

Benvenue Medical Completes Enrollment in KAST Study Evaluating Kiva® vs. Kyphoplasty

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First Randomized Controlled Study Comparing Benvenue's Kiva VCF Treatment System to Medtronic's Kyphon Balloon Kyphoplasty Concludes Ahead of Schedule - Pre-Defined Criteria for Early Stopping of Subject Enrollment Met

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SANTA CLARA, Calif., July 31, 2012 /PRNewswire/ -- Benvenue Medical, Inc., a developer of minimally invasive solutions for spine repair, announced it has met the pre-determined stopping rules for enrollment completion in the KAST (Kiva System as a Vertebral Augmentation Treatment - A Safety and Effectiveness Trial) clinical trial.

The KAST trial enrolled 300 patients and is being conducted to support a subsequent 510(k) filing for market clearance from the U.S. Food and Drug Administration (FDA). It is evaluating the Kiva Vertebral Compression Fracture (VCF) Treatment System in

one of the largest randomized studies to date versus the current standard of care in the treatment of VCFs, balloon kyphoplasty. "The KAST study enrolled ahead of schedule, and we believe the positive response we received is due to our investigators' enthusiasm for a new treatment option for painful and debilitating osteoporotic vertebral fractures moving away from traditional vertebroplasty or balloon-based vertebral augmentation," said Sean M. Tutton, MD, FSIR, Co-Principal Investigator in the KAST Study and Professor of Radiology and Surgery at the Medical College of Wisconsin in Milwaukee.

"We appreciate the efforts of the investigators and research coordinators, as well as the spine community's enthusiasm to evaluate the potential benefits of the Kiva System. The results will be important to guiding treatment recommendations for VCFs," said Steven R. Garfin, MD, Co-Principal Investigator of the KAST Study and Professor and Chairman of the Department of Orthopaedic Surgery at the University of California, San Diego Medical Center.

"We continue to work very closely with the FDA, and we are pleased with the collaboration and progress we have made working together," said Robert K. Weigle, CEO of Benvenue Medical, Inc. The Kiva VCF Treatment System, commercially available in Europe, has now been used to treat more than 800 VCFs globally. Kiva is distributed by Zimmer Spine in Europe. The National Osteoporosis Foundation estimates that there are 700,000 osteoporosis-related vertebral compression fractures annually in the U.S. alone, yet 200,000 kyphoplasty procedures are done globally.

About KAST

The KAST study is a randomized controlled trial comparing Kiva to balloon kyphoplasty, which is the current standard of care in

the treatment of VCF. The trial enrolled patients at 21 medical centers in the United States, Canada, Belgium, France and Germany. Success will require non-inferiority on the primary endpoint, which is a composite of pain, function, and safety at one year of follow-up on patients treated on study. The study is designed to evaluate superiority on key secondary endpoints including PMMA cement volume, extravasation rate, and height restoration as well as other endpoints. (ClinicalTrials.gov Identifier: NCT01123512)

About the Kiva VCF Treatment System

The Kiva VCF Treatment System provides an innovative approach to the treatment of painful VCFs. The Kiva VCF Treatment System features a proprietary flexible implant made from PEEK-OPTIMA[®], a biocompatible polymer that is widely used and well accepted as a spinal implant. The Kiva Implant is designed to function as a mechanical support structure and a reservoir to contain and direct the flow of bone cement.

The Implant is delivered percutaneously in a continuous loop fashion into the vertebral body with an all-in-one disposable device through a small diameter, single incision. The amount of the Kiva Implant delivered can be physician-customized during the procedure to adjust to various fracture types. Delivered over a removable guidewire, the Implant is designed to provide structural support to the vertebral body and to directionally control and contain bone cement.

The minimally invasive Kiva System is designed to:

- o Reduce polymethyl methacrylate (PMMA) bone cement volume
- o Preserve cancellous (porous and mesh-like, as opposed to dense) bone structure

- o Potentially reduce adjacent level vertebral fractures
- o Potentially reduce extravasation rate (leakage into surrounding tissue) versus comparable technologies

About Benvenue Medical, Inc.

Founded in 2004, Benvenue Medical, Inc. is advancing spine repair through the development of proprietary, minimally invasive surgical and interventional solutions. The company is privately held and funded by Versant Ventures, DeNovo Ventures, Domain Associates and Technology Partners. Its first products are designed for the treatment of vertebral compression fractures and degenerative disc disease, which have combined revenues of \$1.6 billion globally. For more information, visit www.benvenuemedical.com.

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