ZimVie Announces Expanded Reimbursement and Exemplary Clinical Rating for Mobi-C®

April 3, 2023

Mobi-C obtains French government reimbursement and the highest quality rating from the British clinical data panel ODEP

WESTMINSTER, Colo., April 03, 2023 (GLOBE NEWSWIRE) -- ZimVie Inc. (Nasdaq: ZIMV), a global life sciences leader in the dental and spine markets, today announced that the French Republic has published its approval for the reimbursement of the Mobi-C® Cervical Disc in both the public and private sectors in France. In addition, the clinical data for Mobi-C was awarded the highest quality rating of 10A* by the Orthopaedic Data Evaluation Panel in the United Kingdom. Physicians have used Mobi-C, ZimVie's market-leading device for cervical disc replacement at one level or two contiguous levels, to treat patients in France and the U.K. since 2004.

"This reimbursement of the Mobi-C prosthesis is really excellent news. After almost twenty years of communicating the results of a French multi-center study, reimbursement for Mobi-C for both one- and two-level applications has been obtained," noted Dr. Thierry Dufour, spine neurosurgeon at Clinique Geoffroy Saint Hilaire in Paris, France. "This decision was eagerly awaited by the French surgical community, as the Mobi-C prosthesis was invented, designed, and manufactured in France. With the economic obstacle of reimbursement addressed, cervical disc arthroplasty will now be more broadly available."

On March 19, 2023, the French Republic's Ministry of Health and Prevention issued in JORF N° 0067, a new version of the List of Products and Services (Liste des Produits et Prestations, or LPP) reimbursable by health insurance and covered by the Health Insurance Fund (otherwise known as standard coverage). The LPP (Text No. 24) now includes the newly introduced medical device code 3174999 for "Cervical Disc Prostheses - Mobi-C Plug & Fit." Implants included on the LPP must be CE-marked devices that have a therapeutic, diagnostic, or assistive added value, supported by clinical studies demonstrating the benefits of the solution.

Another validation of the Mobi-C Cervical Disc came through the recent 10A* rating from the Orthopaedic Data Evaluation Panel (ODEP) in the United Kingdom. ODEP provides the objective, systematic review and rating of the strength of evidence supporting the performance of medical devices. Its rating is comprised of several components: The numerical portion of the rating indicates the number of years of clinical evidence, with ten years representing full compliance with the benchmark from the National Institute for Health and Care Excellence (NICE), which provides national guidance and advice to improve health and social care in the United Kingdom. The "A" designates "Strong Evidence" based on a generally higher number of patients (giving greater confidence in the results presented), with all patients being subject to follow-up (their outcomes recorded). Finally, the addition of the star denotes a benchmark replacement rate of less than 1 in 20 (5%) at 10 years. There is no higher quality rating than A*.

"We applaud the French reimbursement decision for Mobi-C and welcome the exemplary 10A* rating from ODEP," said Rebecca Whitney, Global President of ZimVie Spine. "We believe that these wins further validate the confidence that surgeons worldwide have demonstrated for Mobi-C since its first use in France in 2004 and FDA approval for one- and two-level use in the United States in 2013. Products like Mobi-C fuel our mission to preserve motion and restore daily life for patients."

About ODEP
The Orthopaedic Data Evaluation Panel is an independent panel of experts providing objective ratings of the strength of evidence available on the performance of medical implants. ODEP works with surgeons, manufacturers, and hospitals to promote evidence-based selection of implants so that patients receive the very best and safest implants. The Panel assesses data provided by the implant manufacturer against performance benchmarks, or standards, set by clinical experts, and awards ratings for those implants that meet the required benchmarks. More information about ODEP and its rating system is available at www.odep.org.uk.

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.

Media Contact Information:

ZimVie
Laura Driscoll • Laura.Driscoll@ZimVie.com
(774) 284-1606

ZimVie Spine
Mark Richards • Mark.Richards@ZimVie.com
(512) 913-9572

Investor Contact Information:

Gilmartin Group LLC
Marissa Bych • Marissa@gilmartinir.com