

## **BONESUPPORT receives "breakthrough device designation" for CERAMENT G for the indication trauma**

**Lund, Sweden, 10:00 CET, 17 06 21 BONESUPPORT™, an emerging leader in orthobiologics for the management of bone injuries, today announced that the company's antibiotic eluting product CERAMENT G has been categorized as a breakthrough device for the indication trauma by the US Food and Drug Administration (FDA).**

The categorization "breakthrough device" can be assigned to products that are considered to provide a more effective treatment of severe disease states, where there is no comparable equivalent on the market. The categorization is intended to expedite the regulatory review of medical devices so that patients receive faster access to new treatment options.

"We will submit a regulatory application including trauma by the end of 2021. The decision from the FDA is of course important regarding the upcoming reimbursement process and with which priority our application will be processed," said Emil Billbäck, CEO of BONESUPPORT.

CERAMENT G has been classified as a breakthrough device for the indication osteomyelitis (bone infection) since March 2020 and BONESUPPORT is currently working to supplement previously submitted application, with the aim of reaching a potential approval for bone infection during the first quarter of 2022. A potential approval for the indication trauma may become effective at the end of 2022.

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### **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 [CERAMENT](#). The company is conducting several clinical studies to further demonstrate the clinical and health economic benefits its products deliver. The company is based in Lund, Sweden, and the net sales amounted to SEK 181 million in 2020. Please visit [www.bonesupport.com](http://www.bonesupport.com) for more information.

BONESUPPORT and CERAMENT are [registered trademarks](#) of BONESUPPORT AB.