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K2M Expands MIS Portfolio With Addition of ItsÂ EVEREST® Minimally Invasive XT Spinal SystemÂ

First Surgical Cases Using EVEREST MI XT Completed Following FDA 510(k) Clearance

LEESBURG, Va., Dec. 16, 2015 (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 technologies, techniques, and minimally invasive procedures, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the EVEREST® Minimally Invasive (MI) XT Spinal System, the Company's latest addition to the family of EVEREST products. In addition to U.S. regulatory clearance, K2M also received a CE Mark for the system, which allows the Company to expand the global availability of the product.

The EVEREST MI XT Spinal System is a cannulated top-loading pedicle screw system featuring rigid closed-top break-off extension tabs for minimally invasive rod passage. The system's implant design offers a one-step true percutaneous delivery of the screw and built-in extension, which does not require intraoperative assembly. The closed-top design provides a rigid connection for in-situ rotation of the screw heads and internal threads of the extension tabs allow for rod reduction.

"The EVEREST MI XT spinal system has been developed to simplify minimally invasive spinal surgery for a wide range of clinical applications. The XT screw's mixed-metal design allows for a slim profile while maintaining a robust tab-to-screw connection," said Dr. Andrew Kam, Director of Spinal Trauma at Westmead Hospital in Sydney, Australia. "The EVEREST MI XT instrumentation was designed to address the limitations of some minimally invasive systems. For example, some systems can fail to secure the set screws properly when compression is applied to the pedicle screws due to inadequately tightened set screws under load. The new EVEREST MI XT Kampressor aims to address this by allowing free movement of the polyaxial heads under compression and during set screw locking."

The system's streamlined instrumentation provides surgeons with multiple insertion options in one system and includes several new designs for simplifying surgical application of the implants, including a simple extension tab removal technique. The screw head is compatible with all EVEREST system instrumentation post-tab removal. The EVEREST MI XT screw features the EVEREST platform technology providing a 70° range of polyaxial motion and features a mixed-metal (Ti/CoCr) head to minimize head splay (when compared to an all-titanium screw), a dual-lead thread pattern for faster insertion and increased pullout strength, a set screw featuring a modified square thread design to facilitate set screw introduction, and the ability to accept rods in diameters of 5.5 and 6.0 mm.*

"The EVEREST MI XT System exemplifies K2M's commitment to advancing their Minimally Invasive Spine technology platform," said Dr. Kornelis Poelstra, Chairman of the Department of Surgery at Sacred Heart Hospital on the Emerald Coast in Destin, Florida, and Co-chairman of the Global Forum for the Society for Minimally Invasive Spinal Surgery. "With the addition of the XT system, the EVEREST MI platform becomes one of the most comprehensive minimally invasive screw systems on the market, offering both rigid extensions and flexible retractors that can be used with the same screw system.Â K2M's SERENGETI® Retractor and XT technology both create new avenues for addressing the complexities associated with minimally invasive spinal deformity correction procedures."

"We are excited to receive U.S. regulatory clearance and a CE Mark for our EVEREST Minimally Invasive XT Spinal System, and are pleased with surgeon feedback following the completion of the first surgical cases in the U.S. and Australia," stated Eric Major, K2M's President and CEO. "Whereas our SERENGETI Minimally Invasive Retractor System offers a flexible design, the EVEREST MI XT System further strengthens our MIS portfolio by offering a rigid design and providing surgeons another innovative minimally invasive option."

The EVEREST MI XT Spinal System is the fourth offering in the EVEREST family of products, which also includes the EVEREST Minimally Invasive Spinal System, the EVEREST Deformity Spinal System, and the EVEREST Degenerative Spinal System.

For more information on the EVEREST MI XT Spinal System and K2M's complete product portfolio, visit www.K2M.com.Â

*Support data available upon request. Mechanical testing may not represent clinical results.

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 our current views with respect to, among other things, our operations and financial performance. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "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; pricing pressure from our competitors, hospitals and changes in third-party coverage and reimbursement; competition and our ability to develop and commercialize new products; 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; 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 in operations at our headquarters facility or an 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; failure to obtain or maintain regulatory approvals and clearances; requirements for new 510(k) clearances, premarket approvals or new or amended CE Certificates of Conformity; medical device reporting regulations, voluntary corrective actions or agency enforcement actions; a recall of 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; the results of clinical trials; procurement and use of allograft bone tissue; environmental laws and regulations; compliance by us or our sales representatives with 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 may fluctuate over the course of the year; uncertainty in our future capital needs; 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; our ability to comply with the Foreign Corrupt Practices Act and similar laws associated with our activities outside the United States; control by and possible conflicts of interest with our controlling shareholder; 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; 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 Annual Report on Form 10-K filed with the SEC on March 18, 2015, 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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