



DePuy receives FDA Advisory Panel Recommendation for Pinnacle(R) CoMplete(TM) Acetabular Hip System

FDA Advisory Panel Recommends Approval of First Ceramic-On-Metal Implant for Hip Replacement

WARSAW, IN - August 18, 2009 - DePuy Orthopaedics, Inc., a global leader in devices for joint replacement, today announced that the Orthopaedic and Rehabilitation Devices Advisory Committee of the U.S. Food and Drug Administration (FDA) has unanimously recommended FDA approval of the Pinnacle® CoMplete™ Acetabular Hip System, the first ceramic-on-metal hip bearing to be considered for approval in the U.S.

The panel's recommendation was based in part on results from a two-year controlled, randomized, blinded, prospective, multicenter, non-inferiority clinical study and laboratory testing that compared the safety and effectiveness of the Pinnacle CoMplete System to a commonly used DePuy metal-on-metal implant.

The clinical study showed no significant difference in adverse events, revision rates and survivorship after two years, and patients experienced similar pain relief, improved function and range of motion. Laboratory testing on the Pinnacle CoMplete System showed a greater than 90 percent reduction in wear compared to the metal-on-metal system under normal gait conditions and a more than 80 percent reduction in wear under adverse conditions.

"We are pleased with the panel's recommendation, and if approved by the FDA, the Pinnacle CoMplete System would represent an important innovation for hip replacement in the United States," said Pamela Plouhar, Ph.D., Vice President, Worldwide Clinical Affairs, DePuy Orthopaedics, Inc. "Each new implant provides orthopaedic surgeons and their patients more choices, which result in more individualized treatment based on specific patient anatomy, lifestyle, age, medical condition and surgeon preference."

If approved by the FDA, the Pinnacle CoMplete System would be used in adult patients who suffer from severe pain and disability due to osteoarthritis or post-traumatic arthritis. Conditions for approval recommended by the panel include refinements to the proposed product labeling and a post-approval study.

The Pinnacle CoMplete System is currently an investigational device limited by U.S. law to investigational use only. A DePuy ceramic-on-metal bearing has been marketed in 40 countries outside the U.S. since 2007.

According to the American Academy of Orthopaedic Surgeons (AAOS), about 33 million Americans are affected by osteoarthritis, a degenerative joint disease, and more than 193,000 total hip replacements (THR) are performed each year in the U.S., mostly due to some form of degenerative arthritis.

DePuy Orthopaedics has a wide range of implants for hip replacement made from other combinations of materials including metal-on-metal, ceramic-on-ceramic, metal-on-polyethylene and ceramic-on-polyethylene. This is the first time ceramic and metal bearing surfaces are being combined in a hip replacement system in the U.S., which requires FDA approval.

The hip is a "ball and socket" joint and when it gets damaged, it can produce severe pain and limit movement. Hip replacement surgery involves removing the diseased joint and replacing it with an artificial one designed to recreate the natural ball and socket joint of the hip. Successful hip replacement surgery can relieve pain and restore movement.

About DePuy Orthopaedics, Inc.

DePuy Orthopaedics, Inc., a Johnson & Johnson company, is a leading global provider of orthopaedic devices for hip, knee, extremities and trauma, as well as bone cement and operating room products. It is part of the DePuy Family of Companies, which have a rich heritage of pioneering a broad range of products and solutions across the continuum of orthopaedic and neurological care. These companies are unified under one vision -- Never Stop Moving™ to express their commitment to bring meaningful innovation, shared knowledge and quality care to patients throughout the world. Visit www.depu.com for more information.

¹ American Academy of Orthopaedic Surgeons, <http://orthoinfo.aaos.org/topic.cfm?topic=A00377>, <http://www6.aaos.org/news/pemr/releases/release.cfm?releasenum=769>