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Amedica announces FDA Clearance of the Valeo C+CSC with Lumen Interbody Fusion Device

SALT LAKE CITY, UT, March 06, 2018 (GLOBE NEWSWIRE) -- Amedica Corporation (NASDAQ: AMDA), an innovative biomaterial company that develops and commercializes silicon nitride as a platform for biomedical applications, is pleased to announce the U.S. Food and Drug Administration (FDA) clearance of the Valeo C+CsC with Lumen Interbody Fusion Device.

The Valeo C+CsC with Lumen Interbody Fusion Device is a composite spinal fusion implant that combines different densities of Amedica's proprietary medical grade silicon nitride ceramic. An outer shell of solid silicon nitride is manufactured around a porous core, called CsC (Cancellous structured Ceramic). The Valeo C+CsC device is already used in Europe, and the Valeo C+CsC with Lumen is the introduction of this porous technology in the USA.

"This FDA clearance of CsC is a significant milestone for Amedica. CsC reflects a truly unique technology. In addition to being the first structural porous bioceramic available in a medical implant, our published clinical data from the CASCADE clinical trial have shown that CsC can achieve spinal fusion *sua sponte*, i.e., in the absence of added bone grafts, and with success rates at least as favorable as bone autograft, i.e., the gold standard in bone fusion. The European device design was submitted earlier to the FDA, and the approved version is a design modification of the same material, based on feedback provided by the FDA." stated Dr. Sonny Bal, Chairman and Chief Executive Officer for Amedica.

"Since developing silicon nitride for spinal fusion, Amedica has investigated this highly-differentiated biomaterial platform extensively, and its most recent scientific data show that under appropriate experimental conditions, silicon nitride induces the expression of hydroxyapatite and collagen, the key constituents of bone, even in the absence of living cells. Medical-grade titanium, and polymers like PEEK, which are widely used in spinal fusion, do not exhibit this osteoinductive property" added Dr. Bal.

"In addition to attracting new surgeon users and investigators, approval of the Valeo C+CsC with Lumen Interbody Fusion Device in the U.S. market opens the door to new designs of spinal fusion devices that may reduce or eliminate the need for added bone grafts. In the value-based economic climate of health care today, the ability of CsC to achieve bone healing without the added expense and complexity of bone grafts is a practical advantage. When combined with the other well-established attributes of silicon nitride, i.e., ease of viewing on every radiographic imaging modality available today, and bacteriostatic properties against a variety of bacterial species, CsC is truly without parallel among biomaterials"

Dr. Bal further stated that “beyond CsC, Amedica will continue its commitment to a strong R&D program that remains focused on developing additional key technologies related to silicon nitride.”

The Valeo C+CsC with Lumen Interbody Fusion Device is indicated for intervertebral body fusion of the cervical spine in skeletally mature patients. Additional information about Amedica's complete line of products can be found at www.amedica.com.

About Amedica Corporation

Amedica is focused on the development and application of interbody implants manufactured with medical-grade silicon nitride ceramic. Amedica markets spinal fusion products and is developing a new generation of wear- and corrosion-resistant implant components for hip and knee arthroplasty as well as dental applications. The Company's products are manufactured in its ISO 13485 certified manufacturing facility. Amedica's FDA-cleared and CE-marked spine products are currently marketed in the U.S. and select markets in Europe and South America through its distributor network and its growing OEM and private label partnerships.

Forward-Looking Statements

This press release contains statements that constitute forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995. Forward looking statements include: the statement that approval of the Valeo C+CsC with Lumen Interbody Fusion Device CsC in the U.S. market opens the door to new designs of spinal fusion devices; that when combined with the other well-established attributes of silicon nitride, CsC is truly without parallel among biomaterials. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated within this press release. A discussion of those risks and uncertainties can be found in Amedica’s Risk Factors disclosure in its Annual Report on Form 10-K/A, filed with the Securities and Exchange Commission (SEC) on December 27, 2017, and in Amedica’s other filings with the SEC. Amedica disclaims any obligation to update any forward-looking statements.

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