



February 9, 2016

## **LDR Announces Publication of Five-Year Results of Cost Utility Analysis of Mobi-C Cervical Disc**

### **Study Finds Mobi-C Appears to be Highly Cost-Effective Compared With ACDF for Treating Two-Level Cervical Disc Disease Out to Five Years**

AUSTIN, Texas, Feb. 09, 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 NEUROSURGERY<sup>®</sup> has published a peer-reviewed article that evaluated the cost-effectiveness of two-level cervical Total Disc Replacement (cTDR) with the Mobi-C<sup>®</sup> Cervical Disc as compared to anterior cervical discectomy and fusion (ACDF) based on five-year outcomes data.

The paper, *Cost Utility Analysis of The Cervical Artificial Disc versus Fusion for The Treatment of 2-Level Symptomatic Degenerative Disc Disease: 5-Year Follow-Up*, was published online by NEUROSURGERY on February 5, 2016, with print publication to follow. The full article is available online at [http://journals.lww.com/neurosurgery/Abstract/publishahead/Cost\\_Utility\\_Analysis\\_of\\_the\\_Cervical\\_Artificial.97385.aspx](http://journals.lww.com/neurosurgery/Abstract/publishahead/Cost_Utility_Analysis_of_the_Cervical_Artificial.97385.aspx).

The study, authored by Jared Ament, M.D., MPH with the UC Davis Health System Neurosurgery Department, utilized the clinical data from the two-level Mobi-C vs. ACDF randomized controlled trial in order to assign health states for the patient population. The objective of the paper was to determine the cost-effectiveness of cTDR compared to ACDF for two-level cervical disc disease. The study concludes that for patients with 2-level degenerative disc disease, cTDR appears to be a "highly cost-effective surgical modality compared with ACDF" and that, "from a societal perspective, cTDR imparts greater quality of life at less cost than ACDF."

"The clinical superiority of Mobi-C compared to ACDF for two-level indications has been demonstrated through the Investigational Device Exemption (IDE) trial for the overall composite primary effectiveness endpoint at 60 months," said Christophe Lavigne, President and CEO of LDR. "We are excited to have this very important, long-term economic analysis of Mobi-C published, especially in such a prestigious journal as NEUROSURGERY. The principal finding of this study, that two-level Mobi-C appears to offer improved cost-effectiveness compared to ACDF (based on the 60-month outcomes), represents further evidence to support broader payer coverage for two-level cervical disc replacement, and greater surgeon adoption of Mobi-C."

As part of the research, costs were derived from institutional billing data at the IDE trial sites. The research team used decision analytical modeling to generate Quality-Adjusted Life-Years (QALY) and Incremental Cost-Effectiveness Ratios (ICER) for both treatment groups on which to base their conclusions. QALY is a measure of disease burden and assesses the value for the money associated with a medical intervention. ICER is the ratio of the change in costs to incremental benefits of a therapeutic intervention or treatment. An intervention with a lower cost to QALY gained ratio such as 2-level cTDR would be preferred over an intervention with a higher ratio like 2-level ACDF.

The cost-effectiveness of 2-level Mobi-C over fusion was first studied, peer-reviewed and published by Dr. Ament, et al. in the December 2014 issue of the *Journal of the American Medical Association (JAMA) Surgery*. That study was based on analysis of IDE trial data through the first 24 months, and also concluded that cTDR with Mobi-C appears to be a highly cost-effective surgical modality compared with ACDF for the treatment of two-level cervical disc disease. One notable takeaway when comparing the two studies, is that the ICER for the five-year data far exceeded that of the two-year data, suggesting that cTDR with Mobi-C becomes more cost-effective over time.

#### **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<sup>®</sup> non-fusion and VerteBRIDGE<sup>®</sup> 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](http://www.ldr.com) or [www.cervicaldisc.com](http://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, including the data regarding Mobi-C's cost-effectiveness as compared to ACDF, and the potential impact on Mobi-C sales, 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 20, 2015, and in LDR's other filings with the SEC. LDR disclaims any responsibility to update any forward-looking statements.*

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