UK’s NICE Offers Guidance Supporting EXOGEN Device

The Associated Press

DURHAM, N.C.--(BUSINESS WIRE)--Jan 23, 2013--New guidance from a British health agency released earlier this month supports the use of an ultrasound bone healing device that can be an alternative to surgery for thousands of patients with ‘problem’ fractures.

The agency, the National Institute for Health and Clinical Excellence (NICE), provides evidence-based guidance about medicines, treatments, procedures and devices that represent the best quality care and which offer the best value for the money for England’s National Health Service (NHS), the world’s largest publicly funded health service.

The guidance from NICE assessed both the clinical effects and the potential cost savings of the EXOGEN ® Ultrasound Bone Healing System, which uses a unique ultrasound signal to stimulate broken bones to heal naturally, in comparison to surgical management. The product, manufactured by U.S.-based Bioventus LLC and distributed in the UK by Smith & Nephew, has been used worldwide since 1997 and is currently the market leader in the US for fracture stimulation. 1 Patients using EXOGEN place an ultrasound probe on the skin for 20 minutes a day and the treatment, done at home, is entirely pain free and there are no known side effects. Clinical studies have shown EXOGEN to have an equivalent 86% success rate as surgery. 2 NICE looked at 17 separate clinical studies involving over 1700 patients and concluded that the clinical benefits were clear: “ the available clinical data on the effectiveness of EXOGEN for treating long bone fractures with non-union show high rates of fracture healing.” NICE examined the product’s claims that there could be cost benefits from using EXOGEN more widely in the NHS and found: “EXOGEN is cost saving compared with current management for the treatment of non-union.” Thousands of patients worldwide have benefited from the product 3 but its use in the NHS has been inconsistent, with some UK doctors having to persuade hospital managers to fund it. However, the new NICE guidance found that surgery costs £1164 more.

Applying NICE’s calculations to the UK population as a whole, the savings could add up to £11.6 million, not including the lifestyle costs of patients being unable to work and often reliant on friends and family to get about.

The device is used by many of the UK’s leading surgeons such as Angus MacLean, Senior Orthopaedic Consultant at Glasgow Royal Infirmary, who said: “By accelerating health there is significant potential for this technology to save money for the NHS by reducing the need for surgery and returning patients to work more quickly than before. Cost savings and clinical effectiveness therefore make a potential ‘win-win’ situation for the NHS and the patient.” About Bioventus

Bioventus is a biologics company that delivers clinically proven, cost-effective products that help people heal quickly and safely. The company's innovative products include market-leading devices, therapies and diagnostics that make it a global leader of active orthopaedic healing. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behaviour, Bioventus is a trusted partner for physicians worldwide.

For more information, visit www.BioventusGlobal.com References: 1. Based on company reports for global sales Jan-Dec 2011 2. Nolte PA, van der Krans A, Patka P, Janssen JMC, Ryaby JP, Albers GHR. Low-intensity ultrasound in the treatment of nonunions. J Trauma 2001;51:693–703.

3. Company data on file Bioventus LLC EXOGEN is a registered trademark of Bioventus LLC *EXOGEN Summary of Indications for Use: The EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of established non-unions † excluding skull and vertebra. In addition, EXOGEN is indicated for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization.

There are no known contraindications for the EXOGEN device. Safety and effectiveness has not been established for individuals lacking skeletal maturity; pregnant or nursing women; patients with cardiac pacemakers; on fractures due to bone cancer; or on patients with poor blood circulation or clotting problems. Some patients may be sensitive to the ultrasound gel. Full prescribing information can be found in product labeling, at www.exogen.com or by contacting customer service at 1-800-396-4325.

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