



K2M Surpasses 100th Product Milestone with FDA Clearance and Launch of OZARK™ Cervical Plate Systems

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Achievement highlights K2M's broad impact on treating spinal disease

LEESBURG, Va., June 07, 2018 (GLOBE NEWSWIRE) -- [K2M Group Holdings, Inc.](#) (NASDAQ:KTWO) (the "Company" or "K2M"), a global leader of complex spine and minimally invasive solutions focused on achieving three-dimensional Total Body Balance™, today surpassed its 100th product milestone with the announcement of U.S. Food and Drug Administration (FDA) 510(k) clearance and commercial launch of its OZARK™ Cervical Plate Systems—designed for anterior screw fixation to the cervical spine (C2-T1) in patients with degenerative disease, deformity, tumor, or trauma. This milestone highlights the depth and breadth of K2M's 3D spinal balance portfolio, its cervical solutions offering, and crystalizes the Company's commitment to improving surgical outcomes for people living with spinal disease.

"K2M is excited to celebrate our 100th product milestone following regulatory clearance for the OZARK Cervical Plate Systems, the latest in our growing portfolio of cervical solutions," said K2M Chief Medical Officer and Co-founder John P. Kostuik, MD. "At K2M, excellence in innovation is at the heart of all that we do. Since our founding we've focused on developing groundbreaking solutions for patients with spinal disease and remain dedicated to furthering this legacy."

The OZARK Cervical Plate Systems are available in two designs, [OZARK Guide](#) and [OZARK View](#), both featuring an advanced per-level, integrated locking cover that provides surgeons with clear visual and tactile confirmation of the final lock position. They both include a full range of plate and screw sizes and instrumentation for creating constrained, semi-constrained or hybrid screw constructs. The systems are compatible with K2M's [CASCADIA™ Cervical 3D Interbody System](#) featuring [Lamellar 3D Titanium Technology™](#), which uses an advanced 3D printing method to create structures that are impossible with traditional manufacturing techniques.

"K2M was founded on the idea of inventing the world's most advanced technology for treating spinal deformity," said K2M Chairman, President, and CEO Eric Major. "Today, we are proud to further realize this vision through our 100th product milestone in the OZARK Cervical Plate Systems. We remain committed to continue building out our differentiated product portfolio, that when supported by our comprehensive Balance ACS Platform, helps surgeons address important surgical needs to improve the lives of spinal deformity patients worldwide."

[Balance ACS®](#) or (BACS®) is a comprehensive platform applying three-dimensional solutions across the entire clinical care continuum to help drive quality outcomes in spine patients. BACS provides solutions to help surgeons achieve balance of the spine by addressing each anatomical vertebral segment with a 360-degree approach to the axial, coronal, and sagittal planes, emphasizing Total Body Balance as an important component of surgical success.

For more information on the OZARK Cervical Plate Systems and K2M's complete product portfolio, visit www.K2M.com. For more information on Balance ACS, visit www.BACS.com.

About K2M Group Holdings, Inc.

K2M Group Holdings, Inc. is a global leader of complex spine and minimally invasive solutions focused on achieving three-dimensional Total Body Balance. Since its inception, K2M has designed, developed, and commercialized innovative complex spine and minimally invasive spine technologies and techniques used by spine surgeons to treat some of the most complicated spinal pathologies. K2M has leveraged these core competencies into Balance ACS, a platform of products, services, and research to help surgeons achieve three-dimensional spinal balance across the axial, coronal, and sagittal planes, with the goal of supporting the full continuum of care to facilitate quality patient outcomes. The Balance ACS platform, in combination with the Company's technologies, techniques and leadership in the 3D-printing of spinal devices, enable K2M to compete favorably in the global spinal surgery market. For more information, visit www.K2M.com and connect with us on [Facebook](#), [Twitter](#), [Instagram](#), [LinkedIn](#) and [YouTube](#).

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. 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 in the future; our ability to demonstrate to spine surgeons and hospital customers the merits of our products and to retain their use of our

products; pricing pressures and our ability to compete effectively generally; collaboration and consolidation in hospital purchasing; inadequate coverage and reimbursement for our products from third-party payers; lack of long-term clinical data supporting the safety and efficacy of our products; 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 to our products; proliferation of physician-owned distributorships in the industry; decline in the sale of certain key products; loss of key personnel; our ability to enhance our product offerings through research and development; our ability to maintain adequate working relationships with healthcare professionals; our ability to manage expected growth; our ability to successfully acquire or invest in new or complementary businesses, products or technologies; our ability to educate surgeons on the safe and appropriate use of our products; costs associated with high levels of inventory; impairment of our goodwill and intangible assets; disruptions to our corporate headquarters and operations facilities or critical information technology systems or those of our suppliers, distributors or surgeon users; our ability to ship a sufficient number of our products to meet demand; our ability to strengthen our brand; fluctuations in insurance cost and availability; our ability to remediate the material weaknesses in our IT general controls; our ability to comply with extensive governmental regulation within the United States and foreign jurisdictions; our ability to maintain or obtain regulatory approvals and clearances within the United States and foreign jurisdictions; voluntary corrective actions by us or our distribution or other business partners or agency enforcement actions; recalls or serious safety issues with our products; enforcement actions by regulatory agencies for improper marketing or promotion; misuse or off-label use of our products; delays or failures in clinical trials and results of clinical trials; legal restrictions on our procurement, use, processing, manufacturing or distribution of allograft bone tissue; negative publicity concerning methods of tissue recovery and screening of donor tissue; costs and liabilities relating to environmental laws and regulations; our failure or the failure of our agents to comply with fraud and abuse laws; U.S. legislative or Food and Drug Administration regulatory reforms; adverse effects associated with the exit of the United Kingdom from the European Union; adverse effects of medical device tax provisions; potential tax changes in jurisdictions in which we conduct business; our ability to generate significant sales; potential fluctuations in sales volumes and our results of operations over the course of a fiscal year; uncertainty in future capital needs and availability of capital to meet our needs; our level of indebtedness and the availability of borrowings under our credit facility; restrictive covenants and the impact of other provisions in the indenture governing our convertible senior notes and our credit facility; worldwide economic instability; our ability to protect our intellectual property rights; patent litigation and product liability lawsuits; damages relating to trade secrets or non-competition or non-solicitation agreements; risks associated with operating internationally; fluctuations in foreign currency exchange rates; our ability to comply with the Foreign Corrupt Practices Act and similar laws; increased costs and additional regulations and requirements as a result of being a public company; our ability to implement and maintain effective internal control over financial reporting; potential volatility in our stock price; our lack of current plans to pay cash dividends; potential dilution by the future issuances of additional common stock in connection with our incentive plans, acquisitions or otherwise; anti-takeover provisions in our organizational documents and our ability to issue preferred stock without shareholder approval; potential limits on our ability to use our net operating loss carryforwards; 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. Unless specifically stated otherwise, our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or other strategic transactions we may make.

Media Contact:

Zeno Group on behalf of K2M Group Holdings, Inc.
Christian Emering, 212-299-8985
Christian.Emering@ZenoGroup.com

Investor Contact:

Westwicke Partners on behalf of K2M Group Holdings, Inc.
Mike Piccinino, CFA, 443-213-0500
K2M@westwicke.com

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