Alphatec Advances Clinical Distinction With OsseoScrew® Clearance

September 26, 2018

CARLSBAD, Calif., Sept. 26, 2018 (GLOBE NEWSWIRE) -- Alphatec Holdings, Inc. (“ATEC” or the “Company”) (Nasdaq: ATEC), a provider of innovative spine surgery solutions with a mission to improve patient lives through the relentless pursuit of superior outcomes, today announced that it has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its OsseoScrew® System, making it available for clinical use for the first time in the United States.

"I am exceptionally pleased that OsseoScrew has been cleared for the U.S. market,” said Pat Miles, Chairman and Chief Executive Officer. “The system will create new market opportunities for ATEC by uniquely addressing an unmet need for an underserved patient population. We are building an organic innovation machine and today’s announcement represents another significant step toward creating a clinically distinguished portfolio.”

The OsseoScrew System

OsseoScrew is a next-generation expandable pedicle screw system, intended to restore the integrity of the spinal column in elderly patients with advanced stage tumors involving the thoracic and lumbar spine. It is designed to be implanted into the pedicle, then expanded after implantation to achieve increased screw fixation and reduced post-operative pullout in bone with poor density. OsseoScrew has been clinically proven to increase pullout and holding strength, improving fixation in the bone-implant interface by 29%, as compared to conventional pedicle screws. It performs comparably to cemented fenestrated screws without the risk associated with cement leakage.

Alphatec will display OsseoScrew this week at the North American Spine Society (NASS) 2018 Annual Meeting, which is being held from September 26-29 at the Los Angeles Convention Center.

About Alphatec Holdings, Inc.

Alphatec Holdings, Inc., through its wholly-owned subsidiaries, Alphatec Spine, Inc. and SafeOp Surgical, Inc., is a medical device company that designs, develops, and markets technology for the treatment of spinal disorders associated with disease and degeneration, congenital deformities and trauma. The Company's mission is to improve lives by providing innovative spine surgery solutions through the relentless pursuit of superior outcomes. The Company markets its products in the U.S. via independent sales agents and a direct sales force.

Alphatec, Alphatec Spine, the Alphatec logo, SafeOp Surgical and OsseoScrew are trademarks or registered trademarks of Alphatec Holdings, Inc., its affiliates and/or subsidiary companies. All other marks are the property of their owners. Additional information can be found at www.atecspine.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainty. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The Company cautions investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors. Forward-looking statements include the references to the Company’s strategy in significantly repositioning the ATEC brand and turning the Company into a growth organization. The important factors that could cause actual operating results to differ significantly from those expressed or implied by such forward-looking statements include, but are not limited to: the uncertainty of success in developing new products or products currently in the Company’s pipeline; the uncertainties in the Company’s ability to execute upon its strategic operating plan; the uncertainties regarding the ability to successfully license or acquire new products, and the commercial success of such products; failure to achieve acceptance of the Company’s products by the surgeon community, including OsseoScrew, Battalion and Arsenal Deformity; failure to obtain FDA or other regulatory clearance or approval for new products, or unexpected or prolonged delays in the process; continuation of favorable third party reimbursement for procedures performed using the Company’s products; unanticipated expenses or liabilities or other adverse events affecting cash flow or the Company’s ability to successfully control its costs or achieve profitability; uncertainty of additional funding; the Company’s ability to compete with other competing products and with emerging new technologies; product liability exposure; an unsuccessful outcome in any litigation in which the Company is a defendant; patent infringement claims; claims related to the Company’s intellectual property and the Company’s ability to meet its financial obligations under its credit agreements and the Orthotec settlement agreement. The words “believe,” “will,” “should,” “expect,” “intend,” “estimate” and “anticipate,” variations of such words and similar expressions identify forward-looking statements, but their absence does not mean that a statement is not a forward-looking statement. A further list and description of these and other factors, risks and uncertainties can be found in the Company's most recent annual report, and any subsequent quarterly and current reports, filed with the Securities and Exchange Commission. ATEC disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law.

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