

## **BONESUPPORT™ - POSITIVE RESULTS FROM THE CERTiFy STUDY COMPARING CERAMENT®|BONE VOID FILLER WITH AUTOGRAFT**

**Lund, Sweden, 08.00 CET, 19 November 2018** – BONESUPPORT™, an emerging leader in orthobiologics for the management of bone voids, today announces positive top-line data from the CERTiFy (CERAMENT® Treatment of Tibia Plateau Fracture defects) study comparing CERAMENT|BVF with autologous iliac bone graft (autograft).

BONESUPPORT CEO Emil Billback said:” Successfully completing the ground-breaking CERTiFy study, to demonstrate CERAMENT BVF is non-inferior to autograft in treating tibia plateau fracture defects, is a major milestone for BONESUPPORT. We expect the results from the study to catalyse a change in the standard of care for this kind of injury given that our synthetic bone graft is now proven to be as good as autograft, which requires a second surgical procedure to harvest bone from the patient’s hip. These data, which clearly differentiate CERAMENT BVF, will play a key role in our commercial strategy to increase our share of the synthetic bone graft substitute market in both Europe and the U.S..”

CERTiFy, a prospective, multi-center, controlled, randomized trial, enrolled 137 patients with fresh traumatic depression fracture of the proximal tibia across 20 participating centers in Germany. Patients were randomized to receive either CERAMENT BVF or autograft. Professor Pol. M. Rommens, Head of Department of Orthopaedics and Traumatology at The University Medical Centre Mainz was the study’s Principle Investigator.

The CERTiFy study met its primary endpoint with CERAMENT BVF being non-inferior to autograft in terms of Physical Component Summary (SF-12 v2) at week 26. A publication providing more complete data from the CERTiFy study is expected in Q1 2019.

Professor P.M. Rommens said: “We are pleased to report positive top-line results from the CERTiFy study. Bone graft substitutes are widely used for augmentation of post-traumatic bone defects. However, no direct randomized clinical comparison to autologous bone grafting, the so-called “gold-standard” in reconstruction of bone defects, has been previously conducted. CERTiFy clearly demonstrates that CERAMENT BVF is non-inferior to autograft across several key clinical parameters. These findings pave the way for a potential change in the standard of care for post-traumatic bone defects given the ease of use and other benefits that CERAMENT BVF delivers. I look forward to providing more data from this ground-breaking study in a publication which is planned for Q1 2019”

## Press Release

### About CERAMENT® | BONE VOID FILLER

CERAMENT | BONE VOID FILLER is used to fill gaps and voids in bone, for example those caused by trauma and benign bone tumors. It is the only injectable and moldable synthetic bone substitute that remodels to host bone within 6-12 months, and is radiopaque, making it ideal for minimally invasive surgery and open procedures. CERAMENT can be used to augment hardware during surgery, and the unique material combination resists crack formation and propagation when drilled.

### About BONESUPPORT™

BONESUPPORT is an innovative commercial stage orthobiologics company, based in Lund, Sweden. The Company develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient's own bone and have the capability of eluting drugs directly into the bone void.

BONESUPPORT's bio-ceramic bone graft substitutes CERAMENT® | BONE VOID FILLER (BVF), CERAMENT® | G\* and CERAMENT® V\* are all based on the Company's novel and proprietary technology platform.

The Company's products are targeting a large addressable market opportunity across trauma, chronic osteomyelitis (bone infection), revision arthroplasty (replacement of a joint prosthesis), ortho-oncology and foot and ankle.

BONESUPPORT's total sales increased from SEK 62 million in 2015 to SEK 129 million in 2017, representing a compound annual growth rate of 45%.

BONESUPPORT is currently conducting two important clinical trials to generate data demonstrating the clinical and health economic benefits its products deliver. The first trial, CERTiFy, is comparing CERAMENT BVF with autograft, the most widely used approach for managing bone voids. Top line results from this successful study showed that CERAMENT BVF met its primary endpoint of being non-inferior to autograft. A publication providing more complete data from the CERTiFy study is expected in Q1 2019.

The FORTIFY study is assessing 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 a reduction in the number of secondary procedures intended to promote fracture union. Data from this study will be used for a planned Premarket approval filing with FDA in 2020.

The Company's research and development is focused on extending the use of its CERAMENT technology into further indications via the incorporation of additional drugs and therapeutic agents. The Company currently has a pipeline of pre-clinical product candidates that have been designed to promote bone growth.

BONESUPPORT is also preparing to expand its product offering in the US and has entered into strategic agreements with Collagen Matrix Inc. and MTF Biologics to gain access to products that are complementary to CERAMENT BVF.

BONESUPPORT is listed on Nasdaq Stockholm and trades under the ticker "BONEX" (ISIN code: SE0009858152). Further information is available at [www.bonesupport.com](http://www.bonesupport.com).

\*CERAMENT G: Not available in the United States, for investigational use only.

CERAMENT V: Not available in the United States.

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## Press Release

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