Zimmer Biomet Receives FDA Approval for Oxford® Cementless Partial Knee, Only Cementless Partial Knee Replacement Implant in the U.S.

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WARSAW, Ind., Nov. 25, 2024 /PRNewswire/ -- Zimmer Biomet Holdings, Inc. (NYSE and SIX: ZBH), a global medical technology leader, today announced U.S. Food and Drug Administration (FDA) Premarket Approval Application (PMA) Supplement approval for the Oxford® Cementless Partial Knee. The approval is based on safety and effectiveness data from an Investigational Device Exemption (IDE) study and non-clinical testing for cementless partial knee replacement (PKR).[1] The Oxford Cementless Partial Knee allows surgeons to perform a PKR with improved fixation,[2] better long-term implant survival rate[2,3] and improved efficiency in the operating room[4] (OR) compared to the Oxford Cemented Partial Knee procedure. Following more than 20 years of clinical experience and over 300,000 procedures across Canada, Europe, Middle East, Africa, and Asia,[5] the Oxford Cementless Partial Knee is now the only FDA-approved cementless partial knee implant in the U.S.

"Cementless knee replacement procedures are increasingly preferred by surgeons seeking to improve surgical efficiency. The Oxford Cementless Partial Knee is coming into the U.S. with a proven track record of retaining more healthy anatomy with a less invasive approach and improved outcomes[6] as compared to a total knee replacement," said Joe Urban, President, Knees at Zimmer Biomet. "We are excited to address the unmet U.S. demand for a cementless partial knee with a new offering which has 20 years of clinical experience in more than 50 countries.[5]"

Compared to traditional partial knee replacements that use bone cement to secure the implant in place, a cementless approach allows patients' natural bone growth to secure the implant for better long-term fixation.[2] The Oxford Cementless Partial Knee features a mobile bearing that can move with

the femoral component throughout the entire range of motion to mimic natural knee movement. This design provides better range of motion, a more natural feel and a more stable implant-to-bone fixation for improved long-term implant survival.[2,3] The system's tibial and femoral components have a titanium and hydroxyapatite coating to promote bone growth into the implant[7]. The UK national joint registry has more than 33,000 patients treated with Oxford Cementless Partial Knees recorded with a 94.1% rate of implant survival at 10 years after surgery,[3] which is higher than the average 10-year survivorship for all other partial knees (89.9%).[3] Enthusiasm and usage of partial knee replacement continues to grow around the world as published research continues to demonstrate that PKR in appropriate cases provides improved patient outcomes compared to TKR.[6]

"For younger and more active patients, the Oxford Cementless Partial Knee amplifies the benefits of a traditional partial knee replacement by offering knee flexion that resembles natural knee movement, and stronger adhesion of the implant to the bone for better long-term durability," said Adolph V. Lombardi Jr., MD, FACS, President of JIS Orthopedics in New Albany, Ohio. "In my own practice, a cementless approach has increased OR efficiency by shortening my surgery time and reducing costs associated with cement preparation."

Since its initial launch in England in 2004, the Oxford Cementless Partial Knee has become the preferred partial knee implant for Zimmer Biomet's European customers.[5]

As part of the U.S. nationwide launch in Q1 2025, Zimmer Biomet will provide FDA-required training, focusing on the cementless surgical technique and proper patient selection. For patients in the U.S., the Oxford Partial Knee is the only implant with a lifetime limited warranty that covers the cost of Zimmer Biomet replacement implants.*

Important Safety Information:

The Cementless Oxford Partial Knee System is intended for use in unilateral knee procedures with osteoarthritis or avascular necrosis limited to the medial compartment of the knee. It is intended to be implanted without the application of cement for patients whose clinical condition would benefit from a shorter surgical time compared to the cemented implant. The Oxford Partial Knee is not indicated for use in the lateral compartment or for patients with ligament deficiency, or for use in simultaneous bilateral surgery or planned staged bilateral procedures. Potential risks include, but are not limited to, loosening, dislocation, fracture, wear and infection, any of which can require additional surgery. For a full list of product indications, contraindications and warnings, as well as further information on product IDE data, please see the associated product Information for Use (IFU) and Surgical Technique available at https://labeling.zimmerbiomet.com/

For more information about the Oxford Cementless Partial Knee, visit

www.zimmerbiomet.com/oxfordcementless.

About Zimmer Biomet

Zimmer Biomet is a global medical technology leader with a comprehensive portfolio designed to maximize mobility and improve health. We seamlessly transform the patient experience through our innovative products and suite of integrated digital and robotic technologies that leverage data, data analytics and artificial intelligence.

With 90+ years of trusted leadership and proven expertise, Zimmer Biomet is positioned to deliver the highest quality solutions to patients and providers. Our legacy continues to come to life today through our progressive culture of evolution and innovation.

For more information about our product portfolio, our operations in 25+ countries and sales in 100+ countries or about joining our team, visit www.zimmerbiomet.com or follow on LinkedIn at www.linkedin.com/company/zimmerbiomet or X / Twitter at www.twitter.com/zimmerbiomet.

Cautionary Statement Regarding Forward-Looking Statements

This news 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 Zimmer Biomet'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 and expectations of management and are subject to significant risks, uncertainties and changes in circumstances that could cause actual outcomes and results to differ materially. For a list and description of some of such risks and uncertainties, see Zimmer Biomet'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 Zimmer Biomet's filings with the SEC. Forward-looking statements speak only as of the date they are made, and Zimmer Biomet 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 news 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 statement is applicable to all forward-looking statements contained in this news release.

*Subject to terms and conditions set forth within the written warranty

References:

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6. Liddle, A. D., et al. "Patient-reported outcomes after total and unicompartmental knee arthroplasty: a study of 14 076 matched patients from the National Joint Registry for England and Wales." The bone & joint journal 97.6 (2015): 793-801.
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Media
Heather Zoumas-Lubeski
445-248-0577
heather.zoumaslubeski@zimmerbiomet.com

Kirsten Fallon
781-779-5561
kirsten.fallon@zimmerbiomet.com

Investors
David DeMartino
646-531-6115
david.demartino@zimmerbiomet.com

Zach Weiner
908-591-6955
Zach.weiner@zimmerbiomet.com

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