# **♦** BONESUPPORT

### Press release

## BONESUPPORT<sup>™</sup> CERTIFY STUDY ON CERAMENT<sup>®</sup> BONE VOID FILLER NOW PUBLISHED IN THE JOURNAL OF BONE AND JOINT SURGERY

Lund, Sweden, 08:45 CET, December 9 2019 BONESUPPORT<sup>™</sup>, an emerging leader in orthobiologics for the management of bone injuries, today announced the publication of the Level I clinical study CERTiFy in the highly ranked Journal of Bone and Joint Surgery. The authors concluded that CERAMENT<sup>®</sup> BVF was as good as autograft with regard to both patient-reported and radiographic outcomes in tibial plateau fractures.

"Publishing the successful results of this Level I therapeutic study is a major milestone for BONESUPPORT. Showing that CERAMENT BVF is as good as autograft eliminates the need for harvesting and transplanting the patient's own bone tissue. We expect the results from CERTiFy to catalyze a change in the standard of care. The strong data for CERAMENT BVF will play a key role in our commercial strategy to increase our share of the bone graft market in both Europe and the U.S." said BONESUPPORT's CEO Emil Billbäck.

Professor Pol. M. Rommens, Head of the Department of Orthopaedics and Traumatology at the University Medical Centre Mainz and Professor Alexander Hofmann, Head of the Department of Traumatology and Orthopaedics 1, Westpfalz-Clinics, Kaiserslautern, Germany were the study's Principal Investigators.

Professor Rommens said: "The positive top-line results of the study were published already last year and we are glad that the results of the CERTiFy study have now been published in JBJS, the most respected journal in the field of orthopaedic surgery. This is a great recognition of our work, which took us seven years. This trial is unique as it is the first and only 1/1 randomized clinical comparison between the so-called "gold-standard", autologous bone grafting, and a ceramic bone graft substitute including patient reported outcome measurements. CERTiFy clearly demonstrates that CERAMENT BVF is non-inferior to autograft across several key clinical parameters."

Professor Hofmann added: "Our results show a benefit for the patients concerning post-operative pain and blood loss and 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."

#### More about the CERTiFy study

CERTIFY (**CER**AMENT® Treatment of **Ti**bia Plateau **F**racture defects), a prospective, randomized, open-label, multicenter study, enrolled 135 patients with acute depression and split-depression fractures of the proximal part of the tibia across 20 participating hospitals in Germany. Patients were randomized to receive either autograft (autologous iliac bone graft) or CERAMENT | BVF for reconstruction of the bone defect.

The primary outcome measures were the Short Form (SF)-12 Physical Component Summary (PCS) score and the pain level (VAS) at 26 weeks postoperatively.

Age, sex, fixation methods, and fracture pattern were comparable in both groups. There were no



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significant differences in the SF-12 PCS or VAS scores at postoperative week 26. There was a significant reduction of blood loss and pain levels at postoperative day 1 in the CERAMENT BVF group. The rates of fracture-healing, defect remodeling, and articular subsidence were not significantly different in both groups.

#### **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™ (Nasdaq Stockholm: BONEX) 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. BONESUPPORT's bone graft substitutes are based on the patented technology platform <a href="CERAMENT">CERAMENT</a>. The company is conducting several clinical studies to further demonstrate the clinical and health economic benefits its products deliver and a Premarket approval filing with the FDA (USA) for <a href="CERAMENT G">CERAMENT G</a> is planned in 2021. The company is based in Lund, Sweden, and the net sales amounted to SEK 97 million in 2018. Please visit <a href="www.bonesupport.com">www.bonesupport.com</a> for more information.

BONESUPPORT and CERAMENT are registered trademarks of BONESUPPORT AB.

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