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Amedica Corporation Provides Update on FDA Questions and Femoral Head Testing Protocol Feedback

SALT LAKE CITY, July 07, 2015 (GLOBE NEWSWIRE) -- Amedica Corporation (Nasdaq:AMDA), a company that develops and commercializes silicon nitride ceramics as a biomaterial platform, today announced that responses to the U.S. Food and Drug Administration (“FDA”) inquiries regarding the Company’s cervical composite silicon nitride interbody device were submitted to the FDA on June 30, 2015. Additionally, the Company has received feedback from the FDA regarding its wear testing femoral head protocols.

Submission for 510(k) clearance of the Valeo C Interbody with CsC Osteo-Conductive Scaffolding (“Valeo C CsC”), which was submitted in the first quarter of 2015, relates to the Company’s CASCADE clinical trial of its composite silicon nitride spinal interbody devices. Since submission, the Company received a list of questions from the FDA requesting additional information pertaining to the product’s clinical performance data, as well as indications for use and device description. The Company has responded to the questions and now awaits clearance of the Class II medical device for commercial distribution or additional communication from the FDA.

“After successfully completing an important surveillance audit with no non-conformities being identified, we’ve submitted responses to the FDA questions regarding our composite silicon nitride device,” said Dr. Sonny Bal, chairman and CEO of Amedica Corporation. “Our submission starts the clock once again with the FDA, and we remain hopeful for a final response during the third quarter of this year. As sales momentum of this unique device continues to build in Europe, we look forward to beginning domestic shipments as soon as we achieve clearance.”

“We also received very constructive feedback on our proposed wear testing protocol and have a clearer understanding of the pathway to market for our silicon nitride femoral heads in the U.S.,” continued Dr. Bal. “The comments by the FDA will ensure that the testing of our material, as compared to other ceramic predicate devices on the market, will meet or exceed existing testing standards. Silicon nitride is the toughest, most fracture resistant, chemically stable bioceramic available today. We look forward to a direct comparison to all other femoral head materials, which is slated to begin later this year, to confirm our claim that silicon nitride is *the* ideal biomaterial of choice.”

About Amedica Corporation

Amedica is focused on the development and application of medical-grade silicon nitride ceramics. Amedica markets spinal fusion products and is developing a new generation of

wear- and corrosion-resistant implant components for hip and knee arthroplasty. The Company manufactures its products in its ISO 13485 certified manufacturing facility and through its partnership with Kyocera, one of the world's largest ceramic manufacturers. Amedica's spine products are FDA-cleared, CE-marked, and are currently marketed in the U.S. and select markets in Europe and South America through its distributor network and its growing OEM partnerships.

For more information on Amedica or its silicon nitride material platform, please visit www.amedica.com.

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 contained in this press release include the intent, belief or current expectations of Amedica and members of its management team with respect to Amedica's future business operations as well as the assumptions upon which such statements are based. Such forward-looking statements are subject to risks and uncertainties such as the timing and success of new product introductions, FDA review and clearance, physician acceptance, endorsement, and use of Amedica's products, regulatory matters, competitor activities, changes in and adoption of reimbursement rates, potential product recalls, effects of global economic conditions and changes in foreign currency exchange rates. Additional factors that could cause actual results to differ materially from those contemplated within this press release can also be found in Amedica's Risk Factors disclosure in its Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 24, 2015, and in Amedica's other filings with the SEC. Amedica disclaims any obligation to update any forward-looking statements.

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Source: Amedica Corporation