European Study Concludes Kiva Effective in Treating Severe Pain from Vertebral Metastases

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Published in Pain Physician Journal, Study Also Concludes Implant Design May Reduce Extravasation vs. Vertebroplasty and Kyphoplasty

A physician-driven prospective study of patients with painful osteolytic vertebral metastases treated with the Kiva VCF Treatment System byBenvenue Medical, Inc. found all patients experienced a clinically relevant improvement in pain and statistically significant functional improvement. The peer-reviewed study results were published online and in the March/April edition of *Pain Physician Journal,* the official publication of the American Society of Interventional Pain Physicians.

"The Kiva implant represents a new therapeutic option for treatment of painful vertebral metastasis where radiation therapy, traditional surgical stabilization, or balloon-based vertebral augmentation procedures may not be an option," said Giovanni Carlo Anselmetti, MD, Interventional Radiologist in Turin, Italy and author of the study. "Patients with osteolytic metastasis that involve the vertebral wall have a greater risk for cement extravasation, and in our experience, the design of the Kiva Implant may reduce the risk for PMMA extravasation versus traditional vertebral augmentation procedures."

Osteolytic vertebral metastases are malignant bone tumors that can cause the spine to collapse, and they can cause significant pain, disability and even death. Many traditional treatments are inappropriate for patients suffering from vertebral metastases due to a poor risk-benefit profile. While vertebroplasty and kyphoplasty are often performed to alleviate pain, these patients have a higher risk of serious complications, especially cement extravasation.

The single-arm study, titled "Percutaneous Vertebral Augmentation Assisted by Peek Implant in Painful Osteolytic Vertebral Metastasis Involving the Vertebral Wall," included 40 patients suffering from osteolytic metastasis with vertebral wall involvement. All underwent a vertebral augmentation procedure with the

Kiva System with its PEEK-OPTIMA® implant, and post-procedure they were evaluated using CT and the Oswestry Disability Index with self-evaluation questionnaire (ODI). Pain and analgesic drug use and the use of external braces were also recorded. The study results were:

- All patients achieved a clinically meaningful improvement in pain at one month ($P < 0.001$)
- All patients on opiates could be switched to NSAIDS or no treatment at all following surgery ($P < 0.001$)
- This patient cohort experienced a 95% median functional improvement during follow-up after the procedure ($P < 0.001$)
- None of the 37 patients who wore a brace prior to intervention required a brace post-procedure

"This study adds to the growing breadth of published clinical evidence demonstrating Kiva's performance in the treatment of VCFs as a result of osteoporosis, trauma, and now cancer. We're pleased that the Kiva System offers a new option for the many patients in Europe who are suffering from the devastating pain of vertebral metastases," said Robert K. Weigle, CEO of Benvenue Medical, Inc., a developer of minimally invasive solutions for spine repair.

The Kiva VCF Treatment System is commercially available in Europe and is indicated for the treatment of vertebral compression fractures and the pain associated with osteolytic vertebral metastasis. Kiva is investigational in the United States and is currently the subject of an approved IDE study - the KAST (Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial) clinical trial, sponsored by Benvenue Medical. The KAST trial completed enrollment of 300 patients in June 2012, more than 200 of whom completed their one-year follow-up. KAST is being conducted to support a 510(k) filing for market clearance from the U.S. Food and Drug Administration (FDA), whichBenvenue Medical expects to submit in the third quarter of 2013. (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. 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 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 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 offer the following potential benefits:

- Reduce polymethyl methacrylate (PMMA) bone cement volume
- Preserve cancellous (porous and mesh-like, as opposed to dense) bone structure
- Implant's biomechanical properties may contribute to a reduced rate of adjacent level fractures
- Reduce extravasation rate (bone cement leakage into surrounding tissue)

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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