Bioventus Updates US Label for EXOGEN Ultrasound Bone Healing System

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DURHAM, NC – February 10, 2020 – Bioventus, a global leader in orthobiologic solutions, has updated the indications for use for its EXOGEN Ultrasound Bone Healing System. **EXOGEN** uses low-intensity pulsed ultrasound (LIPUS) to help stimulate the body's natural bone healing process and promote fracture healing. It has an 86% heal rate for fractures not healing on their own[1] and provides 38% faster healing of indicated fresh fractures.[2, 3]

The updated label now prominently features indications for using **EXOGEN** as an adjunctive non-invasive treatment of established nonunions in patients:

- With internal or external fracture fixation hardware present
- Undergoing treatment for infection at the fracture site
- Believed to have diminished bone quality

"This label update underscores important usage scenarios where fracture management protocol may have limited consideration. Now, **EXOGEN** may be confidently prescribed in these indications," said Peter Shaw, MBBS DRCOG, Chief Medical Officer, Bioventus. "Patients with comorbidities such as osteoporosis and bone infection can benefit from use of **EXOGEN** by helping to progress fracture healing and resolve nonunion. In addition, **EXOGEN** will heal fractures in the presence of infection at the fracture site and also serve as an important adjunctive therapy when stabilizing fractures with instrumented fixation."

About Bioventus

Bioventus is an orthobiologics company that delivers clinically proven, cost-effective products that help people heal quickly and safely. Its mission is to make a difference by helping patients resume and enjoy active lives. The orthobiologic products from Bioventus include offerings for osteoarthritis, surgical and non-surgical bone healing. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behavior, Bioventus is a trusted partner for physicians worldwide. For more information, visit www.BioventusGlobal.com and follow the company on LinkedIn and Twitter.

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Summary of Indications for Use
EXOGEN is indicated for the non-invasive treatment of established nonunions† excluding skull and vertebra. The EXOGEN device has also been reported as effective as an adjunctive non-invasive treatment of established nonunions† in patients:

- With internal or external fracture fixation hardware present. EXOGEN cannot penetrate metal and therefore should not be applied directly over hardware.
- Undergoing treatment for infection at the fracture site. EXOGEN is not intended to treat the infection.
- Believed to have diminished bone quality. EXOGEN is not intended to treat diminished bone quality.

EXOGEN is also indicated for the acceleration of fresh fracture heal time, repair following osteotomy, repair in bone transport procedures and repair in distraction osteogenesis procedures. There are no known contraindications for the EXOGEN device. Safety and effectiveness have 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 exogen.com or by calling Bioventus Customer Service at 800-836-4080.

† A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

1. Nolte PA, van der Krans A, Patka P, Janssen IM, Ryaby JP, Albers GH Low-intensity pulsed ultrasound in the treatment of non-unions. *J Trauma*. 2001; 51(4):693−703.
2. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF Acceleration of tibial fracture-healing by non-invasive, low intensity pulsed ultrasound. *J Bone Joint Surge [Am].*1994; 76(1):26−34.
3. Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo controlled study. *J Bone Joint Surg [Am].* 1997; 79(7):961−973.