Press Release

BONESUPPORT™ Announces First Patient Enrolled in FORTIFY Trial with CERAMENT®|G, a novel injectable, antibiotic-eluting bone graft substitute

FORTIFY trial to assess CERAMENT G as part of the surgical repair of severe tibial fractures

Lund, Sweden, 22 May 2017– BONESUPPORT AB, an emerging leader in innovative injectable bioceramic bone substitute products to treat bone voids caused by trauma, infection, disease or related surgery, today announced that the first patient has been enrolled by Dr Ravi Karia at the University of Texas Health Science Center at San Antonio into the company's pivotal Investigational Device Exemption (IDE) trial: *A Prospective, Randomized, Multicenter Controlled Trial of CERAMENT G as Part of Surgical Repair of Open Diaphyseal Tibial Fractures* (the FORTIFY trial: ClinicalTrials.gov Identifier: NCT02820363).

CERAMENT G is an injectable antibiotic-eluting bone graft substitute that has proven remodeling capabilities and provides local sustained delivery of gentamicin. The data from the trial will support BONESUPPORT's PMA (Premarket Approval) filing for CERAMENT G in the US.

In spite of modern day care of open tibial fractures, bone loss coupled with wound contamination and soft tissue damage continue to impair healing and recovery, particularly if infection develops. In addition, open tibial fractures result in a general infirmity, long-term disability and reduction in quality of life for patients, and a significant clinical challenge for orthopedic surgeons.

The FORTIFY trial will assess CERAMENT G's ability to improve on the standard-of-care management of patients with open fractures of the tibial diaphysis. The primary endpoints of the trial will include the absence of deep infection at the fracture site and the lack of secondary procedures intended to promote fracture union. The trial will also evaluate the safety of CERAMENT G in these patients. The trial will enroll up to 230 patients at up to 30 centers in the US and Europe.

Dr. Douglas Dirschl, the trial's Principal Investigator, said: "I am excited to take part in the FORTIFY clinical trial. The open tibial fracture remains the most common and one of the most troublesome open fractures managed by orthopedic surgeons. Even with modern treatment protocols, patients suffering this fracture continue to be at substantial risk of infection, fracture non-union, and prolonged disability. A product that could be inserted into the fracture site at the time of definitive treatment that could promote bone formation at the same time as reducing the risk of subsequent infection, would be a major advance in the treatment of these troublesome fractures and would have the potential to provide benefit to thousands of patients each year in the United States."
Douglas R. Dirschl, MD is the Lowell T. Coggeshall Professor of Orthopedic Surgery and Chairman, Department of Orthopedic Surgery and Rehabilitation Medicine at The University of Chicago Medicine.

"The treatment of the first patient in the FORTIFY trial is another key corporate milestone for BONESUPPORT. This clinical trial in a complex trauma indication is designed to demonstrate proof-of-concept that CERAMENT G can be used to improve and protect the healing process in open bone fractures in combination with standard procedures, minimizing the risk of deep infections which would result in the need for additional remedial procedures," added Richard Davies, CEO of BONESUPPORT. "We plan to use the clinical data to support our planned PMA filing for CERAMENT G in the US. We also intend to generate additional clinical data with CERAMENT G to gain a broad US label for this novel, injectable antibiotic-eluting bone graft substitute, which is rapidly being adopted in Europe."

CERAMENT G combines the bone healing and bone remodeling properties of CERAMENT with the antibiotic, gentamicin. CERAMENT G drug-eluting properties enable it to provide an initial high concentration of gentamicin to the environment of the bone fracture and then a longer sustainable dose above the minimum inhibitory concentration of many of the bacteria that could cause a bone infection at the fracture site. This unique antibiotic-eluting profile helps protect the bone healing process and to promote bone remodeling.

CERAMENT G received the European CE Mark in February 2013 and is now marketed in 19 countries outside the US.

Notes to Editor

About BONESUPPORT

BONESUPPORT 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 12 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, SE 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.

CERAMENTG 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 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. www.bonesupport.com

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