

BONESUPPORT FORTIFY PATIENT ENROLLEMENT FINALIZED EARLIER THAN ORIGINAL PLAN

Lund, Sweden, 16.30 CET, 15 June 2020 – BONESUPPORT™, an emerging leader in orthobiologics for the management of bone injuries, today announced that the enrollment of the FORTIFY study on CERAMENT® G has been completed with 198 subjects enrolled.

BONESUPPORT has recently requested a study protocol amendment to reduce the sample size by approximately 30 subjects due to anticipated enrolment challenges during the COVID-19 pandemic. A blinded sample size review by an independent clinical study statistician ensured that closing enrolment at 198 subjects has only a minimum impact on the statistical power of the study. The American Food and Drug Administration (FDA) has approved the request and the enrolment for FORTIFY is now closed.

The FORTIFY study was initiated in 2017 with the purpose to evaluate the safety and efficacy of CERAMENT G as part of surgical repair of open diaphyseal tibial fractures versus standard of care. The results of the study are intended to support a FDA Premarket Approval (PMA) filing for CERAMENT G in the US. As previously communicated, BONESUPPORT aims to be able to submit a PMA application at the end of 2021.

For more information, please contact:

BONESUPPORT AB

Emil Billbäck, CEO
+46 (0) 46 286 53 70

Håkan Johansson, CFO
+46 (0) 46 286 53 70
ir@bonesupport.com

Cord Communications

Charlotte Stjerngren
+46 (0) 708 76 87 87
charlotte.stjerngren@cordcom.se
www.cordcom.se

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 that its products deliver and



Press Release

a Premarket approval filing with the FDA (USA) for [CERAMENT G](#) is planned in 2021. The company is based in Lund, Sweden, and the net sales amounted to SEK 155 million in 2019. Please visit www.bonesupport.com for more information.

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