LDR to Present Results of Clinical Studies on Mobi-C® Cervical Disc at the 2012 North American Spine Society Meeting

The Associated Press

AUSTIN, Texas--(BUSINESS WIRE)--Oct 26, 2012--LDR, a privately held medical device company offering innovative spinal implants for both non-fusion and fusion applications, today announced multiple scientific talks related to the Mobi-C® Cervical Disc (Mobi-C) to be presented at the 2012 North American Spine Society (NASS) annual meeting. The presentations are part of the Cervical Arthroplasty Concurrent Sessions on Oct. 26 from 3:40 – 4:40 p.m. CT in Ballroom A 1 & 2 and on Oct. 27 from 10 – 11 a.m. CT in Ballroom A 4 of the Dallas Convention Center.

Mobi-C has been designed for cervical intervertebral disc replacement to maintain segmental motion and restore disc height. The cobalt chrome alloy and polyethylene device is designed to accommodate the segmental instantaneous center of rotation via a mobile-bearing core, reducing bone stresses and eliminating the need for invasive vertebral anchorage. Mobi-C has been used in more than 15,000 implantations outside of the United States since 2004 in more than 20 countries and is currently under Pre-Market Approval (PMA) review by the U.S. Food and Drug Administration (FDA) for both one- and two-level indications.

“We are enthusiastic about the volume of clinical data that supports the use of Mobi-C in total disc replacement (TDR) as compared to anterior cervical fusion for treating one- and two-level cervical degenerative disc disease (DDD),” said Christophe Lavigne, President and CEO of LDR. “We look forward to offering a new and potentially superior treatment alternative to indicated patients in the United States.” The data include: Cervical disc replacement: Evolution of adjacent segments after 3 Years - JP Steib, MD, et al Oct. 26, 3:46-3:52 p.m. CT, Ballroom A 1&2 (Abstract #159) This study analyzed 224 adjacent segments that have been evaluated after a single or multilevel cervical disc replacement in 142 patients in France. The results at three years support the hypothesis that cervical arthroplasty preserves or at least does not accelerate the degenerative process at adjacent levels. The study will continue for a total of 10 years in order to learn more about long-term adjacent disc status above and below single or multilevel cervical disc replacement.

Results from first completed investigation device exemption trial of cervical arthroplasty for treatment of degenerative disc disease at two levels - Reginald Davis, MD, et al Oct. 27, 10:00 a.m. – 10:06 a.m. CT, Ballroom A 4 (Abstract #191) The results of the FDA regulated investigational device exemption (IDE) trial of 330 patients continue to support the use of cervical arthroplasty in general, but also specifically demonstrate the advantages of two-level arthroplasty with Mobi-C over two-level ACDF in terms of improvements in pain and function and a reduction in revision rates.

Comparison of outcomes after treatment of cervical degenerative disc disease at one or two levels with total disc replacement – Reginald Davis, MD, et al Oct. 27, 10:12 – 10:18 a.m. CT, Ballroom A 4 (Abstract #193) The study results, which compared the efficacy of treatment of cervical DDD with Mobi-C at one or two contiguous levels of the cervical spine, suggest that unlike ACDF, there is no evidence of a reduction in efficacy or an increase in complications as the number of levels treated with Mobi-C increases from one level to two levels. This may represent an advantage of TDR with Mobi-C over ACDF, especially for treating two-level cervical pathology.

Outcomes of cervical total disc replacement with up to 5 years follow-up: A prospective study of 384 Patients – JP Steib, MD, et al Oct. 27, 10:18-10:24 a.m. CT, Ballroom A 4 (Abstract #194) This is a report on 384 patients as part of an ongoing prospective, multicenter study in France evaluating the clinical and radiological outcomes of cervical disc replacement (CDR) with the Mobi-C Cervical Disc. The results suggest that CDR with Mobi-C provides favorable clinical outcomes and maintains motion at the implanted levels. The reoperation rate for the initial indication and the operation rate at the adjacent disc levels are reportedly low at five years suggesting good long-term durability of the procedure.

Number of levels involved at index surgery significantly affects the outcomes after anterior cervical discectomy and fusion: Analysis of data from a multicenter prospective randomized controlled trial – Pierce Nunley, MD, et al Oct. 27, 10:36 – 10:42 a.m. CT, Ballroom A 4 (Abstract #197) The study, which assessed and compared the outcomes for the fusion procedure at 24 months, found that rates of complications and subsequent surgical interventions are higher after two-level ACDF in the 24 months following index surgery.

“LDR’s mission is to truly innovate the spine market and significantly improve clinical benefits for both surgeons and patients alike,” said Mr. Lavigne. “Mobi-C is a reflection of this effort, and we feel strongly that it has the potential to become the gold standard treatment for cervical DDD, especially for two-level cases, for which fusion is currently the only on-label option in the United States.” Abstracts are available upon request. Please visit LDR at NASS from Oct. 24-27 at Booth #201.

Mobi-C is currently not available for use in the United States.

About LDR LDR develops unique implantable spine devices and instrumentation designed to support the clinical goals of surgery while making procedures easier to perform. LDR was founded in 2000 by partners Christophe Lavigne, Hervé Dinville and Patrick Richard in Troyes, France. Currently headquartered in Austin, TX, LDR has experienced growth through product portfolio expansion and an increasingly global presence. More information is located at www.ldrmedical.com.

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