



Myoscience providing opioid alternatives with launch of Iovera Smart Tip system

By Liz Hollis, Staff Writer

Aiming to help a broader patient population and provide an alternative to opioids, [Myoscience Inc.](#), of Fremont, Calif., reported the commercial launch of the [Iovera Smart Tip 309](#).

The launch adds to the company's Iovera system, which treats the genicular nerves through a process called cryoneurolysis. Specifically, it helps patients recovering from total knee arthroplasty surgery, as well as those suffering from chronic knee pain.

Of note, the Smart Tip 309 is intended to help a broader patient population, including those with a

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FDA gives breakthrough designation to first potential IVD test for Alzheimer's to Fujirebio

By Stacy Lawrence, Staff Writer

Diagnostics for [Alzheimer's disease \(AD\)](#) are improving as biomarker and imaging data continue to improve. [Fujirebio Diagnostics Inc.](#) is seeking to offer a further advancement on this front – and the U.S. FDA has reached out with a gesture of support by extending a breakthrough device designation to its Lumipulse G β -Amyloid Ratio (1-42/1-40) quantitative in vitro diagnostic test.

If approved, this could be the first in vitro

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BGN's AI platform for ALS progression holds key to improving care and treatment

By David Ho, Staff Writer

HONG KONG – Israel's [BGN Technologies Ltd.](#) has developed an AI-driven precision medicine platform for monitoring and predicting the progression of neurodegenerative diseases.

The platform from the technology transfer company of Ben-Gurion University (BGU) is currently focused on amyotrophic lateral sclerosis ([ALS](#); also known as Lou Gehrig's disease).

The company believes the technology holds the potential for improving both personalized patient care and drug development.

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Stakeholders revolt over Medicare hit to ultrasound rates

By Mark McCarty, Regulatory Editor

The U.S. Centers for Medicare & Medicaid Services (CMS) has been advised to trim spending on imaging, and the agency has proposed to reset the practice expense component for ultrasound imaging procedures in the draft physician fee schedule for 2019. While CMS eased back from implementing cuts for the current year, stakeholders are scrambling to make the case that the policy is ill-advised and may restrict access, a scenario that could ultimately take a bite out of sales of ultrasound equipment.

The Medicare Payment Advisory Commission had
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Researchers plan phase III GDNF trial in Parkinson's; delivery device is key

By Nuala Moran, Staff Writer

LONDON – Researchers in the U.K. are moving ahead with plans for a phase III study of glial-derived neurotrophic factor (GDNF) in Parkinson's disease, after overcoming the obstacles to repeated delivery of the drug directly into the brain that confounded previous studies.

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BioWorld MedTech's Orthopedics Extra

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

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high body mass index (BMI). “Iovera is a simple, needle-based procedure that uses proven cryotherapy to relieve pain,” Tim Still, president and CEO of Myoscience, told *BioWorld MedTech*. “It’s very immediate, very safe,” and gives long-lasting relief. He also noted that the technology has gained commercial traction in the last 24 to 36 months.

Freezing the nerves

The system’s smart tips deliver precise, controlled doses of cold to freeze peripheral nerves, producing an immediate and long-lasting nerve block.

Clinicians have expressed enthusiasm about the system. “Many patients are looking for non-opioid solutions for managing pain. I have found the Iovera therapy to be an important option to provide lasting pain relief to my patients, resulting in at least a 50 percent reduction in opioid use over the entire recovery period after a total knee replacement. This therapy is a remarkable step forward for patients undergoing total knee replacement, which can cause acute and chronic pain in the months following surgery,” said Pieter Vreede, anesthesiologist at Riverview Health in Noblesville, Ind. He noted that the Smart Tip 309 will provide the opportunity for ease of access to deeper nerves in patients with a high BMI.

Standing alone

“We don’t really have direct competition,” Still added. “The primary purpose is to reduce the use of opioids and [the] pain that’s associated with surgery, recovery and chronic conditions.” Specifically, the platform is in use in the orthopedic market for those undergoing total knee replacement and osteoarthritis.

“It absolutely can,” Still answered when asked whether the technology can be used in areas beyond the knee. “One of the challenges that the company had frankly in the early days was looking at all of the applications of the platform and where to focus.” He added that there is a potential for the platform in shoulders, the lower back, ankle and hips.

Moving forward

“Plans for us basically will be to continue to take advantage of the commercial progress that we’ve had,” Still said of where he saw the company going in the next 12 to 18 months. “We’ve been doubling sales year-over-year, [and] there is quite a bit of market opportunity just in the total knee space.”

He noted that the company finished last year with about \$5.5 million in sales, but there is room for growth. In addition, there is a lot of interest in expanding to the additional indications in other joints. The company hopes to do some clinical work in those areas in the near term, but it plans to continue to place a special emphasis on total knee. “If you look at the end of 2018, some of our market data estimates that there are about 950,000 total knees done on an annual basis,” he said, noting the company has penetrated less than 2 percent of the total market.

When asked about geographic focus, he said the company is

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Pieter Vreede
Anesthesiologist, Riverview Health

concentrating on the U.S., but it is in the process of gaining the CE mark. The company will feature the Smart Tip 309 at the 2019 American Academy of Orthopaedic Surgeons Annual Meeting between March 12 and 16 in Las Vegas.

Last fall, the company reported that it had completed enrollment in its randomized, controlled trial at the Campbell Clinic in Memphis, Tenn. It enrolled 125 patients to evaluate the effect of cryoanalgesia using the Iovera system to the standard of care for managing pain after total knee replacement surgery. The goal was to demonstrate how cryoanalgesia can significantly reduce opioid consumption after the procedure, and lead to improved physical function and enhanced recovery. ♦



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