

BONESUPPORT receives market authorization for CERAMENT G in the US

BONESUPPORT™, an emerging leader in orthobiologics for the management of bone injuries, today announced that the company has received market authorization from the US Food and Drug Administration (FDA), for the company's antibiotic eluting product CERAMENT G, for the indication bone infection (osteomyelitis).

CERAMENT G has received market authorization through a De Novo process, which is one of the regulatory pathways available when there is no previous comparable product ("predicate device") legally marketed. CERAMENT G has been given "Breakthrough device" categorization by FDA, as it adds significant clinical value compared to existing treatment options by enabling natural bone healing protected by locally eluted antibiotics, in a one-stage-procedure. CERAMENT G has been proven to significantly improve the treatment outcomes for patients suffering from bone infection, with a reduced risk of reinfection and amputation.

CERAMENT G is the first and only bone graft, with antibiotic elution, approved for the US market

"The announcement from the FDA means that BONESUPPORT achieves the most important milestone in the company's commercial history to date. The benefits of CERAMENT G for patients and clinics, have been validated in several very strong clinical trials, and have paved the way for our strong sales in Europe, where CERAMENT G accounts for a clear majority of our sales," said Emil Billbäck, CEO of BONESUPPORT.

BONESUPPORT estimates that there are 50 k patients treated each year in the US market for bone infections. The market is growing with 5-7% a year.

BONESUPPORT will hold a conference call and an online presentation on May 18 at 11.00 am CEST. The call will be hosted by Emil Billbäck, CEO and Håkan Johansson, CFO who will share details on the FDA approval and answer questions. The presentation will be held in English.

The dial-in numbers for the conference call are:

SE: +46 856642651 PIN:27492126#

UK: +44 3333000804 PIN:27492126#

US: +1 6319131422 PIN:27492126#

The presentation will be webcasted and can be followed here:

<https://tv.streamfabriken.com/bonesupport-press-conference>

For more information contact:

Press Release
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This information is information that BONESUPPORT Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-05-18 08:24 CEST.

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 213 million in 2021. Please visit www.bonesupport.com for more information.

BONESUPPORT and CERAMENT are **registered trademarks** of BONESUPPORT AB.

Attachments

[BONESUPPORT receives market authorization for CERAMENT G in the US](#)