FDA Advisory Panel Unanimously Recommends DePuy Spine CHARITE™ Artificial Disc for Approval

First Artificial Disc Recommended for FDA Approval in U.S. with Post-Approval Conditions

GAITHERSBURG, Md., Jun 2, 2004 /PRNewswire via COMTEX/ -- DePuy Spine, Inc., a Johnson & Johnson company, today reported the Orthopaedic and Rehabilitation Devices Panel of the U.S. Food and Drug Administration (FDA) unanimously recommended approval, with post-approval conditions, of the company's CHARITE™ Artificial Disc for degenerative disc disease. The CHARITE Artificial Disc is the first artificial disc to be reviewed by the panel and recommended for FDA approval.

The CHARITE Artificial Disc is intended to provide an alternative to lumbar spinal fusion surgery. Lumbar spinal fusion surgery, which helps reduce back pain, but limits a patient's range of motion and may unnaturally stress adjacent anatomy, is performed on more than 200,000 people each year in the United States.

Earl Fender, Worldwide President, DePuy Spine, said, "We are pleased with the recommendation for approval and we will work closely with the FDA to bring this important new option to those patients who can benefit from artificial disc technology as soon as possible. DePuy Spine is prepared to make a major commitment to world class training and education on artificial disc technology and techniques to foster its optimal and appropriate use."

The unanimous recommendation for the CHARITE Artificial Disc came after DePuy Spine presented results from a two-year, 15-center randomized U.S. clinical study of 304 patients that showed those implanted with the CHARITE Artificial Disc maintained or improved their range of motion, experienced pain relief sooner and had a higher degree of satisfaction with the procedure than patients who received lumbar spinal fusion surgery.

"Many of us in the medical community are excited about the potential improvements that artificial disc technology can bring to the treatment of degenerative disc disease," said Scott Blumenthal, M.D., principal investigator in the CHARITE Artificial Disc clinical trial and an orthopaedic spine surgeon from the Texas Back Institute in Plano, site of the largest number of patients enrolled in the clinical trial.

Post-approval conditions recommended by the FDA panel concerned surgeon training, patient implant cards, further biomechanical studies and additional follow up of clinical study patients.

Studies Presented to FDA Panel

In the two-year clinical trial presented to the FDA Panel, patients implanted with the CHARITE Artificial Disc improved more quickly than patients in the control group. Their pain and functional test scores were statistically superior to those of the fusion patients at many points through 12 months of follow-up, and numerically superior at 24 months. Also, on average, patients treated with the CHARITE Artificial Disc were discharged from the hospital a half-day sooner than fusion patients. There were no significant differences in complications between the CHARITE Artificial Disc patient group and the spinal fusion patient group.

Radiographic findings showed an average range of motion of 6.9 and 7.4 degrees for patients with the CHARITE Artificial Disc at 12 months and 24 months. Disc space height was restored from an average of 5.7 mm pre-operatively to 13.0 mm at 12 months and maintained at an average 12.9 mm at 24 months.

At 24 months, 88% of patients with the CHARITE Artificial Disc expressed satisfaction with the procedure, compared with 81% of spinal fusion patients. When asked if they would have the same procedure again, 82% of patients with the CHARITE Artificial Disc said they probably or definitely would, compared to 65% of fusion subjects who answered the same way.

The CHARITE Artificial Disc is made of two metal endplates and a polyethylene core that allows for motion and function very much like a normal disc. To date, 7,000 patients have been successfully treated with the CHARITE Artificial Disc, which is available in more than 30 countries throughout the world. In the United States, the CHARITE Artificial Disc is limited to investigational use.

About DePuy Spine, Inc.

DePuy Spine, Inc., a Johnson & Johnson company, has worked and partnered with leading clinicians, researchers, and thought leaders to develop products to treat spine disorders for over 20 years. Today, DePuy Spine stands in the forefront of the worldwide spine market, with a substantial sales organization in the U.S. and an expanding worldwide distribution network. The company is committed to advancing the knowledge of all health care professionals and their patients in addressing spinal

pathologies.

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