AxioMed® Spine Corporation Announces Freedom® Cervical Disc European Introduction

The Associated Press

GARFIELD HEIGHTS, Ohio--(BUSINESS WIRE)--Feb 12, 2013--AxioMed ® Spine Corporation (www.axiomed.com) announces the commercial introduction of its Freedom® Cervical Disc in Europe with a successful implantation in Switzerland. The Freedom Cervical Disc received CE Mark in 2012. AxioMed will also conduct a multi-center Freedom Cervical Disc study as a post-market assessment of the total disc replacement device for the treatment of cervical degenerative disc disease. The study's clinical results are expected to be used in support of a future Investigational Device Exemption (IDE) application to the U.S. FDA and to support regulatory approval in other markets outside of the EU.

AxioMed's first product, the Freedom Lumbar Disc, received CE Mark in 2009. Results from the lumbar European post-market assessment study were published in the SAS Journal in December 2011. AxioMed is also engaged in a U.S. FDA IDE study of the Freedom Lumbar Disc. The Company is an ISO 13485:2003 certified manufacturer of the Freedom Lumbar and Cervical Discs.

Patrick McBrayer, AxioMed's President and CEO stated, "AxioMed supported a clinical study of its Freedom Lumbar Disc in Europe, and we are likewise committed to a European clinical study of our latest product, the Freedom Cervical Disc. Our European lumbar clinical data was published in a respected peer-reviewed spine journal and demonstrated that the Freedom technology has provided patients lumbar pain relief, reduced disability and improved lifestyle, based on monitored outcomes. We expect similar results from our Freedom Cervical Disc. Spine surgeons at clinics in Switzerland, Germany, and the U.K. will participate in this study."

Jim Kuras, the Company's Chief Operating Officer added, "The Freedom Cervical Disc's unique asymmetrical design and resulting biomechanics represent an advancement beyond the first generation total disc technologies, and better accommodate the cervical anatomy and spinal function. The differentiated design, with multiple footprints and heights combined with a wedge angle, provide the surgeon with an array of implants to address patient specific surgical requirements. First generation total disc replacement devices incorporate a metal-on-metal or metal-on-polyethylene ball and socket design and have resulted in design and functional limitations. The Freedom Lumbar and Cervical Disc technology is a second generation, viscoelastic polymer one-piece spinal disc replacement prosthesis that provides a combination of stability, compressibility and controlled motion that closely replicates the natural function of the native disc. The surgical procedure requires a limited number of instruments, is simple and reproducible, and requires no bone-milling or excess sculpting of the intervertebral body endplates to implant the device."

Neal Defibaugh, AxioMed's Vice President of Clinical and Regulatory Affairs, further commented, "AxioMed is committed to conduct a Freedom Cervical Disc study in Europe that supports our goal of post-market surveillance. The clinical study will provide additional data that complements the current, extensive biomechanical and biocompatibility test data that has been completed for the Freedom Cervical Disc. These results will be used to support the device's IDE regulatory approval pathway as well as additional requirements outside the EU. As with the Freedom Lumbar Disc, AxioMed intends to include economic endpoints to accompany the requirements of the contemplated Freedom Cervical Disc IDE study."

About AxioMed Spine Corporation
AxioMed's mission is to develop products focused on spinal function for patients with degenerative spine disease, thus advancing the standard of care beyond fusion and first generation total disc replacement. The Company's leading products, the Freedom Lumbar and Cervical Discs, were developed and designed by a team of clinicians and experts in the fields of biomechanics, pathology, spinal surgery and polymer science. The Freedom Lumbar and Cervical Discs have received CE Mark approval for distribution in the European Union. Additionally, the Company is pursuing U.S. regulatory approval for its Freedom technology. Focusing on restoration of the natural function of the spine, AxioMed will enhance human health through research, innovation, development and service world-wide. For more information about AxioMed, please visit our website at www.axiomed.com.