BONESUPPORT - CERAMENT® G Approved by Health Canada

Lund, Sweden, 18:00 CET, 16 August 2018 - BONESUPPORT™, an emerging leader in orthobiologics for the management of bone voids, announces that its antibiotic-eluting product CERAMENT G has been approved by Health Canada.

CERAMENT G is the first and only CE-marked gentamicin-eluting injectable ceramic bone graft substitute on the market. CERAMENT G sales have been growing strongly based on the clinical benefits it delivers when used for indications where infection may be present or of concern.

BONESUPPORT is currently conducting the FORTIFY trial to assess CERAMENT G’s ability to improve on the standard-of-care management of patients with open fractures of the tibial diaphysis. The primary endpoints of the trial include the absence of deep infection at the fracture site and the lack of secondary procedures intended to promote fracture union. The trial will also evaluate the safety of CERAMENT G in these patients. The trial will enroll up to 230 patients at up to 30 centers in the US and Europe.

Positive data from the FORTIFY trial will be used to support BONESUPPORT’s PMA (Premarket Approval) filing for CERAMENT G in the US, where the product is expected to be launched in 2021.

Emil Billbäck, CEO of BONESUPPORT said: “We are looking forward to commercializing CERAMENT G in Canada following its approval by Health Canada. CERAMENT G will be the first injectable antibiotic eluting ceramic bone graft substitute to be launched on the Canadian market. We are currently in dialogue with potential distributors to assist us in bringing this novel product to orthopedic surgeons managing bone voids where infection is present or an important risk.”

About BONESUPPORT™

BONESUPPORT is an innovative and rapidly growing commercial stage orthobiologics company, based in Lund, Sweden. The Company 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 directly into the bone void.

BONESUPPORT’s bio-ceramic bone graft substitutes CERAMENT® BONE VOID FILLER (BVF), CERAMENT® G* and CERAMENT® V* are all based on the Company’s novel and proprietary technology platform.

The Company’s products are targeting a large addressable market opportunity across trauma, chronic osteomyelitis (bone infection), revision arthroplasty (replacement of a joint prosthesis), ortho-oncology, foot and ankle, and infected diabetic foot.

BONESUPPORT’s total sales increased from SEK 62 million in 2015 to SEK 129 million in 2017, representing a compound annual growth rate of 45%.

The Company’s research and development is focused on the continuing development and refinement of its CERAMENT technology to extend its use into additional indications by the elution of drugs and therapeutic agents. The Company currently has a pipeline of pre-clinical product candidates that have been designed to promote bone growth.
In addition, BONESUPPORT is looking at opportunities to expand its product offering in the US and has entered into a strategic agreement with MTF Biologics and Collagen Matrix Inc. to market and distribute products that are complementary to CERAMENT BVF.

BONESUPPORT is listed on Nasdaq Stockholm and trades under the ticker “BONEX” (ISIN code: SE0009858152). Further information is available at www.bonesupport.com.

*CERAMENT G: Not available in the United States, for investigational use only.
*CERAMENT V: Not available in the United States.

BONESUPPORT™ and CERAMENT® are registered trademarks.

FOR MORE INFORMATION CONTACT:

BONESUPPORT AB
Emil Billbäck, CEO
+46 (0) 46 286 53 70
Björn Westberg, CFO
+46 (0) 46 286 53 60
ir@bonesupport.com

Citigate Dewe Rogerson
Pip Batty, David Dible, Shabnam Bashir
+44 (0)20 7282 1022
bonesupport@citigatedewerogerson.com

This information is such information as 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 person set out above, at 18.00 CET on 16 August 2018.