Bioventus Receives FDA 510(k) Clearances for two Next-Generation Peripheral Nerve Stimulation Products

July 30, 2025

DURHAM, N.C., July 30, 2025 (GLOBE NEWSWIRE) -- Bioventus Inc. (Nasdaq: BVS), a global leader in innovations for active healing, announced today a significant milestone with the U.S. Food and Drug Administration (FDA) 510(k) clearances for both TalisMann™ and StimTrial™, expanding the Company's innovative portfolio of Peripheral Nerve Stimulation (PNS) solutions for chronic pain management.

These two clearances mark an important step forward for Bioventus and represent a substantial growth opportunity as the Company looks to expand in the PNS market, which is currently estimated to be growing above 20 percent annually and expected to exceed $500 million by 2029. With TalisMann™ and StimTrial™ now FDA-cleared, Bioventus offers a comprehensive PNS portfolio that empowers physicians to potentially treat a broader spectrum of patients—from initial assessment to long-term therapy—with greater confidence and flexibility. This development also reinforces the Company's commitment to delivering non-opioid, minimally invasive therapies designed to address real-world clinical needs.

"*The FDA clearance of both TalisMann™ and StimTrial™ represents a significant step forward in our PNS business, providing patients with innovative technologies. It also creates an exciting growth opportunity for our business*", said Anthony Doyle, General Manager, Pain and Restorative Therapies of Bioventus.

Portfolio Highlights:

- TalisMann™: Combines our patented electric field conduction technology with an integrated pulse generator to potentially reach deeper, larger nerves. This combination is designed to provide long-term relief from chronic nerve pain for patients, potentially increasing the number of patients who respond to neuromodulation therapy. From a physician's perspective, the increase in power allows for easier lead placement and potentially broadens addressable nerves.

- StimTrial™: Bioventus' first trial lead provides physicians the ability to evaluate patient response to PNS therapy, which we expect will facilitate physician adoption and payer reimbursement where trial assessments are required.

Commercial Launch:

Bioventus expects to begin a limited commercial release of both TalisMann™ and StimTrial™ in select U.S. markets during this third quarter, with a broader rollout planned for early 2026.

About Bioventus

Bioventus delivers clinically proven, cost-effective products that help people heal quickly and safely. Its mission is to make a difference by helping patients resume and enjoy active lives. The Innovations for Active Healing from Bioventus include offerings for Pain Treatments, Surgical Solutions and Restorative Therapies. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behavior, Bioventus is a trusted partner for physicians worldwide. For more information, visit www.bioventus.com and follow the Company on LinkedIn and Twitter. Bioventus and the Bioventus logo are registered trademarks of Bioventus LLC.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of federal security laws. Any statements contained herein that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements concerning the effect of regulatory approvals; our ability to commercialize our products and timeframe; sales trends; estimated market opportunities, position and growth; and our business strategy. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events, future trends, and future dates, or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated herein include, but are not limited to: we may be unable to successfully commercialize newly developed or acquired products or therapies within expected timeframes; the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing certain of our products; demand for our existing portfolio of products and any new products, line extensions or expanded indications depends on the continued and future acceptance of our products by physicians, patients, third-party payers and others in the medical community; market opportunities and our focus on a limited number of products; failure to achieve and maintain adequate levels of coverage and/or reimbursement for our products or future products, the procedures using our products; pricing and other competitive factors; governments outside the United States might not provide coverage or reimbursement of our products; risks related to product liability claims; fluctuations in demand for our products; issues relating to the supply of our products or their components due to product quality and regulatory compliance issues, including increased costs, disruptions of supply, shortages, contamination or mislabeling; we may face issues with respect to the supply of our products or their components due to product quality and regulatory compliance issues, including increased costs, disruptions of supply, shortages, contamination or mislabeling; our reliance on a limited number of third-party manufacturers to manufacture certain of our products; economic, political, regulatory and other risks related to international sales, manufacturing and operations; unstable political or economic conditions; legislative or regulatory reforms; and other the other risks identified in our Annual Report on Form 10-K for the year ended December 31, 2024 as such factors may be updated from time to

time in Bioventus' other filings with the SEC which are accessible on the SEC's website at www.sec.gov and the Investor Relations page of Bioventus' website at https://ir.bioventus.com. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement. Actual results may differ materially from those set forth in the forward-looking statements.

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