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LDR Announces Peer-Reviewed Publication Finding Safety and Efficacy of One-Level Mobi-C Cervical Disc at 5 Years

International Journal of Spine Surgery (IJSS) Publishes Comparison of One-Level Mobi-C Versus ACDF With Five-Year Follow-up

AUSTIN, Texas, March 08, 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 "Prospective, Randomized Comparison of One-level Mobi-C® Cervical Total Disc Replacement vs. Anterior Cervical Discectomy and Fusion: Results at 5-year Follow-up" has been published by the International Journal of Spine Surgery, which is the official scientific journal of the International Society for the Advancement of Spine Surgery (ISASS).

The paper, featured in Volume 10 of the International Journal of Spine Surgery (http://ijssurgery.com/10.14444/3010), finds that the "five-year results demonstrate the safety and efficacy of Total Disc Replacement (TDR) with the Mobi-C as a viable alternative to Anterior Cervical Discectomy and Fusion (ACDF)," and also notes that "in comparison to ACDF, the TDR group preserved motion and patients exhibited lower rates of adjacent segment degeneration through 60 months. Also, a significantly lower rate of subsequent surgeries was seen in the TDR group, indicating an additional benefit of this treatment option."

The paper, lead-authored by Dr. Michael S. Hisey, an orthopedic surgeon specializing in spinal surgery at Texas Back Institute, represents peer-reviewed publication of five-year follow-up data on LDR's Investigational Device Exemption (IDE) trial of the Mobi-C Cervical Disc.

The objective of the paper was to review the safety and efficacy, at up to five years, of cervical TDR compared to ACDF for the treatment of one spinal level between C3 and C7. Outcome assessments included a composite overall success score, Neck Disability Index (NDI), visual analog scales (VAS) assessing neck and arm pain, Short Form Health Survey (SF-12), patient satisfaction, adverse events, major complications, segmental range of motion, subsequent surgery, and adjacent segment degeneration. The paper notes the excellent five-year follow-up rates in the study, 85.5% and 78.9%, for the TDR group and ACDF group, respectively. The composite overall success was 61.9% with TDR vs. 52.2% with ACDF, demonstrating statistical non-inferiority. Improvements in NDI, VAS neck and arm pain, and SF-12 scores were similar between groups and were maintained from earlier follow-up through 60 months. There was no significant difference between TDR and ACDF in adverse events or major complications. Range of motion was maintained with TDR through 60 months. Subsequent surgery rates at the treated level and adjacent segment degeneration were significantly lower for TDR patients.

5-year Outcomes	TDR	ACDF	
Follow-up Rate	85.5%	78.9%	
Composite Overall Success	61.9%	52.2%	Statistical non-inferiority
Device-Related Subsequent Surgery Rates at the Treated Level	3.0%	11.1%	p<0.02

Christophe Lavigne, President and CEO of LDR, commented, "LDR is very pleased to see additional five-year follow-up data being published. This paper in particular, as the first review of the composite overall success for one-level Mobi-C at five years, represents the kind of peer-reviewed publication of long-term Level I data that, we believe, payers have viewed as a significant milestone and threshold that supports a positive coverage decision for treatment. The data is also encouraging to surgeons and patients looking to cervical TDR as a new standard of care for treating symptomatic degenerative disc disease with radiculopathy or myeloradiculopathy."

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 6 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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