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News We're Watching: Dexcom Expands In Ireland; Neurostim Updates From NANS; Novel Nanoparticles Treat Cancer In Mice; And More

by Reed Miller

Medtech Insight's News We're Watching highlights medtech industry and R&D developments that you may have missed over the last few weeks. This update covers some late-breaking results announced at the North American Neuromodulation Society (NANS) annual meeting in Las Vegas, as well as an update on Dexcom's new facility in Ireland, and a promising mouse experiment with nanoparticles that kill cancer cells.

Dexcom Breaks Ground On Manufacturing Facility In Ireland

Dexom announced that it has broken ground on a new manufacturing facility in Athenry, Ireland.

"This development demonstrates our commitment to sustainable growth and operational excellence in EMEA (Europe, the Middle East and Africa), as well as to the people we serve," said Alex Moussa, Dexcom's general manager for EMEA and Latin America. (Also see "*Dexcom's G7 Expands Globally After A Long Wait*" - Medtech Insight, 4 Oct, 2022.)

The new facility represents the diabetes company's first manufacturing site in Europe. It will bring more than 1,000 jobs to the area including support in finance, human resources and engineering jobs, ranging from leadership to graduate positions, Dexcom said.

IDA Ireland, Ireland's Foreign Direct Investment Agency, said last May that the project represents an investment of €300m over five years.

Medtronic-Sponsored SCS Trials Presented At NANS

Medtronic is promoting two late-breaking presentations at the North American Neuromodulation Society (NANS) annual meeting in Las Vegas.

The Australian *Closed Loop SCS* study of Medtronic's closed-loop rechargeable system spinal cord system, designed to treat chronic back and leg pain, met its primary endpoint at three months.

Open-loop/fixed-output spinal cord stimulation does not account for patient movements that subtly change the distance between the spinal cord and implanted epidural leads. The closed-loop system senses the body's neural response to stimulation 50 times per second, every second, to prevent uncomfortable overstimulation when the patient coughs, sneezes, or bends.

Lead investigator Marc Russo, of Hunter Pain Specialists in Newcastle, Australia, presented results from the trial at the NANS conference.

At three months, 89% of patients treated with the device reported a significant reduction in overstimulation compared to their experience with an open-loop system; 86% of users said they preferred the closed-loop system.

Also, 86% of users reported at least 50% reduction in overall pain and every patient reported satisfaction with the closed-loop system after three months.

"Could closed-loop spinal cord stimulation eventually become the standard of care? More data is needed, but what we are seeing thus far is encouraging," he said.

Medtronic announced the CE mark for its Inceptiv closed-loop rechargeable spinal cord stimulator in August 2023. It is also available in Japan, but is not yet commercially available in the US or Australia. (Also see "*News We're Watching: GE And Google Announce AI Initiatives, Medtronic Announces Approvals, And More*" - Medtech Insight, 8 Jan, 2024.)

Also featured at the NANS meeting, two-year results from the European DTM Spinal Cord Stimulation randomized trial (DTM SCS RCT) showed Medtronic's proprietary differential target multiplexed (DTM) spinal cord stimulation waveform is more effective at reducing chronic low-back pain than conventional medical management.

"As the first DTM SCS randomized controlled trial in Europe, these results provide additional evidence of the clinical and quality-of-life benefits that DTM SCS offers this patient population, which has few available treatment options," said lead investigator Jan Willem Kallewaard, an anesthesiologist at Rijnstate, a hospital in Elst, The Netherlands.

DTM SCS RCT is the first EU-based randomized trial to show the long-term benefits of the DTM therapy in patients with chronic back pain who are not eligible for surgery.

At 24 months, 88.4% of back-pain patients randomized to spinal cord stimulation with the DTM waveform responded to the therapy compared to just 5.5% of the control group. Also, 93% of patients treated in the trial for leg pain responded to the DTM waveform.

The DTM group also reported a significant reduction in disability and 95% satisfaction.

Trial Of Boston Scientific's WaveWriter SCS Hits Endpoint

[Editor's Note: *Based on the SOLIS results, the US Food and Drug Administration added the treatment of chronic intractable low back and leg pain without prior back surgery to WaveWriter's approved indication on 5 February.*]

New results from the *SOLIS* randomized control study showed *Boston Scientific*'s WaveWriter and WaveWriter Alpha spinal cord stimulation systems are more effective than conventional medical management for the treatment of chronic low-back and leg pain.

James North of the Carolinas Pain Institute in Winston-Salem, NC, presented results from 128 patients in SOLIS on 20 January at the North American Neuromodulation Society (NANS) meeting in Las Vegas.

The trial easily met its efficacy endpoint; 90% of patients treated with the WaveWriter spinal cord stimulation devices reported significant pain relief without taking more opioid drugs. Only 8% of patients treated with conventional medical management alone reported 50% or greater improvement in symptoms.

At one year, 84% of patients treated with the WaveWriter systems reported significant pain relief and sustained improvement in their ability to participate in activities of daily living. The mean improvement in their *Oswestry Disability Index* (ODI) scores was 25 points.

Patients originally randomized to the control group could chose to switch to the WaveWriter therapy and 85% of those crossover subjects achieved at least 50% improvement in their pain symptoms, with a mean ODI improvement of 30 points.

Three-Year Results From EVOKE Support Saluda's Closed-Loop SCS

New results from the *EVOKE* randomized trial showed Saluda's Evoke SmartSCS closed-loop

spinal cord stimulation system offers sustained relief from back and leg pain. The results also showed the superiority of the closed-loop approach compared to traditional open-loop spinal cord stimulation.

Nagy Mekhail from the Cleveland Clinic reported the three-year intention-to-treat and crossover analysis from 134 randomized patients in EVOKE on 17 January at the North American Neuromodulation Society (NANS) meeting in Las Vegas.

"The Evoke system is the only SCS therapy capable of continuously listening to the spinal cord and optimizing neural activation with precise, prescriptive closed-loop dosing based upon an individual patient's unique neural signature," Mekhail said. "We can now see how much patients benefited from more consistent activation of the spinal cord, which is something we were previously unable to do with other SCS systems." (Also see "*Saluda's Evoke SCS Set To Join Competitive US Spine-Stim Market In Late 2022*" - Medtech Insight, 9 Mar, 2022.)

According to Saluda, these data represent the longest follow-up evidence from a US investigational spinal cord stimulation device.

At three years, 83% of patients implanted with the closed-loop device achieved at least 50% pain reduction and 59% patients implanted with a closed-loop device achieved at least 80% pain reduction.

None of the devices had to be explanted and 90% of the patients treated with the closed-loop SCS device said they were satisfied or very satisfied with the therapy.

While blinded to whether they were receiving closed-loop or open-loop therapy, patients were able to cross over to the other treatment arm after two years.

Most of the patients who crossed from the open-loop to the closed-loop therapy did so in search of better pain relief, according to Saluda.

About 90% of the patients treated with the closed-loop therapy – either because they were randomized to that therapy initially or they crossed over to it – stuck with the closed-loop SCS for the rest of the study.

"Equally compelling is the Evoke System's ability to deliver a more enduring solution to pain, highlighted by zero explants due to loss of efficacy through 36 months, something we have not seen before," Mekhail said.

Novel Nanoparticles Treat Cancer In Mouse Experiment

A team of researchers at the Pennsylvania State University have developed light-inducible gold-silver-gold, core-shell-shell (CSS) nanoparticles that can deliver nucleic acid therapeutics to precisely kill cancer cells.

Induced by infrared light, the CSS particles can release a micro RNA "mimic payload" that cause apoptosis in targeted human squamous cell carcinoma TE10 cells.

"Cancer treatments such as chemotherapy and radiation often leave patients in severe discomfort, and with injurious loss of tissue in tissues critical for healthy post-treatment quality of life," the authors explained in *Advanced Healthcare Materials*. "As such, devising innovative and efficient techniques to selectively eliminate cancer cells while minimizing side effects and tissue damage is of utmost importance."

The team, led by biomedical engineers Daniel Hayes and Nick Alden, tested their nanoparticle delivery system in nude mice with bilateral human esophageal TE10 cancer cells xenografts. Induced by an LED, the nanoparticles shrank the tumors by at least 87% within 72 hours.

"Taken together, these findings demonstrate that this delivery system can effectively transport operational miRNA mimics into cancer cells and that judiciously chosen miRNA mimics can regulate target gene expression to accomplish cell-specific cytotoxicity."