Servier's Wehealth, Pathmaker team up for neuromodulation device for spasticity treatment

By Liz Hollis

Staff Writer

SAN FRANCISCO – Pathmaker Neurosystems Inc., which has a presence in Boston and Paris and concentrates on bioelectronic medicine, and Wehealth by Servier, the e-health department of France's Servier Group, are partnering to develop and commercialize the first neuromodulation technology for the noninvasive treatment of spasticity.

BioWorld MedTech met with Pathmaker CEO Nader Yaghoubi this week in San Francisco to find out more about the company and this agreement, which establishes an exclusive worldwide distribution arrangement – outside the U.S. and Japan – for the Myoregulator device. That device was one of the first selected under the expedited access pathway program from the U.S. FDA that started in 2015.

Specifically, this new agreement teams Pathmaker up with one of Europe's largest pharmaceutical providers, which operates in 149 countries. "They are very innovative," said Yaghoubi. "In just the last two years, they have established a unit called Wehealth. And Wehealth is focused on investing in e-health and med tech. We are actually the very first neuroscience-related deal that they've done." He also noted that Servier was Pathmaker's first corporate partner.

Wehealth will fund a European clinical trial – which already has kicked off – evaluating Myoregulator to treat spasticity secondary to stroke. France's Brain and Spine Institute at the Pitié-Salpêtrière Hospital in Paris is conducting the study. In addition, Wehealth will back a larger European trial that aims to support reimbursement coverage. For its part, Pathmaker will receive an upfront payment, clinical/regulatory milestones and commercial royalties from future sales of the device and disposable single-use electrodes in the Servier territories.

Other partnerships established by Wehealth are with Mobiosense, of Taipei, Taiwan, on a digital portable heart attack detection test and Deeplink Medical, of Lyon, France, for oncology software.

Bioelectronic medicine

"Pathmaker is a pioneering clinical-stage bioelectronic medicine company, focused on treating chronic neuromotor conditions noninvasively," Yaghoubi said. This would include spasticity, muscle weakness and paralysis due to conditions such as stroke, spinal cord injury, traumatic brain injury, multiple sclerosis and cerebral palsy. "If you take something like stroke, for example, a third of the patients develop spasticity," which is a state of painful muscle contraction.

"We've developed two different interventions and two different devices that allow us to treat these two different conditions: spasticity and paralysis/muscle weakness," Yaghoubi said.

Current treatments for spasticity are oral medications that have been around for about 30 years and have side effects; an implantable baclofen pump that delivers drugs into the spinal cord; surgery that cuts nerves and tendons; and botulinum toxin injection intramuscularly. "Our view is that we're going to be really displacing this very dangerous drug," he said regarding the latter, which is considered a category A bioweapon.

Yaghoubi added that the deal puts the company on track to being able to bring this product to patients by this time next year in Europe. "We're also working toward FDA approval," he said, adding that an agency nod should come one to two years after obtaining the CE mark. Yaghoubi said the company just wrapped up a U.S. trial. "During 2019, we will be initiating a multicenter pivotal U.S. trial that is fully funded by NIH." (See *BioWorld MedTech*, Feb. 8, 2018.) Last year, the company entered a collaborative agreement with NIH to develop Myoregulator. It brought in $5 million in funding through the CREATE devices program and partnership with NIH's National Institute for Neurological Disorders and Stroke.

The company's second product is the Myoamplifier, a noninvasive platform that integrates magnetic and electrical stimulation to treat patients with paralysis and muscle weakness. It is based on the company's Triplestim technology, which provides simultaneous noninvasive stimulation of cortical, spinal and peripheral sites serving afflicted muscles. According to the Feinstein Institute for Medical Research, the Manhasset, N.Y.-based research branch of the Northwell Health enterprise, bioelectronic medicine uses technology to read and modulate the electrical activity within the body's nervous system. Trials using such devices are in clinical studies to treat inflammatory diseases, such as rheumatoid arthritis and colitis. In 2016, Pathmaker launched a clinical trial in conjunction with Northwell Health and Feinstein Institute to evaluate the safety and efficacy of Myoregulator.

Leader in the field

"We're not aware of any other company that is bringing to market a product like this," Yaghoubi replied when asked about potential competitors. He also noted that his company was focused on synchronized stimulation. Specifically, Myoregulator

is based on Pathmaker's proprietary Doublestim technology, providing simultaneous noninvasive stimulation at spinal and peripheral locations.

Other neuromodulation companies, meanwhile, focus on single-site stimulation, putting an electrode into the brain, spinal cord or peripheral nerve. These procedures often are invasive and not effective in the conditions Pathmaker is targeting. "You cannot modulate a pathway and circuits that are involved in these conditions in that manner," he explained.

Looking ahead five years, Yaghoubi said that he expects both products to be approved and on the market helping patients and that the company will be profitable as it helps revolutionize the treatment of chronic neuromotor conditions.

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