Benvenue Medical Completes Follow-Up Phase in KAST Study Evaluating Kiva® VCF Treatment System vs. Balloon Kyphoplasty

Santa Clara, CA,
May 21, 2013 —
Benvenue Medical, Inc., a developer of minimally invasive solutions for spine repair, announced it has completed the 12-month patient follow-up phase in the KAST (Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial) clinical trial. KAST is being conducted to support a 510(k) application for market clearance from the U.S. Food and Drug Administration (FDA), which Benvenue Medical expects to submit in the third quarter of 2013.

The KAST trial 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 primary endpoint is non-inferiority on a composite of pain, function, and safety at one year of follow-up on patients treated in the study. The trial enrolled 300 patients at 21 medical centers in the United States, Canada, Belgium, France and Germany.

"We look forward to the final analysis of the data, as we anticipate the results will be important to guiding treatment recommendations forVCFs," 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 look forward to filing our 510(k) application, and we continue to have positive collaboration with the FDA on our progress. KAST met the pre-determined stopping rules for enrollment completion and also enrolled ahead of schedule. Lastly, 98% of eligible patients were followed out to one year. Our clinical sites did a superb job on this effort and we're excited about our accelerated timetable," said Robert K. Weigle, CEO of Benvenue Medical, Inc. 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. 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 a new 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. TheKiva Implant is designed to function as a mechanical support structure and a reservoir to direct and contain the flow of bone cement.

The Implant is delivered percutaneously in a continuous loop into the vertebral body 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 removableguidewire, the Implant is designed to provide stabilization and structural support to the vertebral body and to directionally control and contain bone cement.

A separate European randomized trial of Kiva and balloon vertebral augmentation was recently published in the February edition of Spine (2013;38:292-299). This Level I data demonstrated Kiva's superiority over balloons in many key areas:

- Significant restoration of the Gardner angle in patients treated with Kiva (p=0.002) where as balloon kyphoplasty did not meet significance (p=0.067)
- Lower cement extravasation rates (3% for Kiva and 9.8% for balloon kyphoplasty, p<0.05)
- Lower cement volume (1.8 mL for Kiva and 2.8 mL for balloon kyphoplasty, p <0.001)

The Kiva VCF Treatment System is investigational in the United States and currently the subject of an approved IDE study - the KAST clinical trial, sponsored by Benvenue Medical.

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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