Bioventus Receives US FDA Clearance for BoneScalpel® Access™

December 20, 2021

DURHAM, N.C., Dec. 20, 2021 (GLOBE NEWSWIRE) -- Bioventus Inc. (Nasdaq: BVS) (“Bioventus” or the “Company”), a global leader in innovations for active healing, announced the US Food and Drug Administration (FDA) has granted 510(k) clearance for the Company’s neXus ® BoneScalpel® Access ™ handpiece. The BoneScalpel Access handpiece is powered by the neXus Ultrasonic Surgical Aspirator System, a next-generation integrated ultrasonic surgical platform driven by a proprietary digital algorithm resulting in more power, versatility, and control. The neXus system combines all the features of soft and hard (e.g. bone) tissue removal into a single fully integrated offering.

“The BoneScalpel Access handpiece provides surgeons with a new option for confined spaces during minimally invasive surgery, enabling safe and powerful bone removal with maximum visualization. In addition, BoneScalpel Access allows for en-bloc resection and the shaving and sculpting of bone, with built-in irrigation and aspiration with improved ergonomics for the end user,” said Sharon Klugewicz, Senior Vice President, Quality and Regulatory Affairs, Bioventus.

“The BoneScalpel Access handpiece represents the latest innovation in our best-in-class ultrasonic surgical platform, and we anticipate that surgeons will want to leverage our portfolio of bone graft substitutes to achieve bone fusion for their patients,” she added.

Bioventus plans to launch BoneScalpel Access in 2022. The neXus Ultrasonic Surgical Aspirator System has been commercialized successfully in the US, Canada, Europe, and Australia.

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 treatment, restorative therapies and surgical solutions. 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. BoneScalpel Access is a trademark and SonicOne, SonaStar and neXus are registered trademarks of Misonix, Inc.

Summary of Indications for Use
The BoneScalpel Access handpiece is indicated for use in the fragmentation and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties: Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecology, External Genitalia – condyloma – benign tumors – (lipomas, fibromas, and leiomyomas) malignant primary metastatic tumors of all types and the following cystic lesions: Bartholin’s cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts. Abdominal Area – any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids. Thoracic Surgery – limited pulmonary reception such as segmetectomies, nonanatomical subsegmetectomies and metastatectomies.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements concerning the benefits of BoneScalpel Access and Bioventus’s plans for commercialization of BoneScalpel Access. 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 and future trends, 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 in this press release include, but are not limited to, the adverse impacts on our business as a result of the COVID-19 pandemic; our dependence on a limited number of products; our ability to develop, acquire and commercialize new products, line extensions or expanded indications; our ability to continue to research, develop and manufacture our products if our facilities are damaged or become inoperable; failure to comply with the extensive government regulations related to our products and operations; and the other risks identified in the Risk Factors section of the Company’s public filings with the Securities and Exchange Commission (“SEC”), including Bioventus’s Annual Report on Form 10-K for the period ended December 31, 2020, as updated by Bioventus’s Quarterly Report on Form 10-Q for the period ended October 2, 2021 and 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 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 from those set forth in this press release due to the risks and uncertainties inherent in the Company’s business.

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