain high-risk breast cancer patients to anthracycline-based chemotherapy. The CE-IVD marked assay is Qiagen's first epigenetic test in breast cancer, as well as the latest addition to the company's broad portfolio of Therascreen tests delivering individualized genetic insights to guide medical decisions in lung, colorectal and other cancers.

Sema4, a Stamford, Conn.-based provider of advanced genomic testing, launched Sema4 Natalis, a supplemental newborn screening test designed to detect 193 childhood-onset diseases or disorders so parents can gain early insight into their baby's health. This genetic test can be performed at home with a gentle cheek swab. The test also includes a pharmacogenetic analysis of how a baby is likely to respond to 38 medications commonly prescribed at an early age.

Titan Medical Inc., Toronto-based developer of a robotic surgical system for application in minimally invasive surgery, reported the successful completion of a single-port prostatectomy procedure using the Sport surgical system in a preclinical setting. This procedure, conducted at the Institute of Image-Guided Surgery at the Institut Hospitalo-Universitaire de Strasbourg, France, is part of the feasibility and validation studies intended to support submissions to regulators in both the U.S. and EU.

Toronto-based **Vitalhub Corp.** reported the introduction of Welllinc, an electronic health record interoperability solution powered by blockchain technology. Vitalhub's Welllinc solution uses blockchain technology to enable the secure and interoperable exchange of critical patient health data, across the continuum of care.