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LDR Receives Approvable Letter from U.S. Food and Drug Administration for Two-Level Mobi-C(R) Cervical Disc

Mobi-C is the first cervical disc to receive an approvable letter for two-level use in the United States following a 600 patient concurrent IDE Clinical Trial for one and two-level cervical disc replacement

AUSTIN, Texas, Nov 06, 2012 (BUSINESS WIRE) -- LDR, a privately held medical device company offering innovative spinal implants for both non-fusion and fusion applications, announced that it has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for its Mobi-C(R) Cervical Disc (Mobi-C). Mobi-C is a metal and polyethylene mobile bearing prosthesis specifically designed as a low-profile cervical intervertebral disc replacement for both one and two level applications.

"We are pleased that the FDA, after an intensive review of our submission for Mobi-C, has determined it to be approvable based on the strength of the data provided in the premarket approval application (PMA). We are confident that we can efficiently complete the remaining requirements inherent in the full approval process and we anticipate commercial U.S. availability of Mobi-C in 2013," said Christophe Lavigne, President and CEO of LDR. "Given the high incidence of two-level cervical disease, we are proud that Mobi-C may become the first cervical disc available to treat patients on-label that suffer from two-level pathology. I would like to thank and attribute this success to everyone involved in this study, especially the clinicians, study coordinators, the FDA, LDR employees, our partners and suppliers, and most importantly the patients who consented to participate in the first prospective study performed comparing Mobi-C to ACDF."

FDA has determined that Mobi-C is approvable for two-level indications, subject to the satisfaction of all applicable requirements of the Quality System Regulations (21 CFR Part 820), as well as finalization of the labeling and post-approval study. FDA will issue an approval order, allowing commercial sale and distribution, after said requirements have been reviewed and determined to be acceptable.

"The Mobi-C two-level study data, as presented at the North American Spine Society (NASS) 2012 Annual Meeting, demonstrate the potential to treat two-level cervical disease using the Mobi-C Cervical Disc as an alternative to ACDF," said Dr. Reginald Davis, Chief of

Neurosurgery and Director of Neurosciences at the Greater Baltimore Medical Center. "The anticipated full approval of Mobi-C will give surgeons a valuable treatment option for patients with two-level disease, where there is no approved motion preserving option."

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, Herve Dinville and Patrick Richard in Troyes, France. 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 .

Caution: The Mobi-C(R) device is for investigational use only and is not available for use in the United States.

SOURCE: LDR

For LDR
Abhi Basu
646-747-7174
917-922-7132
abasu@kwitco.com