ZimVie Announces FDA Approval for New Mobi-C® Implant

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Smaller height implants in all Mobi-C footprints to address patient anatomy

WESTMINSTER, Colo., Aug. 10, 2023 (GLOBE NEWSWIRE) -- ZimVie Inc. (Nasdaq: ZIMV), a global life sciences leader in the dental and spine markets, today announced that on August 1st, 2023, the U.S. Food and Drug Administration approved a smaller height of the Mobi-C® Cervical Disc in seven footprints that will address the anatomical needs of the U.S. patient population. Physicians have used the market-leading Mobi-C device for cervical disc replacement at one level or two contiguous levels to treat patients in France since 2004 and in the U.S. since 2013 when it became the first cervical disc approved for one and two levels by the FDA.

“The 4.5mm height implants are an important addition to the Mobi-C lineup,” said Jad G. Khalil, M.D., orthopaedic spine surgeon at Michigan Orthopaedic Surgeons, PLLC. “Surgeons will be able to use the prostheses in more significantly collapsed discs and avoid over-distraction of the facet joints. This will expand the indications for cervical disc arthroplasty and therefore more patients can benefit from the clinically compelling Mobi-C Cervical disc.”

Kee D. Kim, M.D., Professor and Chief of Spinal Neurosurgery at the University of California, Davis underscores the clinical importance of the approval. “Improper sizing of an artificial disc can lead to problems such as prosthesis migration, subsidence, and segmental kyphosis. We also found from our biomechanical study that increasing the height of an artificial disc by just 1mm reduced the range of motion at that level by around 50%. Even a 5mm height artificial disc may be too tight for some patients. Therefore, FDA approval of 4.5mm height Mobi-C disc is very good news for our patients and allows greater flexibility for the surgeons to choose the best fitting artificial disc.”

“The approval of the 4.5mm Mobi-C is a win for our surgeons and their patients, as well as a validation of thoughtful strategy by our global Regulatory Affairs team who utilized real-world clinical evidence gained from EU studies to show long-term safety and efficacy and secure the FDA approval for the smaller disc,” said Rebecca Whitney, Global President of ZimVie Spine. “We are pleased to provide surgeons the largest range of footprint and height options in the market to bring motion preservation to their patients. We will commercialize the product in the U.S. this fall.”

About the Mobi-C Cervical Disc
Mobi-C is the first cervical disc prosthesis approved by the FDA for reconstruction of a cervical disc at both one and two levels (C3-C7). Mobi-C is a cobalt chromium alloy and polyethylene mobile-bearing prosthesis that is inserted in a single step, without requiring bone chiseling or other vertebral anchorage such as screws or keels. The Mobi-C Cervical Disc Prosthesis is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or neurological deficit) with or without neck pain or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by radiographic imaging (CT, MRI or X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes) and/or visible loss of disc height compared to adjacent levels. The Mobi-C Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least six weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C Cervical Disc Prosthesis.

Common post-operative risks from surgery with the Mobi-C include pain in the neck, arm, back, shoulder, or head, and dysphagia. For complete indications, contraindications, warnings, and risks on the Mobi-C Cervical Disc or to find more information on other ZimVie Spine solutions, please visit https://www.zimvie.com/en/spine.html.

About ZimVie
ZimVie is a global life sciences leader in the dental and spine markets that develops, manufactures, and delivers a comprehensive portfolio of products and solutions designed to treat a wide range of spine pathologies and support dental tooth replacement and restoration procedures. The company was founded in March 2022 as an independent, publicly traded spin-off of the Dental and Spine business units of Zimmer Biomet to breathe new life, dedicated energy, and strategic focus to its portfolio of trusted brands and products. From its headquarters in Westminster, Colorado, and additional facilities around the globe, the company serves customers in over 70 countries worldwide with a robust offering of dental and spine solutions including differentiated product platforms supported by extensive clinical evidence. For more information about ZimVie, please visit us at www.ZimVie.com. Follow @ZimVie on Twitter, Facebook, LinkedIn, or Instagram.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning ZimVie’s expectations, plans, prospects, and product and service offerings, including new product launches and potential clinical successes. Such statements are based upon the current beliefs, expectations, and assumptions of management and are subject to significant risks, uncertainties, and changes in circumstances that could cause actual outcomes and results to differ materially from the forward-looking statements. For a list and description of some of such risks and uncertainties, see ZimVie’s periodic reports filed with the U.S. Securities and Exchange Commission (SEC). These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in ZimVie’s filings with the SEC. Forward-looking statements speak only as of the date they are made, and ZimVie disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. Readers of this press release are cautioned not to rely on these forward-looking statements, since there can be no assurance that these forward-looking statements will prove to be accurate. This cautionary note is applicable to all forward-looking statements contained in this press release.

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