



**BIOMET**  
**PRESS RELEASE**

**BIOMET ANNOUNCES RESULTS OF PHASE I CLINICAL TRIAL FOR CRITICAL LIMB ISCHEMIA UTILIZING AUTOLOGOUS CONCENTRATED BONE MARROW ASPIRATE**

Warsaw, IN, June 8, 2011 — Biomet, Inc., a global leader in the manufacture of orthopedic and biotechnology products, and its subsidiary, Biomet Biologics, announced today the results of the company-sponsored Phase I safety trial for autologous concentrated bone marrow aspirate (BMA) therapy in the treatment of critical limb ischemia (CLI).

The trial, performed under an FDA-approved Investigational New Drug (IND) Application, evaluated the safety of autologous concentrated BMA therapy in 29 “no-option” CLI subjects who were at risk for major amputation due to severe peripheral arterial disease (PAD). The investigational treatment utilized the company’s MarrowStim™ device for point-of-care concentration of the autologous BMA.

The 29-subject data was presented in the June issue of the Journal of Vascular Surgery and reported the following results regarding intramuscular administration of autologous concentrated bone marrow aspirate:<sup>1</sup> no reports of procedure-related deaths; two reports of procedure-related serious adverse events (neither related to the MarrowStim™ device); one-year amputation-free survival rate of 86.3%; improvement in rest pain, quality of life, and perfusion measures at twelve-weeks post-treatment; and overall average MarrowStim™ procedure time (i.e., aspiration, concentration, delivery) of less than two hours.

The trial was performed at the Indiana University School of Medicine in Indianapolis and was led by Dr. Michael P. Murphy, clinical director of the Vascular and Cardiac Center for Adult Stem Cell Therapy and assistant professor of vascular surgery.

Dr. Murphy said, “The results of this study are a crucial step in potentially providing alternative treatment for those patients who have no options other than amputation.”

“We are pleased to reach this important milestone for a potential therapy for patients who would likely progress to amputation,” said Joel Higgins, Vice President and General Manager of Biomet Biologics. “This is another step forward in making autologous, minimally manipulated, point-of-care stem cell therapies available to the U.S. patient population.”

Jeffrey Binder, President and CEO of Biomet stated, “We are proud to have worked with Dr. Murphy and the Indiana University School of Medicine on a landmark study that demonstrates an important advancement in the treatment of a significant unmet clinical need. This program is an important element of Biomet’s emerging biologics platform.”

Upon completion of the Phase I safety study described above, Biomet Biologics advanced the company’s MarrowStim™ concentration technology into a multicenter, prospective, randomized, double-blind, placebo-controlled trial under an FDA-approved Investigational Device Exemption (IDE). This pivotal trial will evaluate the safety and efficacy of autologous concentrated BMA to prevent or delay major amputation and/or death in subjects with CLI. The trial will enroll a total of 152 subjects and is currently

ongoing at 14 investigational sites, with additional sites planned. Subject enrollment began in June 2010 and is estimated for completion in May 2013, with completion of one-year data collection in May 2014. For additional information about this ongoing trial, please visit [www.padstudy.org](http://www.padstudy.org).

### **About CLI**

For patients with CLI, revascularization procedures such as surgical bypass or percutaneous angioplasty are currently the only option to restore perfusion and maintain limb viability. For CLI patients who are non-candidates for revascularization (i.e., extensive occlusive disease, failed previous bypass, insufficient autologous vein to create a viable graft), the remaining treatment option is amputation. It is estimated that over 160,000 amputations are performed in the United States each year due to CLI.<sup>2,3</sup> The number of CLI patients who will not be candidates for revascularization continues to rise as the population ages and the incidence of diabetes and other vascular risk factors increase. For CLI patients who are considered unreconstructable, the amputation and mortality rates at six months approach 40% and 20%, respectively.<sup>4</sup> Furthermore, nearly 30% of patients who undergo below-knee amputation will fail rehabilitation and require chronic institutional care or professional assistance at home.<sup>5</sup>

### **About Biomet**

Biomet, Inc. and its subsidiaries design, manufacture and market products used primarily by musculoskeletal medical specialists in both surgical and non-surgical therapy. Biomet's product portfolio encompasses reconstructive products, including orthopedic joint replacement devices, bone cements and accessories, autologous therapies and dental reconstructive implants; fixation products, including electrical bone growth stimulators, internal and external orthopedic fixation devices, craniomaxillofacial implants and bone substitute materials; spinal products, including spinal stimulation devices, spinal hardware and orthobiologics; and other products, such as arthroscopy products and softgoods and bracing products. Headquartered in Warsaw, Indiana, Biomet and its subsidiaries currently distribute products in approximately 90 countries.

### **Contact**

For further information contact Bill Kolter, Corporate Vice-President, Public Affairs at 574-372-1535 or [bill.kolter@biomet.com](mailto:bill.kolter@biomet.com).

### **References**

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<sup>2</sup> Dillingham TR, et al. Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States. *Southern Medical Journal* 2002; 95: 875-83.

<sup>3</sup> Allie DE. Critical Limb Ischemia and Amputations: A Growing Problem. *Keeping in Circulation* 2009; 9(3): 5-6.

<sup>4</sup> TASC Working Group. Management of Peripheral Arterial Disease. *J Vasc Surg* 2000; 31: S20-S34.

<sup>5</sup> Gupta SK, et al. Cost Factors in Limb-threatening Ischaemia due to Infrainguinal Arteriosclerosis. *Eur J Vasc Surg* 1988; 2(3): 151-4.