

## **BONESUPPORT™ Receives FDA Approval to Initiate IDE Clinical Study**

### **FORTIFY Study to Assess CERAMENT™ |G as part of Surgical Repair of Open Diaphyseal Tibial Fractures**

**Lund, Sweden, 9 August** – 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 it has received approval from the US Food and Drug Administration (FDA) to begin an IDE (Investigational Device Exemption) study with CERAMENT™ G. CERAMENT™ G is an injectable antibiotic-eluting bone graft substitute that provides local sustained delivery of gentamicin. CERAMENT™ G received CE mark approval in February 2013 and is now marketed in 19 countries outside the US.

The FORTIFY study, a randomized multicenter controlled trial, will evaluate the safety and efficacy of CERAMENT™ G as part of surgical repair of open diaphyseal tibial fractures. The trial will enrol up to 230 patients at up to 30 centers globally, with the aim of having at least 50% of the study data coming from US subjects. In addition to evaluating the safety of CERAMENT™ G use, primary endpoints of the study include:

- Absence of deep infection at the fracture site
- Absence of secondary procedures (surgical or nonsurgical) intended to promote fracture union

BONESUPPORT anticipates starting the FORTIFY trial by the end of 2016.

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 ultra-high concentration of gentamicin to the environment of the bone fracture and then a longer sustainable dose above the minimum inhibitory concentration (MIC) of many of the bacteria which could cause a deep bone infection at the fracture site. This unique antibiotic-eluting profile helps protect the bone healing process and to promote bone remodeling.

Richard Davies, CEO of BONESUPPORT, said, “The FDA approval of our planned IDE study with CERAMENT G is a key corporate milestone for BONESUPPORT. We are looking forward to beginning the FORTIFY study before the end of 2016. The results of this study will form a key component of our planned PMA to gain US approval for this novel antibiotic-eluting bone graft substitute.”

- Ends -

#### **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

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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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