AxioMed® Spine Corporation Receives Pivotal Total Disc Design Patent

The Associated Press

GARFIELD HEIGHTS, Ohio--(BUSINESS WIRE)--Apr 2, 2013--AxioMed ® Spine Corporation (www.axiomed.com) announces the Notice of Allowance of a key US patent which describes a device for replacing a damaged spinal disc. The key feature of the allowed patent is the trapezoidal shape which is asserted to be a closer approximation of the spinal disc anatomy. The initial application of this invention is the introduction of the Freedom ® Cervical Disc which received CE Mark in 2012. Closely following the release of the Freedom Cervical Disc is the application of this key feature in treating damaged discs in the lumbar spine.

AxioMed’s first product, the Freedom Lumbar Disc, received CE Mark in 2009 and has now been used to treat over 500 patients with follow-up up to 7 years. Results from the lumbar European post-market assessment study showing clinically significant improvements in pain and disability were published in the SAS Journal in December 2011. One of the key conclusions of the study was the ability of the technology to allow for restoration of the spinal Center of Rotation which correlated in a clinically significant improvement in patient disability. AxioMed is also engaged in a U.S. FDA IDE study of the Freedom Lumbar Disc and an EU post market study of the Freedom Cervical Disc to augment the Company’s cervical IDE submission. AxioMed is an ISO 13485:2003 certified manufacturer of the Freedom Lumbar and Cervical Discs.

Patrick McBrayer, AxioMed’s President and CEO stated, “We are pleased to receive this pivotal patent which augments AxioMed’s intellectual property including an extensive patent portfolio, exclusive rights to the polymer for our Freedom Lumbar and Cervical discs and trade secret assets on device assembly. The asymmetry protected in this patent supports our mission of introducing a proprietary, next generation total disc product platform, designed to replicate the characteristics and performance of a healthy disc.” James Kuras, the Company’s Chief Operating Officer added, “The Freedom Cervical Technology’s unique asymmetrical design and resulting biomechanics represents advancement beyond the first generation total disc technologies. This key feature better accommodates the cervical anatomy and spinal function and will ultimately be employed to the lowest spinal disc L5-S1 which accounts for approximately 60% of all treated lumbar levels. The differentiated design, with multiple footprints and heights combined with multiple wedge angles, provides the surgeon with an array of implants to address patient specific surgical requirements. The Freedom Lumbar and Cervical Disc technology is a second generation, one-piece viscoelastic spinal disc replacement prosthesis that provides a combination of stability, compressibility and controlled motion that closely replicates the natural function of the native disc.” Dr. Edward Benzel, Chairman of the Department of Neurosurgery at Cleveland Clinic and Professor of Surgery at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve

University, commented, “The potential benefit of a total disc replacement to mimic both the anatomical shape and mechanical characteristics of the human disc could have scientific and clinical advantage. The human disc shape in the cervical spine is trapezoidal and a technology that can preserve the natural anatomy and mimic the human disc shape may allow for optimal surgical placement and lead to clinical benefits. In the case of the lumbar spinal level, L5-S1, it too has trapezoidal characteristics that bearing surface technologies do not replicate; this anatomically optimized feature may provide an enhancement for treating this spinal level. Further scientific investigation of the asymmetrical design on patient outcomes and the correlation to the restoration of the Center of Rotation in the spine is warranted.” Disclosure: Dr. Benzel is an inventor of the technology, owns equity in AxioMed and has received compensation for serving on an AxioMed Scientific Advisory Board.

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 US 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.

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