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K2M Expands 3D-Printed MIS CASCADIA™ Lateral Interbody System Featuring Lamellar 3D Titanium Technology™

With FDA 510(k) clearance for CASCADIA Lateral line extension, K2M solidifies position as the global market-leading innovator and provider of 3D-printed spinal devices

LEESBURG, Va., Oct. 06, 2016 (GLOBE NEWSWIRE) -- K2M Group Holdings, Inc. (NASDAQ:KTWO) (the "Company" or "K2M"), a global medical device company focused on designing, developing and commercializing innovative and proprietary complex spine and minimally invasive spine technologies and techniques, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to expand its CASCADIA™ Lateral Interbody System featuring Lamellar 3D Titanium Technology™, the Company's innovative technology that uses 3D printing with the goal of allowing for bony integration throughout an implant. The CASCADIA Lateral Interbody System line extension clearance strengthens K2M's minimally invasive surgery (MIS) portfolio and the Company's leadership in the 3D printing of spinal devices, as evidenced by its having the most comprehensive 3D-printed spinal portfolio available on the market.

"CASCADIA is an exciting innovation for lateral spine fusions," stated Greg T. Poulter, MD, an orthopedic spine surgeon at OrthoIndy. "The unique engineering and 3D printing allows the implant to have the biocompatibility and ongrowth characteristics of titanium, while allowing a stiffness that more closely matches bone. The graft volume and surface area for fusion are generous and the new size options for lordosis allow me to address each patient's individual sagittal plane requirements. CASCADIA has become my go-to implant for lateral interbody fusions."

K2M's Lamellar 3D Titanium Technology uses an advanced 3D printing method to create structures that are impossible with traditional manufacturing techniques. Starting with a titanium powder, the CASCADIA implants are grown through the selective application of a high-energy laser beam, incorporating complex internal geometries and rough surface architecture that pre-clinical data have associated with bone growth activity.

Lamellar 3D Titanium Technology incorporates a porous structure along with rough surfaces to allow the potential for bony integration throughout the implant. K2M's CASCADIA interbodies utilize this technology to create a 70% porous implant with an increased bone graft volume and similar stiffness when compared to K2M PEEK designs.

The CASCADIA Lateral Interbody System is part of the Company's MIS portfolio, designed to promote less invasive access to the spine. The system functions as an invertebral body fusion device to provide support and stabilization of the lumbar segments of the spine. Its reverse hourglass implant design promotes increased endplate contact—compared to an ALEUTIAN® PEEK implant—without sacrificing internal bone graft volume. The system includes a full range of implant sizes and heights that are carefully designed to accommodate vertebral anatomy, and it is intended to work in conjunction with the RAVINE® Lateral Access System to offer a full line of instrumentation for the far lateral transpsoas approach.

"K2M is proud to strengthen our industry-leading portfolio of FDA-cleared, 3D-printed spinal solutions, thus reinforcing our market leadership and competitive advantage in this space," stated K2M President and CEO Eric Major. "MIS procedures and 3D printing are core competencies for K2M, as indicated by the breadth and depth of our product offerings. We continue to be committed to our legacy of innovating the highest quality products with the ultimate goal of creating improved treatments for surgical patients around the globe who suffer from debilitating complex spinal deformities."

The complete CASCADIA portfolio also includes the CASCADIA TL, AN, AN Lordotic Oblique, and Cervical Interbody Systems. For more information on Lamellar 3D Titanium Technology, CASCADIA Interbody Systems, and K2M's complete product portfolio, visit www.K2M.com.

About K2M

K2M Group Holdings, Inc. is a global medical device company focused on designing, developing and commercializing innovative complex spine and minimally invasive spine technologies and techniques used by spine surgeons to treat some of the most difficult and challenging spinal pathologies. K2M has leveraged these core competencies to bring to market an increasing number of products for patients suffering from degenerative spinal conditions. These technologies and techniques, in combination with a robust product pipeline, enable the Company to favorably compete in the global spinal surgery market. Additional information is available online at www.K2M.com.

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Forward-Looking Statements

This press release contains forward-looking statements that reflect current views with respect to, among other things, operations and financial performance. Forward-looking statements include all statements that are not historical facts such as our statements about our expected financial results and guidance and our expectations for future business prospects, including with respect to our international distribution partners in Australia and Japan. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "guidance," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties including, among other things: our ability to achieve or sustain profitability; our ability to successfully demonstrate the merits of our technologies and techniques; pricing pressure from our competitors, hospitals and changes in third-party coverage and reimbursement; competition and our ability to develop and commercialize new products; the greater resources available to some of our competitors; aggregation of hospital purchasing from collaboration and consolidation; hospitals and other healthcare providers may be unable to obtain adequate coverage and reimbursement for procedures performed using our products; the safety and efficacy of our products is not yet supported by long-term clinical data; our dependence on a limited number of third-party suppliers; our ability to maintain and expand our network of direct sales employees, independent sales agencies and international distributors and their level of sales or distribution activity with respect our products; the proliferation of physician-owned distributorships; concentration of sales from a limited number of spinal systems or products that incorporate these technologies; loss of the services of key members of our senior management, consultants or personnel; ability to enhance our product offerings through our research and development efforts; failure to properly manage our anticipated growth; acquisitions of or investments in new or complementary businesses, products or technologies; ability to train surgeons on the safe and appropriate use of our products; requirements to maintain high levels of inventory; impairment of our goodwill or intangible assets; disruptions in our information technology systems; any disruption or delays in operations at our facilities, including our new headquarters facility; our ability to ship a sufficient number of our products to meet demand; ability to strengthen our brand; fluctuations in insurance cost and availability; extensive governmental regulation including by the FDA; in the United States and foreign jurisdictions; failure to obtain or maintain regulatory approvals and FDA clearances; requirements for new 510(k) clearances, premarket approvals or new or amended CE Certificates of Conformity; medical device reporting regulations in the United States and foreign jurisdictions; voluntary corrective actions by us or our distribution or other business partners or agency enforcement actions; a recall of our products; withdrawal or restrictions on our products or the discovery of serious safety issues with our products; possible enforcement action if we engage in improper marketing or promotion of our products; the misuse or off-label use of our products; delays or failures in any future clinical trials; our reliance on the performance of third parties who assist us in clinical trials and pre-clinical development; the results of clinical trials; procurement and use of allograft bone tissue; environmental laws and regulations; compliance by us or our sales representatives with FDA regulations or fraud and abuse laws; U.S. legislative or regulatory healthcare reforms; medical device tax provisions in the healthcare reform laws; our need to generate significant sales to become profitable; potential fluctuations in sales volumes and our results of operations over the course of the year; uncertainty in our future capital needs; failure to comply with restrictions in our revolving credit facility; continuing worldwide economic instability; our inability to protect our intellectual property rights; our reliance on patent rights that we either license from others or have obtained through assignments; our patent litigation; the outcome of potential claims that we, our employees, our independent sales agencies or our distributors have wrongfully used or disclosed alleged trade secrets or are in breach of non-competition or non-solicitation agreements with our competitors; potential product liability lawsuits; operating risks relating to our international operations; foreign currency fluctuations; our ability to comply with the Foreign Corrupt Practices Act and similar laws associated with our activities outside the United States; possible conflicts of interest with our large shareholders; increased costs and additional regulations and requirements as a result of becoming a public company; our ability to implement and maintain effective internal control over financial reporting in the future; volatility in our common stock; our current plans not to pay dividends; potential dilution due to our issuance of common stock under our incentive plans, for acquisitions or otherwise; the amount of common stock held by our pre-IPO owners; the impact of anti-takeover provisions in our organizational documents and under Delaware law; our status as an emerging growth company, our ability to use our net operating loss carryforwards; the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or other strategic transactions we may make; and

other risks and uncertainties, including those described under the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the SEC, as such factors may be updated from time to time in our periodic filings with the SEC, which are accessible on the SEC's website at www.sec.gov. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this release and our filings with the SEC.

We operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this release. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this press release relate only to events as of the date on which the statements are made. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

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