March 29, 2016

LDR Announces Publication of Long-Term Clinical Results Showing Superiority of Two-Level Mobi-C Cervical Disc to ACDF at Five Years

Journal of Neurosurgery: Spine Publishes Independent Peer-Reviewed Five-Year Follow-Up Comparison of Two-Level Cervical Disc Replacement versus ACDF

AUSTIN, Texas, March 29, 2016 (GLOBE NEWSWIRE) -- LDR Holding Corporation (Nasdaq:LDRH), a global medical device company focused on designing and commercializing novel and proprietary surgical technologies for the treatment of patients suffering from spine disorders, today announced that "Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of two-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial" has been published by the Journal of Neurosurgery: Spine. Mobi-C provided statistically significant greater improvement in general and disease specific outcome measures compared to Anterior Cervical Discectomy and Fusion (ACDF). Additionally, there was a lower incidence of index level and adjacent level reoperation with cervical Total Disc Replacement (cTDR).

The paper was authored by Dr. Kris Radcliff, Associate Professor in Orthopedic Surgery and Neurosurgery at Thomas Jefferson University, Dr. Domagoj Coric, Chief of Neurosurgery at Carolinas Medical Center, and Dr. Todd Albert, Surgeon-in-Chief and Medical Director and Korein-Wilson Professor of Orthopaedic Surgery at Hospital for Special Surgery. All of the authors are independent without any institutional or financial bias. They had no prior involvement in the Mobi-C cTDR study or any other consulting or financial relationship with LDR. The authors were given complete and unrestricted access to the Mobi-C cTDR study data, and retained full authority for manuscript content, including the discussion and conclusions.

The authors chose to conduct the data analysis in accordance with the rigorous criteria defined by the U.S. Food and Drug Administration (FDA) standards. Based on the FDA composite outcome measure for success, the overall success rates at five years were 61% and 31% for the cTDR and ACDF groups, respectively ($p<0.0001$). The significantly higher overall success rate for the cTDR group meets superiority and non-inferiority criteria.

The paper, available on the "Publish Before Print" section of the Journal of Neurosurgery website (http://thejns.org/action/showAllForthcomingToc), represents "the first report of long-term outcome of two-level cTDR from a U.S. FDA Investigational Device Exemption (IDE) study." The authors noted that the five-year follow-up rates for both groups (90.7% for cTDR and 86.7% for ACDF) are comparable to or higher than those reported in other long-term randomized control trials of cervical arthroplasty, and enable adequate statistical power to test both non-inferiority and superiority. The Mobi-C patients had a statistically significant greater improvement than ACDF patients in Neck Disability Index (NDI) score, Short Form Health Survey — Physical Component Score (SF-12 PCS), and overall satisfaction with treatment at 60 months.

5-year Outcomes	**cTDR**	**ACDF**	
Rate of Overall Secondary Surgeries	7%	21%	p=0.0006
Neck Disability Index (NDI) Improvement	-37	-28	p=0.0003
Rate of Adjacent Segment Degeneration at the Superior Level	32.6%	70.8%	p<0.0001
Rate of Adjacent Segment Degeneration at the Inferior Level	22.4%	55.1%	p<0.0001
Composite Overall Success	**61%**	**31%**	**p<0.0001**

Christophe Lavigne, President and CEO of LDR, commented, "This publication represents a defining moment for LDR, spine surgeons, and their patients. For the first time in the history of spinal medicine, clinical evidence of two-level cervical disc replacement outcomes, out to five years, has been peer-reviewed and published, and the findings are very encouraging. Two-level cervical total disc replacement has been proven as a safe and effective treatment with statistical superiority in overall outcome as compared to the previous gold standard of treatment, ACDF. Mobi-C is the only cervical disc replacement device available in the U.S. that can be used on-label to treat two-level cervical pathology, and is also associated with the additional benefits of reduced adjacent segment degeneration and significantly lower reoperation rate. Even after 60 months, patients treated with Mobi-C report high levels of satisfaction, pain relief, and willingness to recommend the surgery to a friend. This measurable and consistent improvement in patients' lives has always been our goal at LDR. We believe that this publication will further support the movement among insurance payers to expand

coverage to include two-level cervical disc replacement, allowing more surgeons and patients to benefit from the procedure."

The paper also affirms LDR's belief regarding the extended biomechanical benefits of two-level Mobi-C over ACDF: "Although both ACDF and cTDR satisfactorily treat clinically symptomatic cervical pathology, arthrodesis alters cervical mechanics placing increased stresses on adjacent segments, which may contribute to the development of symptomatic degeneration at those adjacent levels. By preserving the motion of the operated segment, cTDR places comparatively less stresses on adjacent levels which may serve to protect those levels."

Mobi-C Cervical Disc

Mobi-C is a cobalt chromium alloy and polyethylene mobile-bearing prosthesis specifically designed as a bone-sparing, cervical intervertebral disc replacement for both one and two-level indications. All other cervical disc prostheses are FDA approved for one-level use only. In addition to the unique mobile-bearing feature, Mobi-C offers a simplified surgical technique. 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.

About LDR Holding Corporation

LDR Holding Corporation is a global medical device company focused on designing and commercializing novel and proprietary surgical technologies for the treatment of patients suffering from spine disorders. LDR's primary products are based on its exclusive Mobi® non-fusion and VerteBRIDGE® fusion technology platforms and are designed for applications in the cervical and lumbar spine. These technologies are designed to enable products that are less invasive, provide greater intra-operative flexibility, offer simplified surgical techniques and promote improved clinical outcomes for patients as compared to existing alternatives. In August 2013, LDR received approval from the FDA for the Mobi-C cervical disc replacement device, the first and only cervical disc replacement device to receive FDA approval to treat both one-level and two-level cervical disc disease. For more information regarding LDR Holding and the Mobi-C Cervical Disc, visit www.ldr.com or www.cervicaldisc.com.

Forward-Looking Statements

This press release contains statements that constitute forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. Forward-looking statements contained in this press release include the intent, belief or current expectations of LDR and members of its management team with respect to LDR's future business operations, statements regarding the potential effect of published peer-reviewed articles on the adoption of Mobi-C by surgeons and payers, as well as the assumptions upon which such statements are based. Factors that could cause actual results to differ materially from those contemplated within this press release can also be found in LDR's Risk Factors disclosure in its Annual Report on Form 10-K, filed on February 23, 2016, and in LDR's other filings with the SEC. LDR disclaims any responsibility to update any forward-looking statements.

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