businesswire
A BERKSHIRE HATHAWAY COMPANY

CoreValve Receives CE Mark Approval for its *ReValving*™ System and Announces Plans to Initiate Expanded Clinical Evaluation

CoreValve's *ReValving*™ System is the first cath lab-based procedure for percutaneous aortic valve replacement to receive European regulatory clearance

May 16, 2007 09:46 AM Eastern Daylight Time

IRVINE, Calif.--(BUSINESS WIRE)--CoreValve (www.corevalve.com) announced today that it has received CE Mark approval of its CoreValve Percutaneous ***ReValving***™ System for treatment of high-risk patients. The patented ***ReValving***™ System consists of a novel porcine pericardial tissue valve mounted in a self-expanding multi-level frame, which is permanently implanted over the diseased aortic heart valve by an **18-French**-sized catheter. The small size of the delivery catheter is a key element of the system as it greatly improves overall maneuverability and valve placement while also eliminating the need for surgical cut-down of the femoral artery.

CoreValve also announced that it will not immediately market the ***ReValving***™ System. Rather, the Company will proceed with an expanded clinical evaluation at a small number of select international centers to help ensure that interventional cardiologists are well trained, that patients are appropriately selected for treatment, and that appropriate clinical feedback is obtained. CoreValve has established a mandatory expanded clinical evaluation patient registry to gather additional clinical data for submission to the FDA in support of clinical trials and regulatory approval in the USA.

About CoreValve

Founded in 2001, privately held CoreValve—which is headquartered in Irvine, California—has developed a proprietary delivery system and tissue heart valve for percutaneous heart valve replacement. Based on a novel catheter-and-self-expanding-frame approach on a beating heart, the proprietary CoreValve ***ReValving***™ System procedure is intended to avoid open-heart surgery. It can be performed in a cardiac "cath lab" just like angioplasty and stenting, which may result in less trauma to the patient and may offer substantial cost-savings to the healthcare system. For more information about CoreValve, visit the Company's Web site at www.corevalve.com.

(Caution: the CoreValve ***ReValving***™ System will not be available in the USA for clinical trials or for commercialization until further notice.)

Contacts
Ronald Trahan Associates Inc.
Ronald Trahan, APR, 508-359-4005, x108