ZimVie Announces FDA Approval to Launch Mobi-C® Hybrid Study

September 26, 2023

Decision clears the way for enrollment of U.S. patients in a groundbreaking clinical study of cervical arthroplasty adjacent to fusion

WESTMINSTER, Colo., Sept. 26, 2023 (GLOBE NEWSWIRE) -- ZimVie Inc. (Nasdaq: ZIMV), a global life sciences leader in the dental and spine markets, today announced that on September 7, 2023, the U.S. Food and Drug Administration approved its Mobi-C® Cervical Disc Hybrid Investigational Device Exemption (IDE) application. The decision authorizes ZimVie to begin enrolling U.S. patients in the study, which will follow patients who receive simultaneous cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF) at adjacent levels between C3 and C7. In some cases, the best two-level treatment may be just such a hybrid construct, where the disc replacement and fusion can be completed in one surgery, providing a clinical benefit to the patient and surgeon as well as an economic benefit to stakeholders in the healthcare delivery system. Surgeons have implanted over 200,000 Mobi-C implants for cervical disc replacement at one level or two contiguous levels since 2004. In 2013, Mobi-C became the first cervical disc approved for one and two levels by the FDA and remains the market-leading device for cervical disc replacement.

Unlike some competitive implants, the Mobi-C cervical disc features low-profile endplates that do not require keel cuts or additional hardware that could interfere with implants at an adjacent level. This has made Mobi-C a compelling choice for surgeons performing two-level disc replacement, and will likely prove attractive in hybrid constructs with fusion at an adjacent level.

Kee D. Kim, M.D., Professor and Chief of Spinal Neurosurgery at the University of California, Davis, and one of the investigators in the study, shared, “The FDA approval of the IDE application will allow us to move forward with this important study. Good clinical data is an important step in broadening the approved indications for cervical disc replacement in hybrid constructs with fusion at an adjacent level. I am delighted to be part of this groundbreaking study, which may ultimately lead to more patients gaining access to the most appropriate treatment.”

“The decision to move forward with the Mobi-C hybrid study demonstrates our ongoing leadership and significant investment in continuing to develop the cervical arthroplasty market,” said Rebecca Whitney, Global President of ZimVie Spine. “We are committed to and passionate about driving the expansion of this market to provide a greater number of patients with the gift of motion. We are pleased to be at the forefront of important clinical studies to make motion preservation a reality for more patients.”

The company intends to begin enrollment over the next several months and conduct the IDE study with multiple surgeons at six sites over the next five years.

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 of 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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