

BONESUPPORT™ ANNOUNCES POSITIVE DATA HIGHLIGHTING THE USE OF CERAMENT™ |G IN THE MANAGEMENT OF OSTEOMYELITIS IN THE INFECTED DIABETIC FOOT

Two separate studies confirm efficacy of CERAMENT™ |G, an antibiotic eluting bone substitute, as a new option in the surgical management of osteomyelitis in the infected diabetic foot.

Lund, Sweden, (PRNEWSWIRE) January 5, 2016 – BONESUPPORT™, an emerging leader in injectable bone substitutes for orthopedic trauma, bone infections and instrument augmentation related to orthopedic surgery, today announced data from two studies confirming the efficacy of the Company's CERAMENT™ antibiotic eluting bone substitute technology as a step in the management of osteomyelitis (OM) in infected diabetic foot. CERAMENT™ |G, which releases Gentamicin, received CE-mark in 2013, and is the first approved antibiotic eluting bone substitute indicated to promote and protect bone healing in the management of bone infections.

Contiguous bone infection is a common complication of diabetic foot ulcers, and overall approximately 20% of patients with a diabetic foot infection (and over 60% of those with severe infections) have underlying osteomyelitis.¹ Prevalence of diabetes is growing rapidly and is the most common cause of non-traumatic lower limb amputation, with approximately 30% of patients with a diabetic foot ulcer leading to amputation. The risk for amputation in acute diabetic infections is four times higher with OM than with soft tissue infection alone². Additionally 50% of patients will go on to another amputation within 3-5 years, and 70% percent of patients die within 5 years of an amputation for diabetes.

Overall, the studies confirmed previously unpublished experience with CERAMENT™ |G and published off label clinical use of CERAMENT™ which was shown to induce bone and soft tissue healing and preservation of proper anatomy in the infected diabetic foot. Of significance, 11 of 12 patients who had mid-foot or hind foot partial resections healed rapidly, with the other patient follow up ongoing. In the second study six patients with OM of the metatarsal head were managed with CERAMENT™ |G, with none requiring additional surgery.

“The results of these studies confirm that CERAMENT™ |G has the potential to be an effective new surgical option for patients with osteomyelitis,” said Enrico Brocco, Chief, Diabetic Foot Unit, Policlinico Abano Terme, Diabetic Foot Referral Center, Italy, and author of one of the studies. “In these studies, CERAMENT™ |G was associated with the rapid resolution of osteomyelitis, rapid soft tissue closure and preservation of the foot structure. We are very optimistic that CERAMENT™ |G holds great promise in the management of osteomyelitis in diabetic foot ulcers.”

“The data generated from these studies support the feedback we've received from European physicians regarding the efficacy of CERAMENT™ |G,” said Lloyd Diamond, CEO of BONESUPPORT™. “Importantly, our physician adoption rate in Europe continues to grow significantly, and we anticipate initiating a pivotal U.S. clinical trial for CERAMENT™ |G in the second quarter of 2016.”

The results from these studies were presented at the 34th Annual Meeting of the European Bone and Infection Society in September. BONESUPPORT™ is currently pursuing a pathway for FDA clearance in order to bring this novel treatment to the U.S.

References

1. *Eneroth M, Larsson J, Apelqvist J. Deep foot infections in patients with diabetes and foot ulcer: an entity with different characteristics, treatments, and prognosis. J Diabetes Complications 1999;13:254–263.*
2. *Mutluoglu M, Sivrioglu AK, Eroglu M, Uzun G, Turhan V, Ay H, et al. The implications of the presence of osteomyelitis on outcomes of infected diabetic foot wounds. Scand J Infect Dis. 2013;45:497–503.*

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Notes to Editor

About BONESUPPORT™

BONESUPPORT AB has developed CERAMENT™ as an innovative range of radiopaque injectable osteoconductive bioceramic products that have a proven ability to heal defects by remodeling to host bone in six to twelve months. Our products are effective in treating patients with fractures and bone voids caused by trauma, infection, disease or related surgery. Our lead product, CERAMENT™ |BONE VOID FILLER (BVF) addresses important issues facing health care providers, such as avoiding hospital readmissions and revision surgery that result from failed bone healing and infection caused by residual bone voids. CERAMENT™ |BVF is commercially available in the U.S., EU, S.E. Asia and the Middle East.

CERAMENT™'s distinctive properties as a drug eluting material have been validated in clinical practice by CERAMENT™ |G and CERAMENT™ V, the first CE-marked injectable antibiotic eluting bone graft substitutes. These products provide local sustained delivery of gentamicin and vancomycin, respectively. The local delivery feature enables an initial high concentration of antibiotics to the bone defect and then a longer sustainable dose above the minimal inhibitory concentration (MIC) to protect bone healing and promote bone remodeling.

CERAMENT™ |G and CERAMENT™ V have demonstrated good results in patients with problematic bone infections including osteomyelitis. They are also used prophylactically in patients who are at risk for developing infection. CERAMENT™ |G and CERAMENT™ V are available in the EU.

BONESUPPORT AB was founded in 1999 by Prof. Lars Lidgren, an internationally respected scientist who has been the President of various musculoskeletal societies. BONESUPPORT's mission is to bring people with bone and joint diseases back to an active life. The company is based in Lund, Sweden.

BONESUPPORT™ is a registered trademark.

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PRESS RELEASE

