Study results on FORTIFY are inconclusive

Lund, Sweden, 19:40 CET, 09 09 21 – BONESUPPORT™, an emerging leader in orthobiologics for the management of bone injuries, today announced inconclusive results for the company's Investigational Device Exemption (IDE) study; FORTIFY. The primary safety endpoint for CERAMENT G was met.

The FORTIFY study was initiated in 2017 with the purpose to evaluate the ability of CERAMENT G to improve the treatment outcomes for patients with open tibia fractures G-A II-IIIB. Last patients follow up took place in June 2021.

The drop-out rate, defined as difference between enrolled and completed patients, was 29% and lost to follow up was 18% and 9 % for the treatment group and control group respectively.

Subjects drop out is generally high with all trauma studies. In the FORTIFY study, with a majority of the patient final follow-ups taking place during the COVID pandemic, the drop-out rate has been very high with only 143 qualified subjects of 201 enrolled for the composite efficacy endpoint at 12 months. The very high drop-out rate has led to FORTIFY not qualifying to the requirements of a PMA application.

The primary composite end point success was 64% in the treatment group (CERAMENT G) and 66% in the control group; non-significant difference. None of the secondary parameters were conclusive.

The severe trauma that patients with open tibia fractures G-A II-IIIB have been exposed to is known by high variability in bone healing, infection incidence and soft tissue recovery. Nevertheless, the failure to reach conclusion on the study data is both surprising and disappointing.

BONESUPPORT will work with FDA to review possible regulatory pathways for CERAMENT G for the indication trauma.

Conference call and online presentation
BONESUPPORT will host a conference call and an online presentation Friday, SEPT 10, at 10:00 CET. The call will be hosted by Emil Billbäck, CEO, Håkan Johansson, CFO, and Michael Diefenbeck, CMO. The presentation will be held in English.

The dial-in numbers for the conference call are:
SE: +46 856642651 PIN:19381497#
UK: +44 3333000804 PIN:19381497#
US: +1 6319131422 PIN:19381497#

The presentation will be webcasted and can be followed here:

https://tv.streamfabriken.com/press-conference-sept-2021

This information is such that BONESUPPORT AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact person below, on 09 09, 2021 at 19:40 p.m. (CET).

BONESUPPORT HOLDING 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 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 for more information.