MEDTECH INSIGHT
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News We're Watching: Boston Scientific Closes Relievant, Medtronic's PFA Earns CE Mark, And More

by Reed Miller

Medtech Insight's News We're Watching highlights medtech industry news developments you may have missed over the last few weeks.

Medtronic Earns CE Mark For PulseSelect PFA

Medtronic's PulseSelect pulsed field ablation (PFA) system has earned a CE mark, the company announced on 20 November.

PulseSelect is indicated to treat atrial fibrillation with pulmonary vein isolation ablation. One-year results from the *PULSED AF* trial of the PulseSelect PFA system showed a 0.7% adverse event rate in 300 patients with atrial fibrillation. (Also see "*Medtronic Earns CE Mark For Affera Ablation System, Touts New PFA Results*" - Medtech Insight, 17 Mar, 2023.)

A growing body of clinical evidence shows pulsed field ablation is safer than radiofrequency or cryoablation, so Medtronic is just one of at least six companies developing PFA technologies. Boston Scientific's Farapulse PFA system has been available commercially in Europe since 2021, but the US Food and Drug Administration has not yet approved a PFA device.

With the launch of PulseSelect, Medtronic will be the only company marketing both single-shot and focal PFA tools to treat arrhythmias.

In March, Medtronic announced the CE mark for the Affera mapping and ablation system, including the Sphere 9 and the Affera Prism 1 mapping software. Sphere 9 can create point-by-point/focal ablations with either pulsed field or radiofrequency energy while also providing high-density mapping to treat atrial arrhythmias.

Medtronic also announced a new CE mark for the Nitron CryoConsole, which supports

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Medtronic's Arctic Front and Freezor cardiac cryoablation catheters. It features an optimized workflow and a new graphical user interface. It also automates the capture of important procedural data and creates a summary report after each procedure.

Pantheon Vision Raises $2.5M To Develop Bioengineered Corneal Implants

Pantheon Vision will use its new seed funding to develop a bioengineered corneal implant.

The Baltimore-based early-stage ophthalmic medical device company received $2.5m in seed funding from Baltimore-based KeraLink International, a non-profit organization focusing on eradicating corneal blindness, the company announced on 13 November.

The company is led by CEO John Sheets, the former head of the Office of Device Evaluation at the US Food and Drug Administration. Sheets has led companies including Hoya and Elisar and Alcon, Bausch + Lomb, and Johnson & Johnson.

Boston Scientific Closes Relievant Acquisition

Boston Scientific closed the previously announced acquisition of Relievant Medsystems, the companies announced on 17 November.

To acquire Minnesota-based Relievant, Boston Scientific is paying $850m and undisclosed additional contingent payments based on sales performance over the next three years. (Also see "*Boston Scientific Puts Charge In Neuromodulation Business By Acquiring Relievant*" - Medtech Insight, 21 Sep, 2023.)

Relievant's current owners include New Enterprise Associates, Endeavor Vision, Vensana Capital, Canaan, Morgenthaler Ventures, Lightstone Ventures, and Ally Bridge Group.

On an adjusted basis, the transaction is expected to be immaterial to Boston Scientific's adjusted earnings per share in 2024, and slightly accretive in 2025, increasingly accretive thereafter. Boston Scientific expects the transaction to be more dilutive due to amortization expense and acquisition-related charges.

The deal is worth about 12 times Relievant's expected 2023 sales.

Boston Scientific is paying the high premium to add Relievant's Intracept intraosseous nerve ablation system to its neuromodulation business, which currently markets the WaveWriter Alpha spinal cord stimulator, Precision Spectra spinal cord stimulator, Vertiflex indirect compression

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system, and devices for radiofrequency nerve ablation to treat pain.

Mammogen Earns CLIA Validation For Plasma-Based Breast Cancer Test

Mammogen, a unit of early detection company IVBH, achieved a major milestone by completing the Clinical Laboratory Improvement Amendments (CLIA) validation for its plasma-based clinical assay genTRU-breast for detecting the earliest stages of breast cancer.

"After two decades effecting change in commercial diagnostics, this achievement is the brightest spot of my career with a profound culmination of scientific, clinical and social impact," Mammogen CEO Elizabeth Cormier-May said.

Mammogen plans to launch genTRU-breast in the second half of 2024, a timeline aligned with the nationwide implementation of the Mammography Quality Standards Act (MQSA). The intent of the legislation was to establish minimum standards that ensure that all women have access to quality mammography services, according to the American College of Radiology.

The federal regulation, which will take effect in September 2024, defines a major unmet clinical need in breast health, unlocking an estimated $2.5bn to $12bn in immediate market opportunity and a total addressable market exceeding $35bn, according to the company.

"Knowing how vital reimbursement is to our test's success, we have spent the last year building novel, patient-centric pricing and revenue pathways that prioritize affordability and access, keeping the total cost of the test well below any other modalities currently available," Cormier-May told *Medtech Insight*.

Leveraging artificial intelligence and machine learning, the genTRU-breast clinical assay achieved a statistically significant greater-than-99% sensitivity, and 89% specificity in stage I breast cancer detection with an overall accuracy reported at 94.5%, Mammogen said in a 15 November announcement.

The peer-reviewed data were accepted for a poster presentation at the 2023 San Antonio Breast Cancer Symposium, to be held from 5-9 December in San Antonio.

NOVA Study Results Support Medtronic's DTM SCS

One-year results from the *NOVA study* showed that Medtronic's DTM (differential target multiplexed) spinal cord stimulation (SCS) programming approach provides significant, long-term pain relief compared to conventional spinal cord stimulation therapy in patients with

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chronic back pain caused by degenerative disc disease, herniated disc, or radicular pain syndrome that is not amenable to surgery.

Results from the study's modified intention-to-treat analysis set at 12 months showed that 91% of patients using DTM SCS programming reported at least a 50% reduction in back pain symptoms. Only 25% of patients treated with conventional SCS showed at least a 50% reduction in back pain symptoms.

Over the same period, 91% of patients using DTM SCS programming reported at least a 50% reduction in leg pain compared to just 35% of patients treated with conventional SCS.

Patients treated with DTM SCS reported an 82% reduction, on average, in back pain over one year. Using the visual analog scale, the average reduction in pain with DTM SCS was 6.4cm.

The NOVA results build on the one-year results from the *SGX SCS* randomized trial, which showed DTM SCS is more effective than conventional spinal cord stimulation for treating of chronic back pain. (Also see "*Long-Term Data Confirm Durability Of Medtronic's DTM Back Pain Therapy*" - Medtech Insight, 21 Oct, 2020.)

Boston Scientific Advances Trial Of TheraSphere For HCC

Boston Scientific announced the first patient enrollment in *ROWAN*, a single-arm trial assessing the TheraSphere Y-90 glass microspheres in combination with immunotherapy to treat hepatocellular carcinoma (HCC), the most common type of primary liver cancer.

The company expects the trial to enroll about 100 patients from 50 sites over the next two years.

According to the company, TheraSphere can cause the death of tumor cells, leading to the release of new antigens that will boost the immune system's response to cancer cells and limit tumor growth and recurrence.

"This study is incredibly important because it brings together the world of interventional oncology with medical oncology," said Philip Sinclair, the vice president for global medical affairs and clinical development in Boston Scientific's interventional oncology business. "Immunotherapy has revolutionized cancer management, including the treatment of HCC, so this study will give us important data to further understand how the combination of TheraSphere with immunotherapy can improve patient care."

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